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: November 6, 2026

Posted: November 11, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-20 (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 sponsor autoantibody testing for eligible patients to determine whether it may be appropriate to prescribe a certain drug manufactured by Requestor (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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 Proposed 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 advisory opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this advisory 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 Proposed Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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 Proposed

Arrangement would not generate prohibited remuneration under the Beneficiary Inducements CMP.

This advisory opinion may not be relied on by any person[1] other than Requestor, has no applicability to any arrangements other than the Proposed Arrangement, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[redacted] (the "Disease") is a rare syndrome defined by progressive accumulation of surfactant in pulmonary alveoli, which results in an increased risk of secondary infections. The Disease includes multiple subtypes, of which [redacted] ("Disease A"), caused by [redacted] ("Factor") signaling, is the most common. Requestor is a biopharmaceutical company that manufacturers [redacted] (the "Product") for the treatment of Disease A.[2]

A. The Test

Disease A is characterized by [redacted], which can lead to hypoxemic respiratory failure, increased risk of infection, and pulmonary fibrosis. Typical symptoms include dyspnea, chronic cough, fatigue, unintentional weight loss, and chest pain. Requestor certified that delays in accurate diagnosis of the Disease (including the Disease A subtype) have been reported due to nonspecific symptoms and similarities to other conditions.[3] According to Requestor, these challenges often lead to misdiagnoses, such as pneumonia, bronchitis, and asthma. Additionally, Requestor certified that delays in treatment occur because traditional diagnostic and evaluation tools largely have been insufficient to accurately diagnose Disease A in a timely manner. For instance, spirometry and other pulmonary function tests do not detect Disease A because: (i) the test results may be normal in patients with Disease A; and (ii) these tests measure disease progression in other respiratory diseases, including asthma, chronic obstructive pulmonary disease, and pulmonary fibrosis, and do not distinguish from Disease A. Radiological evaluation can identify Disease patterns on imaging, but these patterns are also common in other respiratory diseases, such as cardiogenic pulmonary edema and hypersensitivity pneumonitis. Lung biopsies also have been used to diagnose or confirm the Disease (including the Disease A subtype), although, according to Requestor, a biopsy can miss a diagnosis (i.e., produce a false negative) over 29 percent of the time.

According to Requestor, Factor autoantibody testing is generally the recommended method to accurately confirm Disease A. Factor autoantibody testing measures concentrations of Factor

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[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] The Product is not yet approved by the U.S. Food & Drug Administration ("FDA"). The FDA granted the Product Priority Review with a Prescription Drug User Fee Act target action date of [redacted].

[3] Requestor presented data that suggest that an accurate diagnosis of the Disease is delayed on average by 18 months after the onset of symptoms. [redacted].

autoantibodies: elevated levels are highly sensitive and specific for Disease A and thus help confirm or rule out Disease A. Factor autoantibody testing itself does not diagnose Disease A nor does it assess Disease A severity. Requestor certified that a health care professional considers the patient's full medical history and other data markers (e.g., demographics, symptoms, radiology imaging, laboratory test results, and other pulmonary function tests) before they can make any diagnosis or management decisions for the patient. Moreover, Factor autoantibody testing may rule out a diagnosis of Disease A, thereby enabling a health care professional to reach an accurate diagnosis and initiate appropriate treatment in a more timely manner.

B. The Proposed Arrangement

1. The Laboratory Services Provider

Under the Proposed Arrangement, Requestor would contract with a third-party laboratory (the "Vendor") to provide no-cost Factor autoantibody testing (the "Test") to eligible patients to help confirm or rule out Disease A.[4] The Proposed Arrangement would be open to all patients in 49 states[5] and the District of Columbia—regardless of income or insurance status—who have: (i) an abnormal CT scan suggesting respiratory disease; (ii) at least one of the following: persistent cough, shortness of breath, fatigue, unintentional weight changes, chest or back pain, or pulmonary disease refractory to treatment; and (iii) an attestation from a health care professional that the patient meets the eligibility criteria and that the Test is clinically appropriate for the patient (the "Eligible Patients").

Under the Proposed Arrangement, Requestor, through the Vendor, would provide the Test at no cost to Eligible Patients, including Federal health care program beneficiaries. Requestor certified that it would not shift the cost of the Test to any Federal health care program, patients, or other payors. Requestor certified that, under the Proposed Arrangement: (i) no patient or payor (including Federal health care programs) would be billed for the Test; and (ii) the Test is not reimbursable under Federal health care programs, and there is no assigned reimbursement code or fee schedule for the Test. Requestor further certified that, because Disease A shares clinical features with other respiratory diseases and because the prevalence of diagnoses of the Disease is rare, Requestor anticipates that the majority of Tests that would be ordered through the Proposed

[4] For the purposes of this advisory opinion, the "Test" refers only to Factor autoantibody testing offered by Requestor through its Vendor at no cost to Eligible Patients (as defined herein) and in accordance with other conditions specified in this advisory opinion. Requestor certified that, while no commercially available Factor autoantibody test exists in the United States, there may be other means by which an individual could obtain a Factor autoantibody test outside the scope of the Proposed Arrangement.

[5] Patients who live in New York would not be eligible to participate in the Proposed Arrangement because New York State law requires State approval of certain laboratory tests, including the Factor autoantibody test. Requestor certified that efforts are underway to obtain the necessary approvals for the Factor autoantibody test. If the Factor autoantibody test is approved by New York State authorities, then Eligible Patients (as herein defined) who live in New York would be eligible to participate in the Proposed Arrangement.

Arrangement would be negative. According to Requestor, the Proposed Arrangement is intended to: (i) increase awareness, access, and utilization of the Test as a diagnostic resource for patients with symptoms suggestive of Disease A; and (ii) support the awareness and diagnosis of Disease A, potentially facilitating earlier diagnosis and treatment.

2. The Vendor and Health Care Professionals

Under the Proposed Arrangement, Requestor would compensate the Vendor with a flat, fixed fee, which would be set in advance in a written agreement, for each Test furnished. Requestor also would pay the Vendor a monthly program fee, which would be a flat, fixed fee that would not vary based on the volume or value of Tests rendered and that would include services for program management, customer support, information technology, licensing, and other administrative costs.[6] Requestor certified that the agreement would prohibit the Vendor from: (i) billing any patient or payor—including Federal health care beneficiaries or programs—for Tests provided to Eligible Patients; (ii) using the Proposed Arrangement to market other Vendor products or services; or (iii) offering any inducement to health care professionals.[7]

Under the Proposed Arrangement, the Vendor would provide Requestor with limited, aggregated, de-identified operational data, including: (i) the date a Test was ordered; (ii) Test results; (iii) the number and type of Test ordered; (iv) the length of time it took for the health care professional to receive the Test results; (v) demographic information of the Eligible Patients who received the Test; and (vi) the medical specialty and regional geography of the ordering health care professional.[8] Requestor certified that, under the terms of its agreement with the Vendor, Requestor would be strictly prohibited from receiving identifiable patient or family data or the identity of any of the ordering health care professionals or the institutions with which ordering health care professionals are affiliated. Requestor further certified that its sales personnel would not have access to data from the Proposed Arrangement (including the aggregate, de-identified data Requestor receives from the Vendor) and would be prohibited from receiving data that would allow them to identify a patient or ordering health care professional. Requestor certified that the Vendor would be contractually prohibited from promoting

[6] Requestor also has entered into two other fixed, flat fee agreements with the Vendor. One agreement is for assistance with conducting a study to compare the Factor autoantibody test to an independently developed Factor autoantibody assay. The second agreement is for assistance with gaining approval from the New York State Department of Health for offering the Factor autoantibody test in the state of New York. We have not been asked to opine on, and express no opinion regarding, these arrangements between Requestor and the Vendor.

[7] The Vendor is not a party to this advisory opinion. We have not been asked to opine on, and express no opinion regarding, the specific terms of the written agreement between Requestor and the Vendor, other than those terms expressly described herein.

[8] To help manage the data and ensure Requestor receives only limited, aggregated, de-identified operational data, Requestor has contracted with a third-party company (the "Data Consultant") to receive data from the Vendor and de-identify and aggregate the data for Requestor. We have not been asked to opine on, and express no opinion regarding, the arrangement between Requestor and the Data Consultant.

Requestor's Product and the Vendor's other products or services to health care professionals and patients using the Proposed Arrangement, and the Vendor would not market or promote the Proposed Arrangement. Requestor certified that it would not use data provided by the Vendor for sales and marketing activities.

Health care professionals would order the Test from the Vendor using a specific form (the "Order Form"). As part of the ordering process, the health care professional would attest that: (i) the health care professional is authorized to order the Test under applicable law; (ii) the patient for whom the Test is ordered is an Eligible Patient; (iii) no claim will be submitted to any third party (including Federal health care programs) for the Test; (iv) the health care professional's medical decisions will not be influenced by participation in the Proposed Arrangement; and (v) the health care professional understands that no purchase or prescription of any product or service is a condition of participation. Requestor would permit its Medical Science Liaisons ("MSLs") or other similar non-sales or marketing personnel to distribute up to five collection kits to a health care professional upon request. Requestor certified MSLs or other similar non-sales or marketing personnel who would be allowed to distribute the collection kits would not be compensated based on sales-based incentives and would be trained and instructed to never discuss the Proposed Arrangement in connection with the Product with a health care professional unless it is necessary to respond to an unsolicited request for scientific, clinical, or patient access information that reasonably requires a response that involves both Proposed Arrangement and Product information to be complete and accurate.

3. Marketing

Requestor certified that sales representatives would be prohibited from proactively discussing or promoting the Proposed Arrangement and from discussing the Proposed Arrangement in connection with the Product. Sales representatives would be permitted to make health care professionals aware of the Proposed Arrangement by leaving behind non-branded educational materials about the Proposed Arrangement that: (i) would not reference the Product; and (ii) have been pre-approved by Requestor. Additionally, sales representatives would be able to respond to questions about the Proposed Arrangement by referring health care professionals to Requestor's non-sales personnel, the Vendor, or written, non-branded, educational information approved by Requestor, including a non-branded, health care professional-specific disease-state awareness website that would not discuss the Product or any specific therapeutic options.

Requestor certified sales representatives would not distribute educational materials in a manner that would take into account a health care professional's usage of the Proposed Arrangement or prescribing of Requestor's products. Requestor further certified it would not pay any remuneration to any health care professionals who order the Test under the Proposed Arrangement to induce them to recommend, prescribe, or administer any products manufactured by Requestor. Additionally, Requestor would not condition a health care professional's ability to order the Test pursuant to the Proposed Arrangement on their purchase of any products.

Requestor certified it would not market or promote the Proposed Arrangement to patients. Requestor would maintain a patient-facing, non-branded disease state awareness website, which would describe Disease A and provide information about the Proposed Arrangement. Requestor also would maintain a website directed at health care professionals that would provide general

disease-state education around Disease A. Like the patient-facing website, this website would not discuss specific therapeutic options and would include no branding for the Product.

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.[9] 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 reimbursable by a Federal health care program.[10] 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.[11] 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 beneficiary 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

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

[10] Id.

[11] 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).

Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Proposed Arrangement.

Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to:

> [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and 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 …[12]

B. Analysis

1. Federal Anti-Kickback Statute

The Proposed Arrangement implicates the Federal anti-kickback statute because it would result in remuneration (i.e., the Test) to Eligible Patients and their health care professionals that may induce Eligible Patients to purchase, or their health care professionals to prescribe, the Product.[13] With respect to health care professionals, the Proposed Arrangement would enable them to offer a service at no cost to them or their Eligible Patients that may create an opportunity to bill for other services, such as additional visits with the Eligible Patients to review the results from the testing or other follow-up appointments. No safe harbor applies to the Proposed Arrangement.

We have longstanding and continuing concerns regarding the provision of free items or services by individuals and entities, including pharmaceutical manufacturers, to health care professionals and patients that could lead to the ordering and provision of an item or service payable by Federal health care programs. However, for the combination of the following reasons we believe the risk of fraud and abuse presented by the Proposed Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Proposed Arrangement is unlikely to result in overutilization or inappropriate utilization. Requestor certified that delays in accurate diagnosis of the Disease (including the Disease A subtype) have been reported due to nonspecific symptoms and similarities to other conditions, and the Test may lead to earlier diagnosis and treatment of Disease A. In fact, because Disease A shares clinical features with other, more common, respiratory diseases, the

[12] 42 C.F.R. § 1003.110 (defining "remuneration").

[13] The only contingency remaining before the Proposed Arrangement could be effectuated is FDA's decision whether to approve the Product. The Product is undergoing Priority Review at FDA. If FDA does not approve the Product, then this opinion is without force and effect.

Test is more likely to show that the Product is not indicated for a particular patient. Importantly, Requestor would not pay any remuneration to any health care professionals who order the Test under the Proposed Arrangement (other than through the opportunity to bill for other services) to recommend, prescribe, or administer any products manufactured by Requestor, which further reduces the risk of overutilization or inappropriate utilization. Additionally, Requestor would not condition a health care professional's ability to order the Test pursuant to the Proposed Arrangement on their purchase of any products manufactured by Requestor. Finally, as part of the ordering process, the health care professional would attest that no claim would be submitted to any third party—including Federal health care programs—for the Test.

Second, the risk of skewed clinical decision-making or inappropriate steering would be mitigated because: (i) Requestor's sales representatives would be prohibited from proactively discussing or promoting the Proposed Arrangement and from discussing the Proposed Arrangement in connection with the Product; (ii) Requestor would not market or promote the Proposed Arrangement to patients; (iii) health care professionals would not receive any remuneration from Requestor in connection with the Proposed Arrangement other than the opportunity to bill for other services; and (iv) Requestor would not use data from the Vendor for sales and marketing activities. In particular, Requestor's sales representatives would not distribute marketing materials about the Proposed Arrangement in a manner that would take into account a health care professional's history prescribing Requestor's products. Additionally, there would be limitations on the exchange of data relating to the Proposed Arrangement that would foreclose the potential for Requestor to use the Proposed Arrangement to target specific health care professionals or patients or to encourage prescribing or purchasing the Product. Specifically, the Vendor would provide Requestor with limited, aggregated, de-identified operational data. Requestor would be strictly prohibited from receiving: (i) identifiable patient or family data; or (ii) the identity of any of the ordering health care professionals or the institutions with which they are affiliated. Further, Requestor's personnel would be prohibited from receiving data about the Proposed Arrangement that would allow them to identify a patient or ordering health care professional.

2. Beneficiary Inducements CMP

Although Requestor is a pharmaceutical manufacturer and therefore not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP, an offer of remuneration by a pharmaceutical manufacturer to a beneficiary that is likely to influence the beneficiary to select a particular provider, practitioner, or supplier implicates the Beneficiary Inducements CMP. Here, the Proposed Arrangement would implicate the Beneficiary Inducements CMP because Requestor would provide remuneration to beneficiaries in the form of a Test, and the Proposed Arrangement could influence a beneficiary to seek follow-up care from the health care professional who ordered the Test.

We conclude that the Proposed Arrangement would satisfy the Promotes Access to Care Exception. To reach this conclusion, we first examine whether the remuneration that would be offered under the Proposed Arrangement would improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. Under the Proposed Arrangement, Requestor would furnish the Test to an Eligible Patient to determine whether the patient has elevated Factor autoantibodies indicative of Disease A and, therefore, whether the Product may be effective. Moreover, the Test provided under the Proposed Arrangement may remove a barrier to

awareness—and potentially diagnosis and treatment—of Disease A. Alternatively, the Test may rule out a diagnosis of Disease A, thereby enabling a health care professional to reach an accurate diagnosis and initiate appropriate treatment in a more timely manner. Thus, it is likely that the Test could improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid (when the Product is payable by Medicare or Medicaid).

Next, we examine whether the Proposed Arrangement would pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. The Promotes Access to Care Exception states that remuneration poses a low risk of harm if it: (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns.

Consistent with our analysis under the Federal anti-kickback statute, we believe the risk that the Proposed Arrangement would interfere with, or skew, clinical decision-making is sufficiently low. The Proposed Arrangement is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because the Test would help determine whether it is appropriate for the Product to be prescribed, potentially reducing costs to Federal health care programs by reducing time to diagnosis of Disease A. Finally, the Proposed Arrangement would not raise patient safety or quality-of-care concerns, as the Test would determine whether there are elevated Factor autoantibodies that may be indicative of Disease A, thereby providing information that enhances patient safety.

We therefore conclude that the Proposed Arrangement would pose a low risk of harm and would satisfy the Promotes Access to Care Exception. The Proposed Arrangement thus would not generate prohibited remuneration under 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 Proposed Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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 Proposed Arrangement would not generate prohibited remuneration under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this advisory opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any 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 Proposed 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 advisory opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

OIG would not proceed against Requestor with respect to any action that is part of the Proposed 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 Proposed 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 would not proceed against Requestor with respect to any action that is part of the Proposed 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,

/Kenneth D. Kraft/

Kenneth D. Kraft
Assistant Inspector General for Legal Affairs