DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).*]

Issued: January 10, 2025

Posted: January 15, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-01 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor") regarding a program to provide certain patients with free access to a pharmaceutical product that has limited coverage by Federal health care programs (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts

described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Drug

Requestor is a pharmaceutical company[2] that manufactures [redacted] (the "Product"), which treats [redacted] disease (the "Disease") and is intended for initiation in patients with mild cognitive impairment or mild Disease-related dementia and confirmed presence of amyloid pathology. Requestor certified that there currently are no safety or effectiveness data on initiating treatment with the Product at earlier or later stages of the Disease. The Product targets and affects the underlying disease process of the Disease rather than simply managing the symptoms of the Disease. Consistent with the Product's prescribing information, patients prescribed the Product receive intravenous infusions once every 2 weeks for approximately 1 hour in an outpatient setting. The Product may be infused in the treating physician's office, outpatient locations with some affiliation with the treating physician, or independent infusion centers that are not affiliated with the treating physician who prescribes the Product. Requestor certified that, on average, patients continue using the Product for 3.6 years and that there are no known clinical barriers to discontinuing the Product or switching to an alternate therapy.

While several drugs are available to treat the symptoms of the Disease, only two other drugs, [redacted] and [redacted][3]—both of which are administered by infusion and reimbursable under Part B—have been available to treat the underlying disease, although [redacted] was discontinued in 2024. In addition, two other products are under development. First, Requestor is developing a subcutaneous formulation of the Product, which would be reimbursed under Medicare Part D. Second, Requestor certified that another pharmaceutical company is

[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] Requestor certified that it does not own or operate, directly or indirectly, any pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.

[3] Requestor has collaborated with [redacted] since 2014 in the development and commercialization of treatments for the Disease, including both the Product and [redacted]. Requestor ceased its collaboration with respect to [redacted] in March 2022 (leaving [redacted] with sole decision-making authority), and Requestor serves as the lead of the Product's development and regulatory submissions globally. The U.S. Food & Drug Administration ("FDA") approved [redacted] in July 2024.

developing a product intended for the treatment of the Disease, which Requestor believes will be reimbursed under Medicare Part D.

The FDA granted the Product Breakthrough Therapy and Fast Track designations in 2021, granted accelerated approval for Requestor's Biologics License Application for the Product in January 2023, and converted the Product to the traditional approval process in July 2023. Requestor certified that the current Centers for Medicare & Medicaid Services ("CMS") National Coverage Determination for the Product requires as one condition of Medicare coverage that the treating physician enroll the patient in a CMS-approved prospective comparative study, data from which may be collected in a registry.[4] Requestor also certified that four such registries currently are available and that CMS will continue to review and approve additional study and registry proposals on a rolling basis. When covered by Medicare, Requestor certified that the Product is covered as a Medicare Part B outpatient infusion therapy, and reimbursement is made for both the Product[5] and its administration, where the standard 20 percent Part B coinsurance applies for Medicare Part B fee-for-service enrollees once they meet their Medicare Part B deductible.[6] Requestor certified that all State Medicaid programs also cover the Product, with cost-sharing requirements varying by State. Requestor continues to seek coverage for the Product under other Federal health care programs, which also may require cost sharing from enrollees.

B. The Arrangement

Requestor has implemented the Arrangement to provide the Product at no cost to patients, including Federal health care program enrollees, who meet the Arrangement's eligibility criteria.[7] Requestor certified that the decision to supply free Product is made based on a reasonable, uniform, and consistent assessment of financial need. Specifically, to qualify for free Product under the Arrangement, a patient must:

- reside in the United States;
- be at least 18 years old;

[4] See [redacted].

[5] Requestor certified that, outside the Arrangement, the Product is reimbursed under Medicare Part B at the statutory rate of ASP + 6 percent (which is reduced to ASP + 4.3 percent until 2027 due to sequestration under the Budget Control Act of 2011).

[6] Requestor certified that the provider cannot bill Medicare for administering the Product if the Product is not covered by Medicare for the patient. If the Product is covered by Medicare for the patient, Requestor certified that, for 2024, the administration fee from Medicare would be approximately $129.16 per infusion.

[7] Requestor offers a separate program that provides cost-sharing support (as opposed to free Product) to certain patients, but patients enrolled in Federal health care programs that cover outpatient care—including for physician-administered or prescription drugs—or otherwise cover the Product, are excluded from that support program.

- be prescribed the Product for an on-label indication;
- be uninsured, insured but with no insurance coverage for the Product,[8] or have Medicare coverage for the Product but attest that they are unable to afford their out-of-pocket costs associated with the Product; and
- have a household income equal to or below 500 percent[9] of the Federal Poverty Level.

A patient must apply to Requestor for assistance and work with the patient's treating physician to complete the application for assistance. Requestor validates patient income through either a soft credit check or by reviewing income documentation. Requestor certified that eligibility determinations are made without regard to the patient's insurer or insurance plan, physician, or infusion provider; patients are free to change physicians or infusion providers at any time. Eligibility for the Product is not contingent on past, present, or future purchases of the Product. The vendor[10] responsible for administering the Arrangement may provide applicants with information regarding Medicare, Medicaid, or the Medicare Low Income Subsidy based on the income and other documentation received during the application process. However, patients are not required to apply for these programs as a prerequisite for eligibility for free Product. Additionally, the vendor does not refer patients who qualify for free Product to any other third-party, including independent foundations, other insurance programs (e.g., Medigap), or any other third-party resource.

If a patient qualifies for free Product, Requestor's vendor ships the free Product to the site where the patient will receive the Product and clearly designates each vial containing the Product for use only by the applicable patient. Requestor certified that the vendor ships only the number of vials the provider confirms in writing are needed and clinically appropriate for the designated patient for two administrations of the Product;[11] the provider does not purchase or get

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[8] Requestor considers the patient to have no insurance coverage for the Product if the patient's insurer has denied a first-level appeal of an initial coverage denial.

[9] Requestor maintains a process that allows for patients who exceed the income criteria to apply for an exception if they can demonstrate an unanticipated hardship that leaves them unable to afford the Product.

[10] Requestor's patient services organization manages the Arrangement and uses a third-party vendor to administer the Arrangement. Requestor certified that: (i) the patient services organization is entirely independent of Requestor's sales and marketing organizations, and patient services personnel do not receive incentive compensation tied to Product sales; and (ii) the vendor is a non-commercial pharmacy that administers free product programs for many pharmaceutical manufacturers. Requestor has not asked us to opine on, and we express no opinion regarding, any arrangements between Requestor and the vendor.

[11] Requestor certified that, in the past, it had shipped only enough Product vials necessary and clinically appropriate for a single dose at a time under the Arrangement. However, Requestor certified that it received feedback from a number of administering sites that, due to the requirement for infusions to occur in precise two-week intervals, shipping only one dose at a

reimbursed for the free Product. Any Federal health care program enrollee who qualifies for free Product receives the free Product for the entire remainder of the calendar year, even if their insurance begins providing coverage for the Product at any point during the calendar year. Federal health care program patients must re-apply at the end of each calendar year to ensure that they continue to meet eligibility criteria. Requestor certified that enrollees will be able to re-enroll for subsequent calendar years if they continue to meet the eligibility criteria. Requestor certified that it intends to continue the Arrangement indefinitely, regardless of whether CMS expands Medicare coverage for the Product or new products enter the market. Requestor further certified that the Arrangement would remain available for patients who continue to meet eligibility criteria detailed above, with no Product being billed to Medicare for patients who attest that they cannot afford the associated cost-sharing amounts.

Patients must certify that they: (i) will not submit a request for payment for the free Product to any payor, including a Federal health care program; and (ii) understand that no part of the free Product, or costs associated with the free Product, will count towards any applicable out-of-pocket costs.[12] In addition, treating physicians must certify in writing that they: (i) prescribed the Product for an FDA-approved indication based on the physician's independent professional judgment of medical necessity and taking into account relevant patient safety considerations and the full prescribing information; and (ii) will not submit a request for payment for the free Product to any payor, including any Federal health care program, and will not seek payment from the patient. If the Product is being given for free to a Medicare enrollee under circumstances where it otherwise could be covered by Medicare (i.e., the enrollee cannot afford the applicable cost-sharing amount), the provider who administers the free Product may bill Medicare for the administration cost and the patient for any cost sharing related to only the administration cost.

In addition, prior to each Product shipment, the site where the Product will be administered (whether it is at a site affiliated with the prescribing physician or at an independent infusion provider) must provide an oral acknowledgement that it understands and agrees to follow all requirements associated with receiving the free Product under the Arrangement. Requestor certified that each shipment includes a letter that describes all such requirements, including, but not limited to:

- the provider's agreement not to submit a request for payment for the free Product;
- the provider's acknowledgment that quantities shipped are limited to the number of vials the provider confirms in writing are needed and clinically appropriate for the designated patient for two administrations of the Product; and

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time led to missed doses and delays in treatment (e.g., the need to reschedule appointments and MRIs that are required immediately prior to certain doses of the Product), which can cause undue stress for patients and potentially impact patient benefits and outcomes.

[12] Requestor certified that this statement applies only to the free Product and not to any applicable cost-sharing amounts actually paid by the patient (e.g., in circumstances where a provider is permitted to charge for administering the Product, as described below).

- the provider's agreement to maintain all free Product in a manner that segregates the free Product from Product used for commercial purposes, to administer the free Product only to the designated patient, and to refrain from selling, trading, bartering, transferring, or returning the free Product for credit.

If circumstances arise that cause the provider not to administer free Product to the designated patient, the provider is required to return the free Product to Requestor or certify to its disposal in accordance with Requestor's instructions. If a provider fails to meet any Arrangement requirement, Requestor reserves the right to stop shipments of any additional free Product until the provider comes into compliance.

Requestor certified that neither Requestor, nor anyone acting on Requestor's behalf, including, but not limited to, its sales or marketing representatives, field reimbursement personnel, and hub personnel, are permitted to promote the Arrangement as a reason to prescribe the Product. Requestor also does not promote the Arrangement through any direct-to-consumer advertisement of the Product. Health care professionals may learn about the Arrangement through (i) approved printed materials for general awareness[13] or (ii) reimbursement personnel, who do not receive sales-based incentive compensation and are permitted to educate pharmacists, physicians, and physician office staff about the Arrangement, including enrollment requirements and terms and conditions. Requestor certified that it expects most patients will learn about the Arrangement from: (i) the patient's treating physician; (ii) Requestor's patient support hub, which may inform the patient about the Arrangement if the patient enrolls in Requestor's patient support program after a prescribing decision has been made or a patient or caregiver calls the hub asking about financial support options; or (iii) Requestor's patient support website.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[14] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item

[13] Requestor's sales and marketing representatives are not permitted to discuss the Arrangement proactively, except to provide the approved printed materials. If they receive an unsolicited question about the Arrangement, they may respond with high-level, scripted, reactive talking points describing the Arrangement.

[14] Section 1128B(b) of the Act.

reimbursable by a Federal health care program.[15] For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.[16] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program enrollee that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute with respect to both patients who are Federal health care program enrollees and administering providers. Receiving the Product for free constitutes remuneration to Federal health care program enrollees that might induce the enrollee to continue using the Product once it is reimbursable by the applicable Federal health care program. The Arrangement provides remuneration to administering providers by giving them the opportunity to earn an administration fee when such fee is billable to a Federal health care program. No safe harbor to the Federal anti-kickback statute applies to the Arrangement. However, for the following reasons, we believe the risk of fraud and abuse presented by the

[15] Id.

[16] E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Arrangement is unlikely to inappropriately increase costs to Federal health care programs. No Product given under the Arrangement may be billed to Federal health care programs. The only cost that could be billed to a Federal health care program is the administration fee for the infusion, which would be billable only in circumstances where Medicare could have been billed for the Product (i.e., if a patient cannot afford cost sharing associated with the Product). We recognize that, to the extent that the patient's insurer, including a Federal health care program, begins to cover the Product or a patient has a change in financial status, the patient may no longer qualify for the Arrangement after the end of the calendar year in which free Product was provided, which presents risk that the Arrangement may function as a seeding program for the Product, particularly if any new products are approved and covered under Medicare Part D. However, Requestor certified that there is no barrier to switching products and that eligibility for the free Product is not contingent on past, present, or future purchases of the Product. Moreover, Requestor certified that it intends to offer the program indefinitely, even if the Product receives expanded Medicare coverage or new products enter the market and that the Arrangement would remain available for patients who continue to meet eligibility criteria, with no Product being billed to Medicare for patients who attest that they cannot afford the cost-sharing amounts for the Product.

Second, the Arrangement is unlikely to interfere with clinical decision-making. Prescribers generally do not have a financial incentive to order the Product when the Product is covered by the Arrangement. The treating physician must certify that the physician will not submit a request for payment for the free Product to any payor, including any Federal health care program, and will not seek payment from the patient. In addition, a representative at the site where the Product will be administered (whether it is at a site affiliated with the prescribing physician or at an independent infusion provider) must acknowledge prior to each Product shipment that they understand and agree to follow all requirements associated with receiving the free Product under the Arrangement. Outside of the Arrangement, the administering provider could receive payment for both the Product and the administration fee. Therefore, the administering provider—which is not always affiliated with the prescriber—loses potential profits when patients receive the Product through the Arrangement. The only potential billing opportunity arises if a patient has Medicare coverage for the Product but cannot afford the cost-sharing amount for the Product. While the administering provider can charge the administration fee for those patients, we believe the risk is low that this fee would induce a treating physician to select the Product over a competing product (particularly where the existing competing products are also infused drugs with a billable administration fee).

Finally, the Arrangement does not steer patients to any particular provider, practitioner, or insurance plan. Requestor certified that eligibility determinations are made based on reasonable, uniform, and consistent assessment of financial need and without regard to the providers, practitioners, or insurance plans selected by the patient. In addition, patients are free to change physicians or infusion providers at any time without impacting their eligibility for free Product.

2. Beneficiary Inducements CMP

In the circumstances presented by the Arrangement, Requestor's provision of free Product to qualifying Federal health care program enrollees is not likely to influence any enrollee's selection of a particular provider, practitioner, or supplier. For purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs, and Requestor certified that it does not own or operate any such entities. Requestor certified that its vendor is a non-commercial pharmacy that administers free product programs. Moreover, the free Product will be available without regard to a patient's selection of a prescribing physician or infusion provider, and enrolled patients will be free to change prescribers and infusion providers at any time. Therefore, the Arrangement does not implicate the Beneficiary Inducements CMP.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs