IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VERTEX PHARMACEUTICALS INCORPORATED
50 Northern Avenue
Boston, Massachusetts 02210

Plaintiff,

v.

Case No. _____

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201;

AND

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201;

AND

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL,
330 Independence Avenue, SW
Washington, DC 20201;

AND

CHRISTI A. GRIMM, in her official capacity as Inspector General in the Office of Inspector General for the United States Department of Health and Human Services,
330 Independence Avenue, SW
Washington, DC 20201,

Defendants.

COMPLAINT FOR DECLARATORY JUDGMENT AND FOR A WRIT OF MANDAMUS AND RELIEF UNDER 5 U.S.C. § 706

Plaintiff Vertex Pharmaceuticals Incorporated ("Vertex") seeks a declaratory judgment against Defendants the United States Department of Health and Human Services ("HHS"), Xavier Becerra in his capacity as the Secretary of HHS, the HHS Office of Inspector General ("OIG"), and Christi A. Grimm in her capacity as the Inspector General of OIG (together, "Defendants"). Vertex also seeks a judgment setting aside portions of 42 C.F.R. §§ 1008.39, 1008.41, and 1008.43 as inconsistent with law and an order to compel Defendants to comply with their nondiscretionary duties under 42 U.S.C. § 1320a-7d(b) and 42 C.F.R. § 1008.43 to issue written responses to requests for advisory opinions within sixty days. In support thereof, Vertex states as follows:

INTRODUCTION

1. Vertex brings this action seeking to help Americans suffering from sickle cell disease ("SCD") and transfusion-dependent beta-thalassemia ("TDT") preserve their ability to have biological children after undergoing potentially sterilizing chemotherapy as part of Vertex's breakthrough gene editing therapy, CASGEVY (the "Product")—a potential cure for SCD and TDT. Vertex will offer eligible patients with commercial insurance the fertility treatments necessary to preserve their ability to become biological parents. But without this Court's intervention, Vertex cannot offer the same support to Americans insured by federal health care programs because of the threat of criminal, civil, and administrative penalties arising from OIG's erroneous legal positions. As a result, without relief from this Court, thousands of Americans with SCD or TDT will be forced to choose between a potential cure for their debilitating, ultimately fatal disease, and the dream of becoming biological parents.

2. Vertex is a biotechnology company based in Boston, Massachusetts that develops and manufactures innovative medicines to treat patients with serious diseases like SCD. SCD is a

debilitating genetic blood disorder that affects the shape of blood cells and causes blockages in the blood stream. These blockages lead to vaso-occlusive crises ("VOCs"), which can cause severe pain, organ damage and chronic hospitalization. The median age of death of patients with SCD is only 43 years.

3. Approximately 100,000 Americans suffer from SCD. *Ninety percent* (90%) of SCD patients are Black, and approximately 50% of SCD patients receive healthcare coverage through Medicaid.

4. TDT is a genetic blood disorder that affects approximately 2,000 Americans, and approximately 45% of TDT patients who are insured are covered by Medicare, Medicaid, or the VA. The median age of death for TDT patients is 37 years, highlighting the need for early treatment.

5. In December 2023, the Food and Drug Administration ("FDA") approved CASGEVY, a potentially curative gene editing therapy developed and manufactured by Vertex for patients with SCD. FDA characterized the therapy as a "milestone" in the treatment of SCD.[1] To benefit from CASGEVY, however, patients must first undergo high doses of chemotherapy to obliterate blood stem cells in their bone marrow. This "myeloablative conditioning" can have serious side effects, including infertility.

6. In January 2024, the FDA also approved CASGEVY for TDT, for which CASGEVY is also a potential cure. Treatment for TDT also requires that patients first undergo myeloablative conditioning, with a potential side effect of infertility.

[1] *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease*, FDA News Release (Dec. 8, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease.

7. Unfortunately, in the absence of fertility preservation services, many SCD and TDT patients will make the difficult decision to delay or forego treatment because they wish to be biological parents but cannot access treatments that would preserve their fertility, with the possible consequence that their condition deteriorates to the point that they are no longer eligible for treatment. Such fertility treatments can cost tens of thousands of dollars and are rarely covered by insurance. Indeed, no Medicaid program in the United States provides coverage for fertility preservation in the context of SCD, and nearly half of SCD patients receive their healthcare coverage through Medicaid, reflecting the unfortunate intersection of race and poverty in the United States.

8. Vertex is committed to ensuring that eligible patients suffering from SCD and TDT have equal access to CASGEVY. To that end, Vertex developed a fertility support program ("Fertility Preservation Program" or "Program") that provides financial support for medically necessary fertility services for patients prescribed the Product whose insurance does not cover those services and who meet certain financial need and other eligibility criteria.

9. Vertex will offer the Program to patients with commercial insurance, but because OIG has expressed concern about manufacturers providing certain types of support to patients in the past, Vertex sought an advisory opinion pursuant to 42 U.S.C. § 1320a-7d(b) before offering fertility support to patients insured by federal health care programs. For more than a year, Vertex has engaged with OIG through a formal advisory opinion process to confirm Vertex's view that the Fertility Preservation Program would not involve prohibited remuneration and thus would not implicate the Anti-Kickback Statute ("AKS"), *see* Social Security Act § 1128B(b), or the Beneficiary Inducement Statute ("BIS"), *see id.* § 1128A(a)(5). Despite being required by statute to issue a *written* advisory opinion no later than 60 days after receiving Vertex's advisory opinion

request, *see* 42 U.S.C. § 1320a-7d(b)(5)(B)(i), and despite OIG having first *orally* conveyed its definitive negative determination nearly eight months ago, OIG has yet to issue a written opinion, notwithstanding Vertex having repeatedly asked it to do so over the intervening months.

10. On January 26, 2024, OIG severely and unnecessarily compounded the struggle of SCD and TDT patients when it orally confirmed its decision (first conveyed in November 2023) that it could not issue a favorable advisory opinion regarding the Fertility Preservation Program, because, according to OIG, the Program implicates the AKS and BIS, poses more than a low risk of fraud and abuse, and does not promote access to gene therapy care. *See* Vertex Letter to OIG ("Feb. 2. Letter"), at 1 (Feb. 2, 2024). Even though Medicaid and most other insurers already deny Americans with SCD or TDT fertility coverage, the federal government, through OIG's refusal to issue a favorable advisory opinion, has effectively prohibited those patients from receiving free fertility services *from others*—leaving them with the Hobson's choice between undergoing a potentially curative treatment or becoming biological parents. On February 2, 2024, Vertex requested that OIG issue a written advisory opinion memorializing its determination and reminded OIG of the timeliness requirements for doing so. *See id.* As of the date this complaint was filed, more than five additional months have elapsed, yet OIG has not issued a written advisory opinion.

11. Vertex's Fertility Preservation Program does not implicate the AKS or BIS. The AKS criminalizes corrupt *quid-pro-quo* transactions, like a bribe or kickback, in which remuneration is sought or offered to corruptly skew medical decision making. Specifically, the statute makes it a crime, on one side of the transaction, to knowingly and willfully offer or pay any "remuneration (including any kickback, bribe, or rebate) . . . to induce" a person to take certain actions involving items or services payable by federal health care programs, 42 U.S.C. § 1320a-7b(b)(2), and, on the other side of the transaction, to knowingly and willfully solicit or receive any

"remuneration (including any kickback, bribe, or rebate) . . . in return for" purchasing such federally funded health care goods and services. *Id.* § 1320a-7b(b)(1).

12. The Supreme Court's recent decision in *United States v. Hansen*, 599 U.S. 762 (2023), makes clear that in the context of a criminal statute like the AKS, Congress's use of the phrase "to induce" means that the statute reaches only *corrupt* acts akin to criminal solicitation. This is consistent with the statute's references to "kickback, bribe, or rebate" as exemplary of the statute's reach. The AKS does not prohibit assistance like the Fertility Preservation Program because such assistance merely removes a financial or medical barrier to care and thereby allows patients to receive appropriately prescribed medical treatment. As detailed below, the Fertility Preservation Program would not improperly skew medical decision-making or provide an improper inducement to prescribe the Product. Nor would patients choose to undergo treatment with CASGEVY in exchange for the Fertility Preservation Program. Rather, doctors will prescribe CASGEVY, and patients will choose to undergo treatment with CASGEVY, because it offers a *potential cure* for a debilitating ultimately fatal disease, and, in the case of SCD, because the only alternative gene therapy has a black box safety warning for blood cancer and is significantly more expensive.

13. For its part, the BIS, a parallel civil statute, imposes monetary penalties for offering "remuneration . . . to influence" patient decision-making. 42 U.S.C. § 1320a-7a(a)(5). While that language omits use of "induce" as well as the exemplars of "kickback, bribe, or rebate," and thus would sweep in more conduct than the AKS, the BIS includes an express safe harbor for programs, like the Fertility Preservation Program, that promote access to care and pose a low risk of harm to patients and federal health care programs. *Id*. § 1320a-7a(i)(6)(F).

14. The Fertility Preservation Program plainly qualifies for that safe harbor. The Centers for Medicare and Medicaid Services ("CMS")—another agency within HHS—recently concluded not only that fertility support *promotes access to care*, but that it was *essential* to ensuring patient access. In January 2024, CMS announced the CMS Innovation Center's Cell and Gene Therapy Access Model ("CGT Access Model"), the stated goal of which is to increase access to innovative cell and gene therapies, including CASGEVY, for people who receive their health insurance through Medicaid.[2] The CGT Access Model will *require* participating manufacturers of gene therapies for SCD to cover partial fertility preservation services—collection and storage of oocytes or sperm—because, as CMS acknowledges, the "[l]ack of access to fertility preservation services presents a significant access barrier to individuals considering [cell and gene therapies]."[3]

15. The BIS safe harbor also serves to underscore that the AKS's "to induce" standard does not apply to programs, like the Fertility Preservation Program, that increase access to care and present a low risk for abuse. Indeed, it would be illogical to protect such programs from *civil* liability under the BIS but subject them to *criminal* liability under the AKS—a construction that would effectively negate the desired effect of Congress's safe harbor under the BIS.

16. Yet Vertex cannot implement the Fertility Preservation Program for patients insured by federal health care programs because OIG has concluded that the Fertility Preservation Program would implicate both the AKS and BIS. OIG's position is that Vertex's proposed Program—which is essential to ensuring patients' access to critical health care—would implicate

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[2] *Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments*, CMS Press Release (Jan. 30, 2024), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments.

[3] CMS, *Cell and Gene Therapy (CGT) Access Model Overview Factsheet* at 2, https://www.cms.gov/files/document/cgt-model-ovw-fact-sheet.pdf (last visited June 13, 2024).

the AKS and BIS because, in OIG's view, offering fertility preservation services to counteract the unfortunate side effect of infertility would induce the beneficiary to undergo the arduous, multi-step, months-long process required for treatment with the Product. *See* Feb. 2 Letter, at 1.[4]

17. But it strains credulity to suggest that someone suffering from SCD or TDT would choose CASGEVY *to obtain fertility services* rather than *to be potentially cured of a debilitating illness*. Patients eligible for the Fertility Preservation Program have been diagnosed with SCD or TDT and prescribed CASGEVY by a qualified physician, all before the possibility of fertility services is even raised. Moreover, the services afforded by the Fertility Preservation Program are only necessary to counteract a side effect of the regimen to administer CASGEVY—specifically the course of chemotherapy necessary to prepare the body for gene therapy. If Vertex were able to develop a means of administering gene therapy utilizing a gentler conditioning agent that eliminated the risk of infertility (and Vertex is working diligently on such a program), there would be no need for the Fertility Preservation Program. Of course, if Vertex were to implement such a change, there would be no conceivable argument that doing so violated the AKS, even if it increased the cost of CASGEVY, and even if doing so influenced some patients to take CASGEVY who otherwise would not have. It does not matter, for purposes of criminal liability under the AKS, that Vertex is addressing the side effect of infertility via the Fertility Preservation Program or an improved method of administering CASGEVY.

18. While HHS may wish to avoid the financial cost of providing medically necessary, potentially curative treatment to predominantly Black Americans with SCD or TDT, the AKS is a *criminal* statute, not a policy to discourage Americans who are eligible for federal health care

[4] Of course, courts owe no deference to OIG's erroneous interpretation of the AKS and BIS. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2272-73 (2024).

programs from obtaining the benefit of that insurance. Americans with SCD or TDT who are covered by federal health care programs should be entitled to the same fertility assistance as SCD or TDT patients with commercial insurance if third parties are willing to provide it, particularly when the barrier being removed relates to a serious side effect of the regimen delivering the therapy. Any desire by HHS to save money by keeping eligible patients from obtaining critical healthcare does not render that fertility support an illegal "kickback."

19. Vertex seeks to provide medically necessary, clinically appropriate fertility preservation services so that Americans insured by federal health care programs can overcome a critical barrier to effective treatment of SCD or TDT. OIG's decision not to issue a favorable advisory opinion forecloses that option. Indeed, the federal government now stands as the barrier between thousands of predominantly Black Americans and the necessary medical care that would protect their basic right to have biological children.

20. Violating the AKS is a felony punishable by imprisonment for up to 10 years and a fine up to $100,000, 42 U.S.C. § 1320a-7b(b)(1), (2), and the BIS imposes extensive civil monetary penalties for each violation, *id.* § 1320a-7a. Because Vertex respectfully disagrees with OIG's position that the Fertility Preservation Program would violate the AKS and BIS, it is left with no alternative but to seek judicial relief.

21. Vertex accordingly brings this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and Administrative Procedure Act, 5 U.S.C. §§ 701-706, because OIG's conclusions regarding the Fertility Preservation Program are contrary to law, arbitrary and capricious, and an abuse of discretion.

22. Vertex also seeks to compel Defendants to comply with their nondiscretionary duty under 42 U.S.C. § 1320a-7d(b) to issue a written advisory opinion to Vertex by not later than 60

days after OIG's receipt of the request. On June 13, 2023, Vertex delivered via email its request that OIG issue an advisory opinion that the Fertility Preservation Program does not implicate the AKS or BIS. OIG later confirmed that the June 13 request was sufficient for OIG to proceed. As of the date of this Complaint, it has been more than thirteen months since OIG received Vertex's request, and eleven months since the expiration of the mandatory 60-day period to issue the written opinion. Without judicial relief, there is no end in sight to OIG's gratuitous delay. Just weeks ago, on June 27, 2024, OIG informed Vertex that it had sought and was "awaiting final clearance from" the Department of Justice ("DOJ") prior to issuing its written opinion. Put differently, OIG has now indefinitely delayed the issuance of Vertex's advisory opinion by seeking review of *another* governmental agency, potentially jeopardizing the health of thousands of SCD and TDT patients. The statute adopted by Congress does not permit such delaying tactics. Rather, it specifies that consultation with DOJ is *part of* the OIG's process, and thus *within* the 60-day window by which OIG must issue its written opinion. OIG's failure to issue a written advisory opinion accordingly violates 42 U.S.C. § 1320a-7d(b)(5)(B)(i), and Vertex brings this action under the Mandamus Act, 28 U.S.C. § 1361, and the Administrative Procedure Act, 5 U.S.C. § 706 to declare unlawful OIG's regulatory construction of the statutory deadline, which purports to carve out the time DOJ takes to review the issue, and to compel OIG to issue the requested advisory opinion, which it has already acknowledged it has completed.

23. Vertex more generally seeks a declaratory judgment that OIG's implementing regulations concerning the issuance of an advisory opinion, *see* 42 C.F.R. §§ 1008.39, 1008.41, and 1008.43, are contrary to law. For instance, whereas 42 U.S.C. § 1320a-7d(b)(5)(B)(i) requires that an advisory opinion must be issued no later than 60 days after a request for the opinion is "*received*," the implementing regulations state that OIG need only issue the opinion within 60 days

after the opinion is "*formally accepted*," even when OIG acknowledges that the request was complete when received. 42 C.F.R. §§ 1008.41(e), 1008.43(c)(1). Further, the implementing regulations provide for tolling of the statutory deadline under various circumstances, 42 C.F.R. §§ 1008.39(a), 1008.43(c)(3), none of which are authorized by the statute. As noted above, whereas 42 U.S.C. § 1320a-7d(b)(1) provides that OIG, "*in consultation with the Attorney General*, shall issue written advisory opinions" within the established 60-day timeframe, OIG's implementing regulations purport to permit OIG to toll the statutory timeframe while OIG seeks "expert advice," 42 C.F.R. § 1008.43(c)(3)(iv), which OIG has here determined to include advice from DOJ, the very agency with which OIG is already expected to have consulted within the statutory time limit. Those regulations must be set aside as not in accordance with law under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). And, even if the regulations are deemed not contrary to law, the regulatory deadline for OIG to issue Vertex's requested advisory opinion has long passed. OIG's failure to issue a written advisory opinion accordingly violates 42 C.F.R. §§ 1008.41(e) and 1008.43(c)(1), and Vertex brings this action under the Mandamus Act, 28 U.S.C. § 1361, and the Administrative Procedure Act, 5 U.S.C. § 706(1), to compel OIG to issue the requested advisory opinion.

24. In effect, OIG has improperly converted the *maximum* period of time specifically required by Congress for OIG's issuance of an advisory opinion into the *minimum* period of time a requester must wait for its advisory opinion. With each additional day that Vertex is forced to wait for OIG to carry out its nondiscretionary duty to issue a written opinion, SCD and TDT patients' lives hang in the balance. Vertex's only option is thus to seek relief from this Court.

PARTIES

25. Vertex is a global biotechnology company that develops and manufactures transformative medicines to treat patients with serious diseases like SCD and TDT. One of

Vertex's breakthrough medicines is CASGEVY, a potentially curative therapy approved by FDA to treat SCD and TDT. Vertex is committed to improving lives by providing broad access for eligible patients to its medicines. Vertex is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business in Boston, Massachusetts.

26. Defendant HHS is an executive department of the United States. HHS oversees health care-related federal agencies, including CMS, the federal agency that provides Americans with health care coverage through Medicare, Medicaid, and other programs. HHS is the agency directed to promulgate regulations to implement 42 U.S.C. § 1320a-7d. HHS's headquarters are in Washington, D.C.

27. Defendant OIG is an office within HHS that was established in 1976. OIG oversees certain aspects of HHS's programs. Among other things, OIG is responsible for issuing advisory opinions analyzing whether a requesting party's existing or proposed business activities implicate the AKS and the BIS. *See* 42 U.S.C. § 1320a-7d(b). The Secretary of HHS has delegated to OIG authority to exclude individuals and entities from participation in federal health care programs. *See id.* § 1320a-7(a), (b), (f)(4). OIG promulgated the regulations implementing 42 U.S.C. § 1320a-7d(b), including 42 C.F.R. §§ 1008.39, 1008.41, and 1008.43. OIG's headquarters are in Washington, D.C.

28. Defendant Xavier Becerra is sued in his official capacity as Secretary of HHS, the most senior official in the department. As Secretary of HHS, Secretary Becerra has direct authority to exclude from participation in federal health care programs any individual or entity convicted of certain offenses or deemed by the Secretary to have engaged in certain improper conduct. *See* 42 U.S.C. § 1320a-7(a), (b), (f)(4). Secretary Becerra directly supervises the Inspector General and

is thus responsible for OIG's statutory and regulatory enforcement activities. The Secretary is the officer Congress directed to promulgate regulations to implement 42 U.S.C. § 1320a-7d(b).

29. Defendant Christi A. Grimm is sued in her official capacity as Inspector General of OIG, the most senior official in OIG. As Inspector General, Ms. Grimm is responsible for OIG's oversight, guidance, rule-making process, and enforcement activities, including its issuance of advisory opinions and delegated exclusion authority.

JURISDICTION AND VENUE

30. Vertex brings this action pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, Administrative Procedure Act, 5 U.S.C. § 701-706, and Mandamus Act, 28 U.S.C. § 1361.

31. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361.

32. This Court has authority to grant the relief requested by Vertex pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Mandamus Act, 28 U.S.C. § 1361.

33. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e), because this is an action against agencies of the United States and officers thereof acting in their official capacities. HHS and OIG are United States federal agencies and residents in this judicial district.

34. There is currently an actual, justiciable controversy between the parties regarding whether Vertex may, consistent with the AKS and BIS, provide a program designed to preserve the fertility of patients who undergo chemotherapy as part of Vertex's breakthrough gene therapy that may cure their SCD or TDT.

35. Declaratory relief will resolve this controversy and eliminate the chill that the government's interpretation of the AKS and BIS currently imposes on Vertex's ability to ensure eligible SCD and TDT patients' access to critical health care.

36. There is also an actual, justiciable controversy between the parties regarding OIG's failure to timely issue a written advisory opinion and whether the implementing regulations concerning the issuance of an advisory opinion, *see* 42 C.F.R. § 1008.39 et seq. ("AKS Advisory Opinion Regulations"), are contrary to law. Vertex first sought an advisory opinion from OIG in connection with any product or program in June 2023, in connection with CASGEVY. Thus, Vertex was only recently injured by 42 C.F.R. §§ 1008.39, 1008.41 and 1008.43. As an innovator biotechnology company, Vertex plans to make other advisory opinion requests to OIG in the future.

37. Relief is warranted to compel OIG to perform its obligation to issue a written advisory opinion in response to Vertex's advisory opinion request, which is unlawfully delayed in violation of 42 U.S.C. § 1320a-7d(b)(5)(B)(i) and 42 C.F.R. §§ 1008.41(e) and 1008.43(c)(1), and to prevent OIG from enforcing the AKS Advisory Opinion Regulations that are not in accordance with law.

FACTUAL BACKGROUND

I. Sickle Cell Disease Is a Debilitating Illness That Impacts a Vulnerable Population.

38. Sickle cell disease is a debilitating genetic blood disorder that affects the shape of blood cells. Letter from Vertex to OIG (the "AOR"), at 5-6 (June 13, 2023). SCD is caused by a mutation in a gene that helps make hemoglobin, a protein in red blood cells. *Id.* at 6. In people without SCD, red blood cells containing hemoglobin are round and flexible, enabling the red blood cells to easily navigate through large and small blood vessels to deliver oxygen from the lungs throughout the body. *Id.* But for people with SCD, genetic mutations cause red blood cells to become rigid, sickle-shaped, and sticky. *Id.*

39. Sickled blood cells can form clusters in the bloodstream, which block the flow of blood and oxygen, damaging blood vessels and organs. *Id.* at 6-7. Blockages lead to VOCs, which

cause severe pain, are associated with increased risk of organ damage and death, and are the primary cause of hospitalization for patients with SCD. *Id.* at 7.

40. SCD also causes various physical, emotional, financial, and professional difficulties for many SCD patients. The lack of oxygen in body tissue caused by SCD puts SCD patients at greater risk for serious health issues like stroke, difficulty breathing, and organ damage.[5] Many SCD patients experience depression.[6] SCD also disrupts patients' professional lives, with many patients missing workdays due to VOCs.[7]

41. Approximately 100,000 Americans suffer from SCD.[8] SCD is associated with premature mortality, with a median age of death of 43 years.[9] In 2021, approximately 50% of SCD patients received healthcare coverage through Medicaid.[10] Likely reflecting the high

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[5] PhRMA, *Medicines in Development 2019 Report, Sickle Cell Disease* at 1 (2019), https://phrma.org/en/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Sickle-Cell-Disease-2019-Report.

[6] Soheir S. Adam et al., *Depression, Quality of Life, and Medical Resource Utilization in Sickle Cell Disease*, 1 Blood Advances 1983, 1983 (2017).

[7] Mark E. Swanson et al., *Disability Among Individuals with Sickle Cell Disease*, 41 Am. J. Preventative Med. S390, S394 (2011).

[8] *Data and Statistics on Sickle Cell Disease*, CDC, https://www.cdc.gov/sickle-cell/data/?CDC_AAref_Val=https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited July 8, 2024); *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease*, FDA News Release (Dec. 8, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease.

[9] A.M. Brandow & R.I. Liem, *Advances in the Diagnosis and Treatment of Sickle Cell Disease*, 15 J. Hematol. Oncol. 1, 1 (2022).

[10] Junelle Speller & Sarah Rayel, *New Analysis of Sickle Cell Disease Prevalence Among Medicaid Enrollees Fills Gap in Public Data*, Nat'l Op. Rsch. Ctr. Univ. of Chi. (Dec. 11, 2023), https://www.norc.org/research/library/spotlight-new-analysis-of-sickle-cell-disease-prevalence-among-medicaid-enrollees.html#:~:text=NORC%27s%20analysis%20identified%2052%2C524%20Medicaid,and%20clustered%20in%20Southern%20states.

mortality rate among SCD patients, only 10% of those Medicaid enrollees were 46 years of age or older.[11]

42. SCD disproportionately affects Black Americans. In the United States, SCD occurs in about one in every 365 Black births, and more than 90% of SCD patients are Black.[12] Preventing this patient population from accessing the means to protect their fertility echoes the historical mistreatment of Black Americans by the U.S. medical system, including involuntary sterilization of women deemed unfit to reproduce (a disproportionate number of whom were Black) throughout the 20th century until at least the 1970s.[13]

II. Transfusion-Dependent Beta-Thalassemia Is a Severe Blood Disorder that Requires Patients to Undergo Regular Blood Transfusions to Survive.

43. Beta-thalassemia is a hereditary blood disorder characterized by anomalies in the synthesis of beta chains of hemoglobin, leading to reduced red blood cell production. AOR at 14. TDT is the most severe form of beta-thalassemia and is so named because patients are dependent on regular blood transfusions to avoid severe anemia and debilitating developmental complications. *Id.* Like SCD, TDT also causes various physical, emotional, financial, and professional difficulties for many TDT patients. *Id.* at 15.

44. Approximately 2,000 Americans suffer from TDT, and the median age of death for TDT patients is 37 years. *Id.* at 14. Approximately 45% of TDT patients who are insured are covered by Medicare, Medicaid, or the VA. *Id.* at 15.

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[11] *Id.*

[12] *Data and Statistics on Sickle Cell Disease*, CDC, https://www.cdc.gov/sickle-cell/data/?CDC_AAref_Val=https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited July 8, 2024).

[13] Dan Royles, *Years of Medical Abuse Make Black Americans Less Likely to Trust the Coronavirus Vaccine*, Wash. Post (Dec. 15, 2020), https://www.washingtonpost.com/outlook/2020/12/15/years-medical-abuse-make-blackamericans-less-likely-trust-covid-vaccine/.

III. Vertex Develops CASGEVY, a Potential Cure for SCD and TDT.

45. To address these debilitating disorders, Vertex developed CASGEVY, an innovative gene editing therapy. CASGEVY is a significant improvement over earlier therapies for SCD and TDT because it addresses the underlying causes of the diseases, rather than treating only the symptoms. *See* AOR at 2. CASGEVY is a potential cure for SCD: in clinical trials it has eliminated severe VOCs in 94% of patients with SCD. *Id.* at 1-2 n.1. Similarly, in clinical trials, CASGEVY has eliminated transfusion dependence for 91.4% of TDT patients.

46. CASGEVY is made specifically for each patient by editing an SCD or TDT patient's own blood stem cells to produce elevated levels of fetal hemoglobin in red blood cells. *Id.* at 16. The onset of SCD and TDT symptoms occurs at the same time that fetal hemoglobin levels decrease shortly after birth; before that time, the high levels of fetal hemoglobin prevent the disease symptoms from manifesting. *Id.* The Product thus treats SCD and TDT by increasing the amount of fetal hemoglobin in patients' bloodstream. Having more fetal hemoglobin increases overall hemoglobin levels and has been shown to improve the production and function of red blood cells, which can eliminate severe VOCs in SCD patients and the need for transfusions in TDT patients. *Id.*

47. Vertex's successful clinical trials demonstrate CASGEVY's efficacy and safety. For instance, data from a clinical trial in severe SCD patients, which is ongoing, showed that 94% of patients evaluated 16 months after treatment with CASGEVY achieved the primary efficacy endpoint, defined by the absence of severe VOCs for at least 12 consecutive months. *Id.* at 19. Safety data from the clinical trials was generally consistent with that expected from the high doses of chemotherapy (myeloablative conditioning) that patients must undergo to benefit from treatment with CASGEVY, including a high risk of infertility, as discussed further below. *Id.* at 20.

IV. Preparatory Treatment for CASGEVY Poses Infertility Risks.

48. Administering CASGEVY requires a multi-step, months-long process. SCD patients must first undergo a minimum of eight weeks of red blood cell transfusions (this step is not required for TDT patients). AOR at 17. Once the transfusions are completed, the patient must stay in a hospital for several days while he or she receives injections of certain drugs that stimulate the patient's blood stem cells out of their bone marrow and into the bloodstream. *Id.* Next, the patient's blood stem cells are collected and transported to a location where the Product is manufactured by editing the patient's cells using a gene-editing technology called CRISPR-Cas9. *Id.* at 17-18. The manufacturing process takes approximately five to six months, and if the manufacturing process is not successful, the patient will need to undergo another round of cell mobilization and cell collection. *Id.* at 18.

49. Then, before receiving the Product, a patient must undergo full myeloablative conditioning—which suppresses the patient's bone marrow activity to allow for engraftment of the patient's edited blood stem cells. *Id.* Finally, the patient receives CASGEVY through intravenous infusion. After administration of the Product, the patient must be monitored at a treatment center for four to six weeks before returning home. *Id.*

50. In clinical trials, SCD and TDT patients were treated with CASGEVY after undergoing myeloablative conditioning with the chemotherapy drug busulfan, which can lead to serious side effects, including infertility in male and female patients. *Id.* at 2, 18. Indeed, the label for Busulfex, which is the brand name drug of busulfan, lists infertility as a potential effect of the drug.[14] Other medicines used for myeloablative conditioning are also associated with infertility.

[14] Busulfex, Package Insert, at 10, 17, https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020954s014lbl.pdf (last visited July 8, 2024).

See AOR at 2, 30, 42. As CASGEVY's package insert explains, "[i]nfertility has been observed with myeloablative conditioning," and patients receiving CASGEVY should be advised of "fertility preservation options before treatment, if appropriate."[15] CASGEVY's prescribing information also includes a description of the infertility risks associated with myeloablative conditioning, advising patients that "[a]fter receiving the [myeloablative] *conditioning* medicine, it may not be possible for you to become pregnant or father a child."[16]

51. The effect on fertility of this type of chemotherapy is significant, and it is not unique to the myeloablative conditioning required for administration of CASGEVY. In one study involving 138 female recipients who received conditioning with busulfan prior to hematopoietic stem cell transplantation ("HSCT"), a procedure in which an SCD patient receives compatible stem cells derived from the bone marrow or blood of a matched donor, fertility impairment was suspected in 83% of patients.[17] And in men, the absence of sperm cells "is a frequent finding in male long-term survivors of HSCT" as a result of chemotherapy given before transplantation or as conditioning for HSCT.[18] Vertex is investing in researching alternative conditioning regimens that do not impact fertility, but no such regimens are currently available.

V. Lack of Access to Fertility Treatment May Cause Patients to Delay or Forego Treatment for SCD and TDT.

52. The lack of access to fertility treatment presents a significant barrier to individuals considering treatment for SCD and TDT. The risk of infertility is a leading factor in patients'

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[15] CASGEVY (STN 125787), Package Insert at 10, https://www.fda.gov/media/174615/download?attachment (last visited July 9, 2024).

[16] *Id.* at 18.

[17] *See* André Tichelli & Alicia Rovó, *Fertility Issues Following Hematopoietic Stem Cell Transplantation*, Medscape (2013), https://www.medscape.com/viewarticle/810686_4.

[18] *Id.*

decisions to delay or forego treatment. Letter from Vertex to OIG ("Oct. 10 Letter"), at 6 (Oct. 10, 2023). In a survey of adult SCD patients considering an experimental bone marrow transplant (a prior, alternative treatment), almost two-thirds were willing to accept the risk of dying from the procedure, but infertility was acceptable to only half.[19] In a survey of children and adolescent SCD patients, 44% responded that they were not willing to accept infertility after receiving HSCT. Oct. 10 Letter at 7. And if patients delay therapy until they can start a family, they may no longer be healthy enough to safely undergo treatment. According to a study of 311 SCD patients conducted by Vertex in 2022 to better understand and quantify the number of SCD patients who are medically eligible for myeloablative conditioning, 72% of patients aged 12 to 17 were deemed eligible by their health care providers, but only 34% of patients aged 18 to 35 were eligible, due to inadequate organ function or severe comorbidities. *Id.* at 4. Even when patients are able to undergo treatment with the Product after electing to delay, the progression of their disease during the period of delay can nevertheless have serious and potentially irreversible consequences on their physical and psychological health.

53. Fertility treatments are rarely covered by commercial insurance or government health care programs. Commercial insurers in the United States are not required by federal law to cover fertility care.[20] As explained in the AOR, only 19 U.S. states require insurance companies to cover at least some fertility care, AOR at 13, and no states require Medicaid to cover artificial insemination, in-vitro fertilization ("IVF"), or cryopreservation.[21] As a result, many patients

[19] S. Chakrabarti & D. Bareford, *A Survey on Patient Perception of Reduced-Intensity Transplantation in Adults with Sickle Cell Disease*, 39 Bone Marrow Transplantation 447, 448 (2007).

[20] Adrienne D. Mishkin et al., *Fertility Concerns and Access to Care for Stem Cell Transplantation Candidates with Sickle Cell Disease*, 26 Biol. Blood Marrow Transplantation e192, e193. (2020).

[21] Gabriela Weigel et al., *Coverage and Use of Fertility Services in the U.S.*, KFF (2020),

seeking fertility care must resort to paying out of pocket, even if they have health insurance. AOR at 13. But the high cost of uninsured fertility care—which can run into the tens of thousands of dollars—is prohibitive for a majority of SCD and TDT patients. In a 2021 survey, more than half of the 2,054 SCD patients surveyed reported an annual household income under $25,000, AOR at 13, far less than what would be necessary to afford fertility care.[22]

54. Vertex's innovative therapy offers significant medical benefits to historically underserved patients and tremendous value to the health care system by eliminating the lifelong cost of treating SCD and TDT patients, who often require emergency treatment and hospital stays. The one-time price of CASGEVY is consistent with that strong clinical and economic profile. Vertex has established a wholesale acquisition cost for the Product in the U.S. of $2.2 million. Letter from Vertex to OIG ("Dec. 21 Letter"), at 2 (Dec. 21, 2023). The price for treatment with CASGEVY is ***well below the lifetime cost of care*** for SCD and TDT patients, which is estimated at $5.2 million per patient and $5.4 million per patient, respectively. AOR at 44.

VI. Vertex's Fertility Preservation Program Provides Financial Support for Fertility Treatment, Removing Barriers to Accessing CASGEVY.

55. To remove barriers to accessing a one-time, potentially curative therapy, Vertex developed the Fertility Preservation Program, which provides financial support up to $70,000 for medically necessary fertility services for eligible patients prescribed CASGEVY. AOR at 2-3, 34.

56. To be eligible for the Fertility Preservation Program, patients must be United States (or U.S. territory) residents, have an annual household income at or below 670 percent of the Federal Poverty Level, be prescribed the Product for an FDA-approved use, and not have insurance

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https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/.

[22] Jessica Semega & Melissa Kollar, *Income in the United States: 2021, U.S. Census Bureau* (Sept. 13, 2022), https://www.census.gov/library/publications/2022/demo/p60-276.html.

that covers fertility care. *Id.* at 35. Vertex plans to make the Fertility Preservation Program available to all eligible patients without regard to a patient's selection of health care provider. *Id.* at 54-55.

57. The maximum amount of financial assistance provided through the Fertility Preservation Program was determined based on the average cost per patient of a successful pregnancy from fertility preservation via IVF, which can range from $41,000 to approximately $70,000 for two rounds of IVF. *Id.* at 34. Financial support will only cover the fertility services that a participating patient actually uses, which for some patients could be significantly less than $70,000.

58. Fertility support will be determined on a patient-by-patient basis by independent health care professionals and may include patient counseling, fertility drugs, collection and storage of oocytes or sperm (*i.e.*, harvesting and cryopreservation), genetic testing, intrauterine insemination, and/or IVF procedures, as applicable to each individual patient. *Id.* at 34. The Fertility Preservation Program thus provides financial support for a range of services that when put together can enable a patient to have a biological child. If the fertility services were limited to merely harvesting and cryopreservation, and did not extend to fertilization and implantation procedures, the Fertility Preservation Program would not by itself enable a patient to have a biological child, and therefore would not actually preserve the patient's fertility.

59. A vendor will assist eligible patients and caregivers by identifying fertility health care providers for each patient enrolled in the Fertility Preservation Program. *Id.* Patients and their caregivers, where applicable, will select their own fertility providers and treatments; Vertex will have no involvement in the selection of fertility providers or treatments. *Id.* at 34-35. Vertex will simply pay fertility providers, via a third-party vendor, for the treatments actually provided to

patients enrolled in the Fertility Preservation Program. *Id.* at 35. Neither Vertex nor the vendor will make any payments to patients or their caregivers in the form of a stipend or other payment. *Id.* Payments made under the Program will pass directly from Vertex to the vendor to pay for fertility support on behalf of enrolled patients. *Id.*

60. Vertex will not use the Fertility Preservation Program to solicit new patients for CASGEVY. Indeed, the Fertility Preservation Program will be available to a patient only after the prescribing decision has been made, and Vertex will not promote the Program as a reason to prescribe the Product. *Id.* at 36. Vertex field representatives will not be incentivized in any way to promote the Fertility Preservation Program to health care providers. *Id.* at 37. And Vertex will not advertise the Program, including via direct-to-consumer advertisements, third-party websites, or in magazines. *Id.*

61. Vertex will make the Fertility Preservation Program available to commercially insured eligible patients but currently cannot extend the Fertility Preservation Program to eligible patients insured by federal health care programs, including Medicare and Medicaid, without near certain risk of an enforcement action. A Fertility Preservation Program open to all patients, regardless of their type of insurance, would thus place the many vulnerable Medicaid-insured SCD and TDT patients on similar footing as eligible commercially insured patients battling SCD or TDT, who will benefit from the Fertility Preservation Program.

VII. FDA Hails CASGEVY As a "Milestone," While OIG Resists Fertility Support Necessary to Ensuring Access to It.

62. Because manufacturers like Vertex could fear that their common, lawful business activities might arguably fall within the language of the AKS and BIS—even though they raise no genuine concern of fraud—Congress enacted a process by which manufacturers can seek an advisory opinion that their proposed conduct would not implicate the statutes. 42 U.S.C. § 1320a-

7d(b). Manufacturers can also seek an advisory opinion that the proposed activity does not "constitute[] grounds for the imposition of a sanction" of exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7d(b)(2)(E).

63. On June 13, 2023, Vertex delivered via email a letter requesting that OIG issue an advisory opinion that the Fertility Preservation Program would not implicate the AKS or BIS. AOR at 1. On June 26, 2023, OIG sent a letter to Vertex acknowledging that it received Vertex's June 13 request and formally accepted the request. OIG Letter to Vertex ("June 26 Letter"), at 1 (June 26, 2024). In that letter, OIG requested additional information concerning a separate patient assistance program that was included in the AOR, a program that provides travel and lodging support for eligible patients (the "Travel Program"), and purported to toll the time period to issue the advisory opinion until it received the additional information, citing 42 C.F.R. § 1008.39. *Id.* On August 25, 2023, Vertex responded to OIG's request for additional information regarding the Travel Program.

64. Meanwhile, on July 13, 2023, OIG held a teleconference with Vertex to convey its initial reactions to the two programs that were the subject of the AOR. During this call, OIG expressed its concerns about the Fertility Preservation Program and invited Vertex to provide additional information in support of it. On October 10, 2023, Vertex provided additional information in support of the Fertility Preservation Program. Oct. 10 Letter at 1.

65. On October 26, 2023, OIG informed Vertex that it was splitting Vertex's June 13 request into two separate requests, one related to the Travel Program, and a second for the Fertility Preservation Program. OIG wrote that "[t]his email confirms acceptance" of the request for an advisory opinion regarding the Fertility Preservation Program.

66. On November 22, 2023, OIG orally informed Vertex that Vertex's request for the Fertility Preservation Program would result in an unfavorable opinion. OIG conveyed its conclusion that the Fertility Preservation Program posed more than a low risk of fraud and abuse to federal health care programs and that CASGEVY can be prescribed safely and effectively without the fertility preservation support offered through the Program, even though it acknowledged that infertility is a side effect of the myeloablative conditioning that is a prerequisite to administration of the Product.

67. On December 4, 2023, Vertex sent a letter to OIG requesting that OIG publish the advisory opinion for the Fertility Preservation Program within the time frame provided by 42 C.F.R. § 1008.43. Letter from Vertex to OIG ("December 4 Letter"), at 1 (December 4, 2023). Four days later, on December 8, OIG sent an email to Vertex with a list of questions about the Fertility Preservation Program and purported to toll the time period to issue the advisory opinion until OIG received the requested information.

68. On December 8, 2023, the FDA approved CASGEVY for treatment of SCD in patients twelve years and older with recurrent VOCs.[23] In the FDA's press release announcing the approval of CASGEVY, the FDA called the Product a "milestone" therapy and noted that CASGEVY is "the first FDA-approved therapy utilizing CRISPR/Cas9, a type of genome editing technology."[24]

69. Also on December 8, 2023, FDA approved bluebird bio, Inc.'s gene-editing therapy LYFGENIA™ for the treatment of patients twelve years of age and older with SCD and a history

[23] *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease*, FDA News Release (Dec. 8, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease.

[24] *Id.*

of vaso-occlusive events.[25] LYFGENIA is different from the Product in two important respects. First, LYFGENIA has a wholesale acquisition cost of $3.1 million (which is $900,000 more expensive than the Product). Dec. 21 Letter at 2. Second, LYFGENIA's Prescribing Information has a black box safety warning for hematologic malignancy (also known as blood cancer). *Id.* at Ex. B - 2.

70. On January 16, 2024, FDA approved CASGEVY for treatment of TDT in patients twelve years or older.[26]

71. On December 21, 2023, following FDA approval of CASGEVY for SCD, Vertex sought OIG's reconsideration of the Fertility Preservation Program and provided further support for its proposal. Dec. 21 Letter at 1. At a teleconference on January 26, 2024, OIG again informed Vertex of OIG's determination that it would not issue a favorable advisory opinion. Feb. 2. Letter, at 1. OIG conveyed that it had concluded that the Fertility Preservation Program implicates the AKS and BIS, poses more than a low risk of fraud and abuse to federal health care programs, and does not promote access to gene therapy care. *Id.*

72. On February 2, 2024, Vertex requested that OIG move forward expeditiously with finalizing and publishing a written explanation of its decision not to issue a favorable advisory opinion, and noted that the governing regulations specify that "OIG will issue an advisory opinion . . . within 60 days after the request for an advisory opinion has been formally accepted." *Id.* at 1 (citing 42 C.F.R. § 1008.43). Later that day, OIG responded via email that it would "proceed with this issuance of this advisory opinion."

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[25] *Id.*

[26] FDA, Approval Letter – CASGEVY at 1 (Jan. 26, 2014), https://www.fda.gov/media/175482/download?attachment.

73. Vertex followed up with OIG regarding the status of its advisory opinion request on March 7, and again on April 17, 2024. On April 26, 2024, OIG responded via email that it anticipated issuing a written explanation of its determination in May 2024. On June 7, 2024, Vertex again wrote to OIG noting that the time period to provide any written explanation of its determination had long passed and that Vertex could not wait any longer than June 21 before seeking judicial review of OIG's adverse determination. Letter from Vertex to OIG at 1 (June 7, 2024). Three days later, OIG sent to Vertex a draft factual statement summarizing the information that Vertex provided in its request for an advisory opinion and requested Vertex's certification of those facts. Letter from OIG to Vertex at 1 (June 10, 2024). Vertex provided its final certification of OIG's draft factual statement on June 12, 2024.

74. On June 26, 2024, Vertex sent an email to OIG to ask when OIG would send instructions so Vertex could pay for its requested advisory opinion. The next day, on June 27, 2024, OIG responded that it is "awaiting final clearance from DOJ" before it could issue the advisory opinion, and stated that it has "every expectation that [it] will receive final clearance soon." Per its regulation, OIG regards this period of consultation with DOJ as tolling the deadline for its written opinion. *See* 42 C.F.R. § 1008.43(c)(3)(iv). The practical effect of OIG's decision to seek DOJ clearance—more than a year after OIG received Vertex's advisory opinion request and long past the requisite 60-day period for OIG to issue its opinion—is that the issuance of Vertex's advisory opinion is ***indefinitely*** delayed. As of the date this Complaint was filed, OIG has not issued a written opinion explaining its determination.

VIII. CMS Program to Expand Access to Gene Therapy Requires Participating Manufacturers to Cover Limited Fertility Treatments.

75. On January 30, 2024, CMS announced that SCD would be the first focus of the CMS Innovation Center's Cell and Gene Therapy Access Model.[27] Under the CGT Access Model, CMS will partner with participating states and willing manufacturers such as Vertex to expand access to gene therapies for the treatment of SCD.[28] CMS will negotiate "outcomes-based agreements" with participating manufacturers, which will tie pricing for SCD treatments to positive health outcomes for Medicaid patients.[29] In other words, under these "outcomes-based agreements," spending for a gene therapy varies based on whether certain outcomes are achieved over a defined period of time.[30] CMS's negotiations will also include pricing rebates and a standardized policy for accessing the manufacturer's treatments.[31] Participating states will decide whether to enter into an agreement with manufacturers based on the terms negotiated by CMS.[32] The goal of the CGT Access Model is "improve health outcomes, increase access to cell and gene therapies, and lower health care costs for some of the nation's most vulnerable populations."[33]

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[27] *Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments*, CMS Press Release (Jan. 30, 2024), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments.

[28] *Id.*

[29] *Id.*

[30] CMS, *Cell and Gene Therapy (CGT) Access Model Request for Applications from Applicable Manufacturers* at 6, https://www.cms.gov/files/document/cgt-model-mfr-rfa-march-2024.pdf (last visited July 9, 2024).

[31] *Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments*, CMS Press Release (Jan. 30, 2024), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments.

[32] *Id.*

[33] *Id.*

76. To effectuate its stated goal of improving health outcomes and increasing access to cell and gene therapies, the CGT Access Model will require participating manufacturers of SCD gene therapies "to cover certain fertility preservation services, because the care journey for SCD CGT typically results in infertility."[34] CMS has explained that "[l]ack of access to fertility preservation services presents a significant access barrier to individuals considering [cell and gene therapies]."[35] CMS expects that the CGT Access Model will "expand access to critical supportive services that are likely to increase beneficiary uptake of the [participating drugs] in order to improve health outcomes."[36] CMS thus recognizes that infertility concerns prevent many SCD patients from receiving treatment with a gene editing therapy, and that financial support for fertility preservation services is necessary for more SCD patients to receive innovative treatments like CASGEVY.

77. Fertility preservation services that may be offered through the CGT Access Model include the harvesting, freezing, and storage of mature and immature eggs; sperm collection, freezing, and storage; and testicular tissue extraction, freezing and storage.[37] However, pursuant to the CGT Access Model's terms, services offered cannot include IVF procedures.[38] Thus, unlike the fertility services offered through the Fertility Preservation Program, the services offered through the CGT Access Model do not by themselves ensure that a patient who has gone through

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[34] CMS, *Cell and Gene Therapy (CGT) Access Model Overview Factsheet* at 2, https://www.cms.gov/files/document/cgt-model-ovw-fact-sheet.pdf (last visited July 9, 2024).

[35] *Id.*

[36] CMS, *Cell and Gene Therapy (CGT) Access Model Request for Applications from Applicable Manufacturers* at 7, https://www.cms.gov/files/document/cgt-model-mfr-rfa-march-2024.pdf (last visited July 9, 2024).

[37] *Id.* at 20-21.

[38] *Id.* at 23.

myeloablative conditioning to prepare for treatment with CASGEVY will be able to have a biological child. In other words, by limiting the services allowed under the CGT Access Model to harvesting and cryopreservation—and excluding fertilization and implantation procedures—the services do not actually preserve fertility.

VERTEX'S FERTILITY PRESERVATION PROGRAM IS LAWFUL, AND OIG'S CONSTRUCTION AND APPLICATION OF THE AKS AND BIS ARE LEGALLY FLAWED, ARBITRARY AND CAPRICIOUS, AND AN ABUSE OF DISCRETION.

I. Statutory Framework.

A. The Anti-Kickback Statute

78. The AKS makes it a crime to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to induce such person . . . to purchase . . . or recommend purchasing" a product paid for by federal health insurance or to "solicit[] or receive" such remuneration "in return for" such purchase or recommendation. 42 U.S.C. § 1320a-7b(b)(1), (2). *See* H.R. Rep. No. 95-393(II), at 52-53 (1977).

79. Congress originally enacted the AKS in 1972 with the goal of protecting the Medicare and Medicaid programs from waste, fraud, and abuse. *See* Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). The initial 1972 version of the AKS ultimately proved to have limited deterrent effect, largely owing to the limited nature of the misdemeanor penalties that attached to a violation.

80. Congress accordingly amended the AKS in 1977 to provide felony penalties and substantial monetary fines for violators. *See* Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179-83 (1977). As noted in the amendment's legislative history, the AKS's purpose is to curtail "fraudulent and abusive practices associated with the provision of health services financed by the Medicare and Medicaid programs," which "cheats taxpayers" and "diverts from those most in

need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services." H.R. Rep. No. 95-393(II), at 44 (1977).

81. Congress has further revised the AKS on numerous occasions, consistently expanding the scope of the penalties that attach to violations while retaining (and even narrowing) the language defining the conduct subject to those penalties. *See, e.g.*, Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 119, 759 (2010) (expanding the scope of available penalties for AKS violations to include statutory penalties and treble damages under the False Claims Act); Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980) (amending the statute to narrow liability by requiring that a defendant engage in the prohibited conduct "knowingly and willfully" to be guilty of a crime).

82. Conviction under the AKS can result in severe consequences for pharmaceutical manufacturers, executives, and employees, including the imposition of criminal and civil penalties (including serving as the basis for liability under the False Claims Act), and administrative sanctions. *See* 42 U.S.C. § 1320a-7(b)(15). Conviction can also serve as grounds to exclude the company and its products from reimbursement under federal health care programs, including Medicare and Medicaid. *See id.* § 1320-7(a), (b).

83. Because the language of the AKS was potentially ambiguous and the consequences of conviction are so severe, Congress has enacted various statutory exemptions for different types of conduct that it wanted to ensure were not deterred. *See id.* § 1320a-7b(b)(3). These statutory exceptions demonstrate that Congress intends for the AKS to apply only in circumstances where the remuneration is intended to improperly or corruptly skew the relevant individual's decision-making.

B. The Beneficiary Inducement Statute

84. The BIS, enacted as part of the Health Insurance Portability and Accountability Act in 1996, addresses similar subject matter as the AKS but imposes only civil penalties. *See id.* § 1320a-7a(a).

85. In relevant part, the BIS imposes liability upon anyone who "offers to or transfers remuneration to any individual . . . that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made" under a federal health care program. *Id.* § 1320a-7a(a)(5). Congress's omission of the exemplary phrase "kickback, bribe, or rebate" and its use of the broader term "influence"—rather than "to induce" behavior "in return for" payment—in the BIS reflects Congress's intent that the civil BIS covers additional conduct outside the ambit of the criminal AKS.

C. Safe Harbors and the "Promotes Access to Care" Exception

86. Congress has ordered HHS to promulgate regulatory "safe harbors" for the AKS and BIS, which define certain types of payments and other arrangements that cannot be the basis for criminal or civil liability even if they arguably violate the language of the AKS or BIS if read broadly. *See* 42 U.S.C. §§ 1320a-7a(i)(6); 1320a-7b(b)(3).[39]

[39] The Senate Committee Report explained Congress's intent in creating regulatory "safe harbors" as follows: "It is the understanding of the Committee that the breadth of [the] statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution ... and that will not provide a basis for exclusion from participation in Medicare or the State health care programs." S. Rep. No. 100-109, at 27 (1987).

87. Pursuant to certain safe harbors, not all monetary payments qualify as "remuneration" under the BIS and AKS. As relevant here, the BIS provides that the transfer of a good, service, or other thing of value that "promotes access to care and poses a low risk of harm to patients and Federal health care programs" is not "remuneration . . . likely to influence" for purposes of the BIS (the "Promotes Access to Care Exception"). 42 U.S.C. § 1320a-7a(i)(6)(F). Per the safe harbor regulation that implements the Promotes Access to Care Exception, the exception applies to "[i]tems 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 the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision-making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns[.]" 42 C.F.R. § 1003.110.

88. Because the criminal AKS is by its text already narrower than the civil BIS, Congress had no need to provide such an express exception to the AKS. The broader language of the BIS—*e.g.*, the BIS extends liability to remuneration that the payer "knows or should know is likely to *influence*" the beneficiary, 42 U.S.C. § 1320a-7a(a)(5) (emphasis added), rather than requiring, as the criminal AKS does, that the "remuneration (including any kickback, bribe, or rebate)" be intended "to *induce*" the recipient's behavior, *id.* § 1320a-7b(b)(2) (emphasis added)—requires exceptions to make clear that certain socially beneficial conduct is not covered. The rationale for the Promotes Access to Care Exception necessarily applies to the AKS because to conclude otherwise would make subject to criminal punishment "remuneration" that Congress has specifically excluded from even civil liability because it did not want to deter that activity.

D. The "Inducement" Element

89. A payment only violates the AKS if it is provided "knowingly and willfully . . . to *induce*" the purchase, prescription, or recommendation of items or services payable under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2) (emphasis added).

90. "[I]nduce" in the criminal AKS takes on its specialized criminal-law meaning that restricts the statute's reach to corrupt *quid-pro-quo* transactions akin to criminal solicitation. *See United States v. Hansen*, 599 U.S. 762, 774 (2023) (holding that the criminal immigration statute at issue necessarily "uses 'encourages or induces' in its specialized, criminal law sense—that is, as incorporating common-law liability for solicitation and facilitation"); *see Woodhull Freedom Found. v. United States*, 72 F.4th 1286, 1300 (D.C. Cir. 2023) (relying on *Hansen* to hold that "promote or facilitate" in the felony trafficking statute at issue means "aid or abet," not more general advocacy or education).

91. Like the immigration statute in *Hansen*, the AKS criminalizes both sides of an illegal transaction. *See* 42 U.S.C. § 1320a-7b(b)(1), (2). The AKS makes it a crime to knowingly and willfully "solicit[] or receive" any remuneration "in return for" purchasing federally funded health care goods or services, *id.* § 1320a-7b(b)(1), *and* to knowingly and willfully "offer[] or pay[]" any remuneration "to induce" a recipient to make that purchase. *Id.* § 1320a-7b(b)(2); *see also United States v. Clough*, 978 F.3d 810, 821 (1st Cir. 2020) ("The Anti-Kickback Statute criminalizes any kickback knowingly and willingly offered, paid, solicited, or received *in exchange for*, among other behavior, prescribing a drug for which a federal health care program has picked up the check." (emphasis added)).[40]

[40] As noted in *Hansen*, Black's Law Dictionary has defined "inducement" to mean "that which leads or tempts to the commission of crime." 599 U.S. at 776 (citing *Inducement*, Black's Law

92. The context in which "induce" is used in the AKS further supports construing the term as meaning criminal solicitation, not mere "influence." *See Hansen*, 599 U.S. at 774-75. The AKS criminalizes, as a felony, certain *quid-pro-quo* transactions regarding health care goods and services, and the term "induce" is sandwiched between the statute's quid (*i.e.*, the illegal remuneration) and quo (*i.e.*, the subsequent purchase of federally funded health care). As discussed further below, the statute's listing of "kickback, bribe, or rebate"—each of which connotes a corrupt skewing—as examples of "remuneration" that may not be used "to induce" certain action further confirms that "induce" in the AKS must have the same specialized, criminal-law meaning.

E. The "Remuneration" Element

93. Not all remuneration is unlawful under the AKS. The AKS's use of "kickback, bribe, or rebate" as examples of "remuneration" demonstrates that the statute reaches only transactions that corrupt physicians' and patients' decision-making and thus solicit or facilitate an unlawful act on the part of the recipient.

94. "Kickback" and "bribe" have well-established meanings, each of which involves a corrupting influence on the recipient. *Skilling v. United States*, 561 U.S. 358, 412-13 (2010). In particular, a "kickback" is a thing of value provided "for the purpose of *improperly* obtaining or rewarding favorable treatment," *id.* (emphasis added) (internal quotation omitted), and bribery requires corruption under federal law, *id.* at 412. These crimes reach only *corrupting* influence, not mere "influence" alone. *See Snyder v. United States*, 603 U.S. ___, 144 S. Ct. 1947, 1954-56 (2024).

Dictionary 617 (1891)). That was the criminal-law definition of inducement when the term was added to the AKS. *See Inducement*, Black's Law Dictionary 915 (4th ed. 1951).

95. In the context of the AKS, "rebate" is a term of art that likewise involves corruption. Before the AKS was amended in 1977, the statute prohibited "kickback[s]," "bribe[s]," and "rebates[s], of any fee or charge for referring any such individual" for certain services. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). The statute thus addresses a particular kind of "rebate" that corrupts referrals of certain services.

96. In sum, the exemplary trio of "kickback, bribe, or rebate" within the phrase "remuneration (including any kickback, bribe, or rebate) . . . to induce" indicates that the "remuneration" involved must share the common characteristic of the offered examples—corruption akin to criminal solicitation. *See Fischer v. United States*, 603 U.S. ___, 144 S. Ct. 2176, 2183-84 (2024) (relying on the *ejusdem generis* and *noscitur a sociis* canons of construction to interpret a criminal statute and noting that they "track the common sense intuition that Congress would not ordinarily introduce a general term that renders meaningless the specific text that accompanies it"). Otherwise, the parenthetical serves no purpose, and such an interpretation would impermissibly render the phrase surplusage.

97. The selection of the term "remuneration" in the AKS reinforces the requirement of a *quid pro quo*. Black's Law Dictionary defines "remuneration" as "compensation, esp. for a service that someone has performed," *Remuneration*, Black's Law Dictionary 1550 (11th ed. 2019), *i.e.*, something paid *in exchange for* the conduct the payor seeks to influence. *See also Remuneration*, Black's Law Dictionary 1459 (4th ed. 1951) (noting that the term implies "*quid pro quo*"). Further, as a textual matter, "remuneration (including any kickback, bribe, or rebate)" is inextricably linked to "to induce" or "in return for." *See* 42 U.S.C. § 1320a-7b(b)(1), (2). Each phrase as a whole describes a corrupt *quid pro quo* in which the offer or solicitation of remuneration or payment is made or requested with the "intent to bring about a particular unlawful

act," *Hansen*, 599 U.S. at 771, *i.e.*, the decision to prescribe or purchase the federally reimbursed product or service.

II. Under a Correct Construction, the Fertility Preservation Program Does Not Violate the AKS.

98. OIG's decision not to issue a favorable advisory opinion reflects that OIG applied an incorrect construction of the AKS to its evaluation of the Fertility Preservation Program, and thus its determination that the Fertility Preservation Program implicates the AKS must be set aside as "not in accordance with law." 5 U.S.C. § 706(2)(A). Contrary to the AKS's plain text and numerous canons of construction, OIG construes the phrase "remuneration (including any kickback, bribe, or rebate) . . . to induce" in the criminal AKS to mean essentially "remuneration . . . likely to influence," which is the broader phrase used in the civil BIS. *See* OIG Adv. Op. No. 22-19, at 13 (Sept. 30, 2022) ("[W]e have explained that the meaning of the term to induce is found in the ordinary dictionary definition: to lead or move by influence or persuasion.") (internal quotation marks omitted).

99. Correctly construed, the AKS does not reach Vertex's Fertility Preservation Program, which would not improperly influence or skew the decision of physicians or patients to use CASGEVY. The Fertility Preservation Program does not involve a *quid pro quo* transaction, much less one as part of a corrupt transaction that seeks to unlawfully corrupt a physician's or patient's decision-making akin to criminal solicitation. OIG's position that the Fertility Preservation Program implicates the AKS is thus contrary to law, arbitrary and capricious, and an abuse of discretion. 5 U.S.C. § 706(2)(A).

100. First, physicians will prescribe the Product and patients will choose to use it because it offers a potentially curative treatment of devastating diseases—not because of the Fertility Preservation Program. For instance, recent clinical results demonstrating CASGEVY's

efficacy have shown that the Product eliminated severe VOCs for at least 12 consecutive months in 94% of participating SCD patients evaluated 16 months after treatment. AOR at 37. The elimination or significant reduction of VOCs can dramatically improve an SCD patient's quality of life, as failure to treat VOCs can lead to acute pain crises, stroke, and other severe complications.[41]

101. Second, the Fertility Preservation Program will not improperly interfere with or skew medical decision-making because it does not offer any independent benefit to patients, but is instead designed to mitigate a serious potential side effect caused by chemotherapy that must be undertaken prior to administration of the Product. If Vertex were able to develop a means of administering CASGEVY utilizing a gentler conditioning agent that eliminated the risk of infertility (and Vertex is in fact working to develop such a program), there would be no need for the Fertility Preservation Program. And if Vertex were to implement such a change, there would be no conceivable argument that doing so violated the AKS, even if it increased the cost of CASGEVY to federal health care programs and influenced some patients to take CASGEVY who otherwise would not have. Likewise, the proposed fertility preservation services merely mitigate the risk of infertility that is an unfortunate side effect of the conditioning process presently necessary for successful treatment with CASGEVY; the fertility preservation services are not offered to patients in order to entice them to undergo treatment with CASGEVY. Nor do patients accept the fertility preservation assistance "in return for" undergoing CASGEVY, but rather to counter a known side effect of the treatment. Moreover, as CMS itself has recognized through the

[41] PhRMA, *Medicines in Development 2019 Report, Sickle Cell Disease* at 1 (2019), https://phrma.org/en/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Sickle-Cell-Disease-2019-Report.

CGT Access Model, the provision of medically necessary fertility services is critical to expanding access to gene therapies and thereby improving health outcomes for SCD patients.[42]

102. Third, physicians will prescribe the Product and patients will choose to use it because it has advantages to competing treatments on the market. The safety profile of LYFGENIA, the other FDA-approved gene therapy for SCD, is notably different from CASGEVY's: LYFGENIA's Prescribing Information has a boxed warning for hematologic malignancy, which is another name for blood cancer.[43] In addition to its safety profile, physicians and patients may choose CASGEVY because it is $900,000 cheaper than LYFGENIA. Dec. 21 Letter at 2. The Product may also offer less serious side effects compared to other available, non-gene-based treatments for SCD (and TDT). HSCT, which is another potentially curative therapy for SCD patients, but which only a small subset of patients with SCD with recurrent VOCs receive,[44] requires lifelong immunosuppression therapy and carries significant safety risks, including graft-versus-host disease, infection, and infertility.[45] Other treatment options for SCD include red blood cell transfusions and treatment with medications like hydroxyurea, L-glutamine Oral Powder, Crizanlizumab, and Voxelotor, but each of these treatments only targets the

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[42] CMS, *Cell and Gene Therapy (CGT) Access Model Request for Applications from Applicable Manufacturers* at 7, https://www.cms.gov/files/document/cgt-model-mfr-rfa-march-2024.pdf (last visited July 9, 2024).

[43] LYFGENIA, Package Insert at 1, https://www.fda.gov/media/174610/download (last visited July 9, 2024). Patients who underwent myeloablative conditioning and received either CASGEVY or LYFGENIA experienced otherwise similar adverse reactions, many of which are attributable to the myeloablative conditioning itself. *See id.* at 8; AOR at 20.

[44] Chuka Udeze et al., *Clinical and Economic Outcomes in Patients with Transfusion-Dependent β-Thalassemia and Patients with Sickle Cell Disease with Recurrent Vaso-Occlusive Crises Receiving Hematopoietic Stem Cell Transplants in the United States*, 140 Blood 10741 (2022).

[45] Adetola A. Kassim & Deva Sharma, *Hematopoietic Stem Cell Transplantation for Sickle Cell Disease: The Changing Landscape*, 10 Hematology/Oncology & Stem Cell Therapy 259, 259 (2017).

symptoms of the disease and comes with serious side effects that may lead a physician to instead choose the Product for eligible patients. AOR at 24-26.

103. Fourth, the Fertility Preservation Program's eligibility criteria ensure that the Program does not create a *quid-pro-quo* arrangement or otherwise constitute criminal solicitation. The Program is available only to patients who meet certain criteria and only after a patient has already been prescribed CASGEVY. AOR at 35. Patients will select their own fertility providers and treatments, *id.* at 34-35, and Vertex will make the Fertility Preservation Program available to all eligible patients without regard to a patient's selection of a health care provider. *Id.* at 54-55. Moreover, Vertex will not promote the Fertility Preservation Program to physicians as a reason to prescribe the Product. *Id.* at 36. Rather, Vertex will provide only non-promotional information about the Fertility Preservation Program to physicians and patients, such as the Program's eligibility criteria and terms and conditions. *Id.* And Vertex will not provide any financial incentive to physicians or advertise the Program. *Id.* at 35-36. As a result, a patient's decision to undergo the multi-step, months-long process required for treatment with CASGEVY and a physician's decision to prescribe the treatment are not made in exchange for financial incentives or participation in the Program.

III. The Fertility Preservation Program Meets the "Promotes Access to Care" Exception.

104. The Fertility Preservation Program meets the Promotes Access to Care Exception under the BIS (which must also necessarily apply to the AKS under OIG's proposed statutory construction). OIG's failure to apply the Promotes Access to Care Exception to the AKS is contrary to law, and OIG's position that the Fertility Preservation Program does not meet the

Promotes Access to Care Exception is legally flawed, arbitrary and capricious, and an abuse of discretion, and must accordingly be set aside.[46]

105. Under the safe harbor regulation that implements the Promotes Access to Care Exception, the exception applies to "[i]tems 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 the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision-making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns[.]" 42 C.F.R. § 1003.110; *see* 42 U.S.C. § 1320a-7a(i)(6)(F).

106. The Fertility Preservation Program meets the Promotes Access to Care Exception by its plain terms and by the logic OIG has applied in other advisory opinions, *see, e.g.*, OIG Adv. Op. No. 19-02, at 6-8 (Jan. 29, 2019) (finding a program that increased patient safety and quality of care through the provision of limited-use smartphones fit within the Promotes Access to Care Exception).

107. The Fertility Preservation Program increases access to necessary medical care. Treatment-related infertility concerns are a significant barrier to treatment for SCD and TDT patients, and the risk of infertility deters many patients from pursuing treatment, perhaps until it is

[46] Although OIG has sometimes appeared to apply the Promotes Access to Care Exception when assessing conduct under the AKS, it has also at times refused to recognize that the AKS exempts beneficial transfers of value intended to ensure access to care, along the lines of the BIS exception. *Compare* OIG Adv. Op. No. 19-02, at 8 (Jan. 29, 2019) (concluding a proposed program would fall within the BIS Promotes Access to Care Exception, and stating that "the same analysis applies" under the AKS) *with* OIG Adv. Op. No. 20-05, at 11 (Sept. 23, 2020) ("These exceptions apply only for the purposes of the definition of 'remuneration' applicable to [the BIS]; they do not apply for purposes of [the AKS].").

too late for the patient to be eligible for the treatment. The Fertility Preservation Program facilitates a federal health care program beneficiary's ability to overcome this barrier and access the full scope of their prescribed therapy. Fertility support that could resolve this dilemma is rarely covered by insurance, especially federal health care programs. Because most SCD and TDT patients do not have the means to pay for fertility services out of pocket, they cannot access the fertility care they need. Instead, they face the difficult choice between pursuing a potentially curative therapy whose pre-conditioning leaves them infertile or living with their increasingly debilitating disease until it may be too late. The Fertility Preservation Program removes this significant barrier to access for patients insured by federal health care programs who have been prescribed a medically necessary therapy but lack the resources to fully avail themselves of it. The Fertility Preservation Program thus "improve[s] a beneficiary's ability to obtain" treatment, as required by the first element of the Promotes Access to Care Exception.

108. The Fertility Preservation Program also poses a low risk of harm to patients or federal health care programs, as required by the second element of the Promotes Access to Care Exception.

109. First, the Fertility Preservation Program does not interfere with or skew clinical decision-making. The Program will be offered to patients only *after* their health care providers make the independent decision to prescribe CASGEVY. The Fertility Preservation Program will be available to eligible patients who have been prescribed CASGEVY for an FDA-approved use, without regard to a patient's selection of a health care provider. And the Program will not be advertised to patients.

110. Second, the Fertility Preservation Program promotes appropriate utilization, not overutilization. Only patients who are prescribed CASGEVY for an FDA-approved use by their

physician will be eligible to participate in the Program. CASGEVY is a one-time, potentially curative therapy that could obviate the need for the health care system (funded by federal health care programs) to provide lifetime treatment of SCD and TDT patients' symptoms. As a result, the treatment—which is less expensive than the average lifetime cost of care for SCD and TDT patients[47]—will likely ***decrease*** the financial burden of SCD and TDT on the nation's healthcare system, not increase it. Even if there were additional cost to federal health care programs as a result of the Fertility Preservation Program, that would be because SCD and TDT patients are able to take advantage of a medically appropriate therapy, as determined by their doctors, rather than decline care for fear of losing the chance to be biological parents. This is not "overutilization" or "inappropriate utilization," but rather improved utilization. Thus, the effect of the Program would not be to induce unwarranted utilization of the Product, but to help ensure that SCD and TDT patients have access to a potentially curative therapy. The idea that a patient would undergo (and a doctor would prescribe) an arduous, multi-step, months-long process to receive medically unnecessary gene-editing therapy in order to obtain fertility services defies logic.

111. Third, the Fertility Preservation Program promotes patient safety and quality of care by protecting the fertility of patients undergoing treatment. The Fertility Preservation Program is designed to address serious side effects—infertility risks caused by the myeloablative conditioning regimen that is a prerequisite to administration of the Product—and thus promotes access to care. The Fertility Preservation Program increases patient safety by lifting a barrier that could cause many patients to delay or forego treatment and thus suffer further health deterioration. Many SCD and TDT patients may elect to delay or forego treatment due to concerns about infertility, and that

[47] The lifetime costs of care for SCD patients are estimated at $5.2 million per patient, and the lifetime costs of care for TDT patients are estimated at $5.4 million per patient. AOR at 44. The wholesale acquisition cost for CASGEVY in the United States is $2.2 million.

decision can have fatal consequences. If SCD and TDT patients wait too long to receive treatment with CASGEVY, they may not be physically able to safely undergo myeloablative conditioning, and thus no longer eligible to undergo treatment with the Product. And even if a patient is able to undergo treatment with the Product after electing to delay, the progression of their disease during the period of delay can have serious and potentially irreversible consequences on the patient's physical and psychological health. Without the Fertility Preservation Program, many patients will be left to choose between using the Product that may result in infertility or continuing to live with a debilitating disease and an expected decrease in life expectancy.

112. Tellingly, OIG's finding that the Fertility Preservation Program does not promote access to care contradicts the determination of CMS, its sister agency, in connection with the CGT Access Model. The CGT Access Model is designed to "improve health outcomes, increase access to cell and gene therapies, and lower health care costs for some of the nation's most vulnerable populations."[48] CMS could not be clearer on this point, stating the "[l]ack of access to fertility preservation services presents a significant access barrier to individuals considering [cell and gene therapies]" and then requiring participating manufacturers to cover limited fertility services on that basis.[49] Vertex's Fertility Preservation Program is consistent with CMS's guidance in connection with the CGT Access Model that financial support from drug manufacturers for fertility preservation services is necessary "because the care journey for SCD CGT typically results in

[48] *Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments*, CMS Press Release (Jan. 30, 2024), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments.

[49] CMS, *Cell and Gene Therapy (CGT) Access Model Overview Factsheet* at 2 https://www.cms.gov/files/document/cgt-model-ovw-fact-sheet.pdf (last visited July 9, 2024).

infertility."[50] Indeed, the Fertility Preservation Program's offerings are more extensive than what is required under the CGT Access Model, providing patients with the full, rather than partial, means to overcome this significant barrier to care.[51]

IN LIGHT OF OIG'S CONSTRUCTION AND APPLICATION OF THE AKS AND BIS, VERTEX CANNOT IMPLEMENT THE FERTILITY PRESERVATION PROGRAM WITH RESPECT TO FEDERAL HEALTH CARE PROGRAM BENEFICIARIES IN THE ABSENCE OF AN ORDER FROM THE COURT, WITHOUT SIGNIFICANT RISK OF INCURRING AN ENFORCEMENT ACTION.

113. OIG's overly broad interpretation of the AKS and BIS prevents Vertex from extending its Fertility Preservation Program to SCD and TDT patients who receive insurance through federal health care programs, notwithstanding the benefits of the Fertility Preservation Program, which would remove a significant barrier to SCD and TDT patients access of a potentially curative gene editing therapy. OIG's interpretation is wrong, and Vertex's Fertility Preservation Program is lawful as a matter of proper statutory construction.

114. Congress enacted the AKS and BIS to combat health care fraud and prevent the distortion of medical decision-making. OIG, however, has adopted the view that the AKS and the BIS prohibit pharmaceutical manufacturers like Vertex from providing financial assistance for fertility services to federal health care beneficiaries, irrespective of whether such assistance would provide access to critically needed therapies, rather than improperly corrupt medical decision-making in a manner akin to criminal solicitation.

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[50] *Id.*

[51] Fertility Preservation Program services include patient counseling, fertility drugs, collection and storage of oocytes or sperm, genetic testing, intrauterine insemination, and/or IVF procedures, as applicable to each individual patient. AOR at 34. Services offered through the CGT Access Model cannot include IVF procedures. CMS, *Cell and Gene Therapy (CGT) Access Model Request for Applications from Applicable Manufacturers* at 23, https://www.cms.gov/files/document/cgt-model-mfr-rfa-march-2024.pdf (last visited July 9, 2024).

115. On June 13, 2023, Vertex requested that OIG issue an advisory opinion that the Fertility Preservation Program would not entail prohibited remuneration within the meaning of the AKS or BIS. AOR at 1. On November 22, 2023, OIG orally informed Vertex that Vertex's request for the Fertility Preservation Program would result in an unfavorable opinion. Although Vertex sought reconsideration after the FDA approved CASGEVY, OIG's position remained unchanged, and on January 26, 2023, it again orally informed Vertex that it would issue an unfavorable opinion, even after CMS had opined that offering fertility care was critical to overcoming barriers to access for many patients suffering from SCD. *See* Feb. 2. Letter, at 1. Through its correspondence with Vertex, OIG has conveyed its conclusion that even though the Fertility Preservation Program addresses a potential side effect of the chemotherapy that is a prerequisite to administration of CASGEVY, the Program implicates the AKS and BIS, poses more than a low risk of fraud and abuse to federal health care programs, and does not promote access to gene therapy care. *Id.*

116. OIG's guidance in prior advisory opinions confirms its expansive interpretation of the AKS and BIS. In interpreting the AKS, OIG has ignored key aspects of the statutory framework and history and has adopted an overbroad definition of "to induce," explaining that the term "is found in the ordinary dictionary definition: to lead or move by influence or persuasion." *See, e.g.*, OIG Adv. Op. No. 22-19, at 13 (Sept. 30, 2022) (internal quotation marks omitted). And OIG has at times refused to recognize that the AKS exempts beneficial transfers of value intended to ensure access to care. *See, e.g.*, OIG Adv. Op. No. 20-05, at 11 (Sept. 23, 2020) (explaining that exceptions in the BIS, including the Promotes Access to Care Exception, "apply only for the purposes of the definition of 'remuneration' applicable to [the BIS]; they do not apply for purposes of [the AKS]").

117. OIG's actions expose Vertex to increased risk of criminal and civil enforcement action from the government if it were to implement the Fertility Preservation Program with respect to federal health care program beneficiaries in the absence of a favorable ruling from the Court.

118. Conviction under the AKS can result in severe criminal consequences for pharmaceutical manufacturers and their employees, including the possibility of a pharmaceutical manufacturer's exclusion from federal reimbursement for its medications. *See* 42 U.S.C. § 1320a-7(a), (b). A violation of the BIS can result in civil monetary penalties. *See id.* § 1320-7a(a). A violation of the AKS or BIS may also serve as a predicate violation for the False Claims Act, *id.* § 1320a-7b(g), which the government can use to collect treble damages and additional penalties, 31 U.S.C. § 3729(a)(1).

119. OIG's decision to issue an unfavorable advisory opinion on the proposed Fertility Preservation Program leaves Vertex unable to engage in its desired conduct. Absent this Court's intervention, Vertex's only options are to comply with OIG's current interpretation of the AKS and BIS, or go forward subject to the significant and credible threat of enforcement. If the Court declares, however, that the Fertility Preservation Program does not constitute prohibited "remuneration" or result in any improper "inducement," and thus does not violate either the AKS or BIS, then Vertex would be free to initiate the Fertility Preservation Program to help SCD and TDT patients eliminate a barrier to accessing a breakthrough potentially curative treatment.

THE AKS ADVISORY OPINION REGULATIONS ARE CONTRARY TO 42 U.S.C. § 1320a-7d(b) AND OIG'S FAILURE TO ISSUE THE REQUESTED ADVISORY OPINION WITHIN THE TIME PERIOD ESTABLISHED BY STATUTE AND REGULATION IS UNLAWFUL.

120. Congress enacted a process by which manufacturers like Vertex can seek an advisory opinion that their proposed conduct would not implicate the AKS or BIS. *See* 42 U.S.C.

§ 1320a-7d(b).[52] The statute also grants to the Secretary of HHS the authority to promulgate regulations providing for certain procedures to be followed when a party seeks an advisory opinion. *Id.* § 1320a-7d(b)(5)(A). Importantly, however, the statute imposes a nondiscretionary duty on the Secretary of HHS, in consultation with the Attorney General, to issue a "written advisory opinion" within a specified timeframe. 42 U.S.C. § 1320a-7d(b)(1), (5)(B)(i). The statute provides that under regulations promulgated pursuant to 42 U.S.C. § 1320a-7d(b)(5)(A), the Secretary of HHS "*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) (emphases added). The statute expressly contemplates that OIG shall issue written advisory opinions "in consultation with the Attorney General," *id.* § 1320a-7d(b)(1), and makes no allowance for that consultation to extend the 60-day period in which OIG "shall issue" such opinions. In short, under the statute, the receipt of an advisory opinion request starts a mandatory 60-day clock for OIG to issue the requested written advisory opinion.

121. Despite this clear guidance from Congress, HHS has promulgated AKS Advisory Opinion Regulations providing that the 60-day clock to issue an advisory opinion does not begin when OIG *receives* the request, as specified by statute, but only when OIG *accepts* the request for an advisory opinion, thus giving OIG the say-so as to when to start the clock. Under those regulations, upon receipt of a request for an advisory opinion, OIG will "make an initial determination" whether the request includes sufficient information, and within ten working days, "*[f]ormally accept*" the request, notify the requestor if additional information is needed, or formally decline to accept the request. 42 C.F.R. § 1008.41(a), (b). The AKS Advisory Opinion

[52] Vertex submitted an advisory request pursuant to 42 U.S.C. § 1320a-7d(b) for the first time in 2023.

Regulations further provide that "OIG 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) (emphasis added); *see id.* § 1008.41(e) ("The 60-day period for issuance of an advisory opinion set forth in § 1008.43(c) of this part will not commence until the OIG has *formally accepted* the request for an advisory opinion.") (emphasis added). Moreover, the AKS Advisory Opinion Regulations provide for tolling of the statutory deadline under various circumstances, including consultation with other agencies. *See* 42 C.F.R. § 1008.43(c)(3).[53] OIG believes that this tolling includes its consultation with DOJ, which Congress mandated OIG to do as part of OIG's consideration. 42 U.S.C. § 1320a-7d(b)(1).

122. The AKS Advisory Opinion Regulations are plainly contrary to law; under 42 U.S.C. § 1320a-7d(b)(5)(B)(i), an advisory opinion must be issued no later than 60 days after a request for the opinion is *received*, not when OIG decides that it wants to deem the request *accepted*. Nor does the statute authorize tolling of the 60-day period. 42 U.S.C. § 1320a-7d(b).

123. In any event, the statutory deadline for OIG to issue Vertex's requested advisory opinion has long passed. More than one year ago, on June 13, 2023, Vertex delivered via email its request that OIG issue an advisory opinion that the Fertility Preservation Program would not implicate the AKS or BIS. AOR at 1. On June 26, 2023, OIG sent a letter to Vertex acknowledging

[53] The AKS Advisory Opinion Regulations purport to toll the 60-day period when: (1) OIG notifies the requester that certain costs have reached or are likely to exceed a triggering amount and is waiting to receive written notice from the requestor to continue processing the request; (2) OIG requests additional information from the requestor and is waiting to receive the information; (3) OIG is waiting on the requestor to send the full amount owed for the advisory opinion; and (4) OIG notifies the requestor of the need for expert advice and is waiting to receive such advice. 42 C.F.R. §§ 1008.39, 1008.43(c)(3)(i)-(iv). The regulations further specify that if the requestor provides additional information requested by OIG, or "otherwise resubmits the request, the OIG will process the resubmission . . . as if it was an initial request for an advisory opinion." *Id.* § 1008.41(c).

that it received Vertex's request made on June 13 and formally accepted the request, which confirms that the AOR sent *and received* on June 13, 2024, contained "sufficient information" for OIG to proceed. June 26 Letter at 1. OIG was required to issue Vertex's requested written advisory opinion by no later than 60 days after its June 13, 2023 receipt of Vertex's sufficient request, which period includes any consultation with the Attorney General. 42 U.S.C. § 1320a-7d(b)(5)(B)(i). OIG failed to do so. OIG's failure to perform its statutory duty constitutes agency action unlawfully withheld and unreasonably delayed.

124. Even if the AKS Advisory Opinion Regulations were not contrary to law, the deadline those regulations establish for OIG to issue Vertex's requested advisory opinion also passed months ago, even accounting for the time for which OIG purported to toll the 60-day period. Indeed, in addition to the time between when OIG formally accepted the request until it gave Vertex its oral adverse determination, more than 60 days have passed since Vertex requested, on February 2, 2024, that OIG issue a written explanation of that determination, as required by statute. Feb. 2 Letter at 1. More than four months—129 days—passed between that date and OIG's next substantive communication, on June 10, 2024, which asked Vertex to verify the factual bases for OIG's opinion, which Vertex did on June 12, 2024. Another 33 days have expired since Vertex certified the factual bases for the request, yet *still* OIG has not issued its written opinion.

125. Notwithstanding that OIG had already exceeded the requisite time for its issuance of the requested advisory opinion by more than double, OIG next communicated to Vertex that, although it had finished its written opinion, it would not release it. OIG now improperly purports to exclude from the 60-day time period (even though it has already passed) its consultation with DOJ, however long that might take. *See* June 27, 2024, email from OIG to Vertex (stating OIG was "awaiting final clearance from" DOJ prior to issuing its written opinion). Where the statutory

language plainly requires that OIG will, "in consultation with the Attorney General," issue its written advisory opinion within the 60-day time period, OIG cannot then circumvent its statutory obligations by delegating to DOJ the power to stop the clock indefinitely. *See* 42 U.S.C. § 1320a-7d(b)(1).

126. OIG violated its nondiscretionary duty by failing to issue a written advisory opinion within the time period established by statute and regulation. OIG's failure to issue an advisory opinion is thus unlawful and warrants the issuance of a writ of mandamus, 28 U.S.C. § 1361, and/or relief under 5 U.S.C. § 706(1) to "compel agency action unlawfully withheld or unreasonably delayed."

127. Unreasonable delay claims under the Administrative Procedure Act and the Mandamus Act share the same standards for obtaining relief. *Vietnam Veterans of Am. v. Shinseki*, 599 F.3d 654, 659 n.6 (D.C. Cir. 2010). "The central question in evaluating 'a claim of unreasonable delay' is 'whether the agency's delay is so egregious as to warrant mandamus.'" *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (quoting *Telecomms. Rsch. & Action Ctr. v. FCC*, 750 F.2d 70, 79 (D.C. Cir. 1984)) ("*TRAC*"). Unreasonable delay is analyzed using six factors: (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency

action is unreasonably delayed. *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (quoting *TRAC*, 750 F.2d at 80).

128. Those factors are met here. In particular, Congress has clearly provided that OIG "shall issue [a] written advisory opinion[]" and "shall be required" to do so "by not later than 60 days after the request is received." 42 U.S.C. § 1320a-7d(b)(1), (5)(B)(i). OIG has itself recognized that it "must issue these [advisory] opinions within a sixty (60) day period, *regardless of the complexity of the arrangement in question*." 63 Fed. Reg. 38,311, 38,313 (July 16, 1998) (emphasis added). OIG has violated its statutory and regulatory obligation to issue Vertex's requested advisory opinion within 60 days. Moreover, OIG's lengthy delay puts at risk the health and welfare of scores of Americans: the practical effect of OIG's delay is to deny thousands of patients suffering from SCD and TDT the ability to receive a potentially curative gene therapy.

129. OIG's delay is egregious. As of the date this Complaint was filed, it is more than one year since OIG received Vertex's request for an advisory opinion, and many months past the expiration of the statutory and regulatory periods to issue the opinion. Yet, OIG failed to timely issue its opinion, and continues to delay issuance of a written opinion. Indeed, OIG has confirmed that it has already completed its written opinion, but refuses to issue it because now, long after the 60-day period has expired, OIG has sought DOJ's views. *See* June 27, 2024, email from OIG to Vertex (stating OIG was "awaiting final clearance from" DOJ prior to issuing its written opinion). As OIG's unlawful delay continues to grow, the health of SCD and TDT patients hangs in the balance, heightening the need for relief. Vertex has no alternative but to seek judicial relief, which is warranted to compel OIG to issue Vertex's requested written advisory opinion without further delay and to set aside the provisions of the AKS Advisory Opinion Regulations that violate the

simple and direct statutory command to issue a written advisory opinion within 60 days of receipt of the advisory opinion request.

COUNT I

Vertex Is Entitled to a Declaration That the Fertility Preservation Program Does Not Violate the AKS or BIS.

28 U.S.C. § 2201

130. Vertex incorporates and realleges the paragraphs above as though fully set forth herein.

131. The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

132. Neither the AKS nor the BIS prohibits Vertex's Fertility Preservation Program because the Fertility Preservation Program would not involve improper influence, inducement, and/or remuneration under those statutory schemes.

133. An actual controversy exists between the parties, within the jurisdiction of this Court, regarding whether Vertex may, consistent with the AKS and BIS, provide financial support for fertility treatment to eligible SCD and TDT patients to help them access CASGEVY. This controversy involves the rights and liabilities of the parties under the laws of the United States and may be determined by a judgment of this Court.

134. Vertex is an interested party to the government's actions and is entitled to challenge those actions.

135. Vertex has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile. Vertex has no adequate remedy at law.

136. Vertex is entitled to a declaratory judgment confirming that its Fertility Preservation Program does not violate the AKS or BIS.

COUNT II

The Government's Refusal to Grant Vertex a Favorable Advisory Opinion Is Not in Accordance with Law, Arbitrary and Capricious, and an Abuse of Discretion Under the Administrative Procedure Act.

5 U.S.C. § 702

137. Vertex incorporates and realleges the paragraphs above as though fully set forth herein.

138. Under the Administrative Procedure Act, a person suffering a wrong or adversely affected by agency action is entitled to judicial review of the agency's action, 5 U.S.C. § 702, and the reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "contrary to constitutional right," *id.* § 706(2)(A)-(B).

139. OIG's refusal to grant Vertex a favorable advisory opinion and its guidance in prior advisory opinions establish its position that it is illegal under the AKS and the BIS for Vertex to implement its Fertility Preservation Program for SCD and TDT patients who receive insurance through federal health care programs like Medicaid and Medicare. OIG's erroneous interpretation of the AKS and BIS and its refusal to grant Vertex a favorable advisory opinion result in harm to Vertex. Vertex is entitled to challenge OIG's misinterpretation of the AKS and BIS and failure to issue a favorable advisory opinion. 5 U.S.C. §§ 701-706.

140. OIG's overbroad construction of the AKS—including reading "remuneration (including any kickback, bribe, or rebate)" in the AKS as simply "remuneration," as used in the BIS, and reading "induce" in the AKS as mere "influence," as used in the BIS—is not in accordance with law, arbitrary and capricious, and an abuse of discretion.

141. OIG's application of its overbroad statutory construction to the Fertility Preservation Program and position that the Fertility Preservation Program would implicate the AKS and the BIS is not in accordance with law, arbitrary and capricious, and an abuse of discretion. Neither the AKS nor the BIS prohibits Vertex's Fertility Preservation Program because the Fertility Preservation Program would not involve improper influence, inducement, and/or remuneration under those statutory schemes.

142. OIG's failure to apply the BIS Promotes Access to Care Exception to the AKS, as OIG's erroneous construction of the AKS would require, is not in accordance with law, arbitrary and capricious, and an abuse of discretion. The Fertility Preservation Program meets the Promotes Access to Care Exception under the BIS, which necessarily applies to the AKS, because the Program eliminates a significant barrier to SCD and TDT patients receiving treatment while posing a low risk of harm to patients and federal health care programs.

143. OIG's position that the Fertility Preservation Program, which eliminates a significant barrier to SCD and TDT patients receiving treatment while posing a low risk of harm to patients and federal health care programs, does not meet the Promotes Access to Care Exception is not in accordance with law, arbitrary and capricious, and an abuse of discretion.

144. In combination with its other actions, OIG's oral determination that the Fertility Preservation Program implicates the AKS and BIS is final agency action that prevents Vertex from lawfully extending the Fertility Preservation Program to SCD and TDT patients insured through federal health care programs.

145. Vertex has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile. Vertex has repeatedly requested the issuance

of a written advisory opinion to explain OIG's adverse determination, but OIG has refused to provide one. HHS and OIG provide no further process to prompt further action.

146. Vertex has no adequate remedy at law.

147. Accordingly, Vertex seeks a judgment setting aside OIG's determination that the Fertility Preservation Program implicates the AKS and BIS.

COUNT III

The AKS Advisory Opinion Regulations are Contrary to Law.

5 U.S.C. § 706

148. Vertex incorporates and realleges the paragraphs above as though fully set forth herein.

149. The AKS Advisory Opinion Regulations are final agency action. *See* 5 U.S.C. § 704.

150. Under the Administrative Procedure Act, a reviewing court must hold unlawful and set aside agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

151. The AKS Advisory Opinion Regulations are contrary to law and exceed the Secretary's statutory authority, at least because they purport to (1) alter the point at which the 60-day statutory period for OIG to issue an advisory opinion begins from the time an advisory request is "received" to the time such a request is "formally accepted," and (2) permit OIG to toll the statutory timeframe, including to allow for consultation with "expert[s]," which OIG has apparently deemed to include DOJ.

152. OIG applied the unlawful AKS Advisory Opinion Regulations in connection with Vertex's advisory opinion request. For instance, OIG received Vertex's request on June 13, 2023, but OIG did not "formally accept" the request until June 26, 2023, and has purported to toll the

60-day time period, including an indefinite pause for purposes of consulting with DOJ, even though the 60-day period expired long ago. These delays, among others, have stretched the 60-day timeframe into more than a year, which is contrary to law and exceeds OIG's statutory authority.

153. Vertex was injured by the AKS Advisory Opinion Regulations for the first time in 2023, when Vertex submitted its first advisory opinion request, and OIG failed to issue a written advisory opinion within the statutory deadline, relying on its unlawful regulation.

154. As an innovative biotechnology company that seeks to promote access to its breakthrough treatments, Vertex plans to seek further advisory opinions in the future.

155. Vertex is entitled to a declaration that the AKS Advisory Opinion Regulations are contrary to law and/or in excess of statutory authority insofar as they purport to toll the 60-day deadline for issuing an advisory opinion in ways inconsistent with the statutory command.

156. The Court should issue a declaratory judgment setting aside all such provisions of the AKS Advisory Opinion Regulations that are contrary to law.

COUNT IV

The Government Has Unlawfully Withheld and Unreasonably Delayed Issuance of a Written Advisory Opinion in Violation of the Administrative Procedure Act.

5 U.S.C. § 706

157. Vertex incorporates and realleges the paragraphs above as though fully set forth herein.

158. The Administrative Procedure Act empowers courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

159. The Secretary of HHS has a nondiscretionary duty "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)(i).

160. The AKS Advisory Opinion Regulations impose a nondiscretionary duty on OIG to issue an advisory opinion, subject to tolling in specified instances, "within 60 days after the request for an advisory opinion has been formally accepted." 42 C.F.R. § 1008.43(c)(1).

161. The 60-day period to issue the advisory opinion has long since expired, judged both by the statutory command and the more lenient regulatory provisions, but OIG has not issued a written advisory opinion.

162. The factors set out by the D.C. Circuit Court of Appeals in *TRAC*, 750 F.2d at 80, weigh in favor of Vertex and warrant relief from this Court.

163. The Court should therefore order OIG to issue a written advisory opinion as requested by Vertex without further delay.

COUNT V

The Government Failed to Perform Its Duty to Vertex to Issue a Written Advisory Opinion as Required by Law.

28 U.S.C. § 1361

164. Vertex incorporates and realleges the paragraphs above as though fully set forth herein.

165. The Mandamus Act provides that "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361.

166. The Secretary of HHS has a nondiscretionary duty "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)(i).

167. The AKS Advisory Opinion Regulations impose a nondiscretionary duty on OIG to issue an advisory opinion, subject to tolling in specified instances, "within 60 days after the request for an advisory opinion has been formally accepted." 42 C.F.R. § 1008.43(c)(1).

168. The 60-day period to issue the advisory opinion has long since expired, judged both by the statutory command and the more lenient regulatory provisions, but OIG has not issued a written advisory opinion.

169. Vertex's right to a timely advisory opinion is clear and undisputable, and OIG is in clear violation of its duty to issue such an opinion.

170. Vertex has no adequate alternative remedy.

171. The factors set out by the D.C. Circuit Court of Appeals in *TRAC*, 750 F.2d at 80, weigh in favor of Vertex and warrant relief from this Court.

172. The Court should therefore issue a writ of mandamus compelling OIG to issue an advisory opinion as requested by Vertex without further delay.

PRAYER FOR RELIEF

WHEREFORE, Vertex respectfully requests that this Court:

173. Enter a declaratory judgment that the Fertility Preservation Program does not violate the AKS or BIS;

174. Set aside OIG's determination that the Fertility Preservation Program implicates the AKS and BIS as not in accordance with law, arbitrary and capricious, and an abuse of discretion in violation of the Administrative Procedure Act, 5 U.S.C. §§ 701-706;

175. Enter a declaratory judgment setting aside all provisions of the AKS Advisory Opinion Regulations that are contrary to law and/or in excess of statutory authority;

176. Compel OIG to comply with its statutory and regulatory obligation to issue a written advisory opinion in response to Vertex's request without further delay;

177. Issue a writ of mandamus requiring OIG to comply with its statutory and regulatory obligation to issue a written advisory opinion in response to Vertex's request without further delay;

178. Award Plaintiff such costs and reasonable attorney's fees to which it might be entitled by law; and

179. Award such other relief as this Court may deem just and proper.

Dated: July 15, 2024

Respectfully submitted,

/s/ Douglas Hallward-Driemeier

ROPES & GRAY LLP
Douglas H. Hallward-Driemeier
D.C. Bar Id: 994052
2099 Pennsylvania Avenue, NW
Washington, DC 20006-6807
Tel: (202) 508-4600
Fax: (202) 508-4650
douglas.hallward-driemeier@ropesgray.com

Andrew J. O'Connor (*pro hac vice application forthcoming*)
800 Boylston Street
Boston, MA 02199-3600
Tel: (617) 951-7000
Fax: (617) 951-7050
andrew.oconnor@ropesgray.com

Attorneys for Plaintiff Vertex Pharmaceuticals Incorporated