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: April 8, 2024

Posted: April 11, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-02 (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 patient assistance funds associated with 12 specific diseases ("Disease Funds") operated by Requestor (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.

As explained further in the Analysis section below, this advisory opinion is in force and effect only from the date of issuance of this opinion until January 1, 2027 (the "Effective Period"). Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, during the Effective Period, (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent

were present, 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 or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in 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

Requestor provides financial support to patients with certain medical conditions and demonstrated financial need through various patient assistance programs. Requestor is a nonprofit and is eligible to receive tax-deductible charitable contributions under section 501(c)(3) of the Internal Revenue Code. According to Requestor, each of the Disease Funds[2] is designed around a clinically recognized disease state and is not narrowed to cover only specific treatments, drugs,[3] symptoms, stages of a particular disease, or degrees of disease severity. Requestor considers each of these disease states to be a "rare disorder" that affects fewer than 200,000 Americans. According to Requestor, patients with rare disorders often take multiple, high-cost medications to treat their disorders, and these Disease Funds generally assist patients with out-of-pocket costs associated with the treatment of the disease as well as the disease's symptoms and the side effects of treatment. Each of the Disease Funds has a single donor, and each donor is a pharmaceutical manufacturer that manufactures or markets a drug to treat the disease state addressed by the Disease Fund.

A. Overview of Eligibility and Enrollment

Requestor publicizes its Disease Funds to relevant communities and advocacy groups as well as to the general public, including on Requestor's website and through social media. Patients can apply for enrollment in a Disease Fund via Requestor's website, by phone, or by email, and the application process requires documentation of financial eligibility and medical eligibility. With

[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 currently operates other disease funds that are not included as part of the Arrangement. This advisory opinion addresses only certain forms of remuneration involving the Disease Funds that are part of the Arrangement. OIG expresses no opinion about Requestor's other disease funds, which may present different fraud and abuse risks than the Disease Funds that comprise the Arrangement.

[3] For purposes of this opinion, the terms "drug" and "prescription drug" are intended to reference any drug or biological product that has been approved by the U.S. Food & Drug Administration or that is otherwise authorized for distribution under the Federal Food, Drug, and Cosmetic Act.

respect to financial eligibility, applicants must submit detailed financial information, and Requestor evaluates each patient's financial eligibility based on a number of factors, including income, assets, number of dependents, and other aspects of the patient's financial circumstances. Requestor's financial eligibility determinations also take into account the burden of cost-sharing obligations for expensive prescription drugs and other costs associated with care necessary to treat the patient's disease. With respect to medical eligibility, an applicant must submit a certification of medical necessity, signed by the patient's physician, which states that the patient has the disease for which the particular Disease Fund has been established. Patients who meet the financial and medical eligibility criteria are accepted on a first-come, first-served basis as long as funding is available in the relevant Disease Fund. Requestor certified that neither it, nor any third party with which it contracts, arranges for only certain patients (e.g., patients who take a donor's drug) to receive assistance. Requestor awards assistance to qualifying patients for up to 12 months with the possibility of renewals, subject to the availability of funding in the relevant Disease Fund.

According to Requestor, a patient's eligibility is not contingent on the selection of a particular treating physician or pharmacy, or whether the patient has been prescribed any particular drug or treatment approach. As part of the application process, Requestor does not solicit information concerning what, if any, drugs a patient is taking or has been prescribed. Although Requestor considers out-of-pocket costs for medications as part of its financial eligibility process, it does not ask applicants which drugs they are taking. Accordingly, Requestor generally decides whether to accept patients into its Disease Funds without knowing what drugs the patient may be taking or may have been prescribed.

Requestor's Disease Funds are open to all patients regardless of whether they are enrolled in a Federal health care program, insured by a commercial insurer, or lack insurance coverage. In 2021, the Disease Funds collectively provided financial support to a total of 1,092 patients, approximately 37 percent of whom were Federal health care program enrollees.

B. Overview of Spending

Under the Arrangement, the Disease Funds provide various categories of support to patients, including: (i) cost-sharing subsidies for prescription drugs and other items or services; (ii) financial support to cover, in whole or in part, medical expenses not covered by insurance; (iii) subsidies for insurance premiums; and (iv) emergency relief.[4] Requestor provides at least two categories of support for each of the 12 diseases. In 2021,[5] Requestor spent more than $4.7

[4] Requestor's 2021 data reflect a fifth category of support in connection with three of its Disease Funds: diagnostic testing, and in particular, genetic testing, representing approximately 0.04 percent of overall spending. After 2021, Requestor phased out diagnostic testing as a standalone category of support, and because this category has been discontinued, it is not part of the Arrangement for purposes of this opinion.

[5] Throughout this opinion, we cite data from 2021 reflecting operations of the Disease Funds during that year. Although these data vary from year to year, Requestor certified that the 2021 data—including the relative proportion of different categories of financial support—are

million across the Disease Funds. The following chart illustrates the categories of financial support provided by each of the Disease Funds under the Arrangement:

Disease Fund	Cost sharing subsidies	Medical assistance	Premium assistance	Emergency relief
Fund #1	X	X	X	X
Fund #2	X	X		X
Fund #3	X	X		X
Fund #4	X	X		X
Fund #5	X	X	X	
Fund #6	X	X	X	
Fund #7	X	X	X	
Fund #8	X		X	
Fund #9	X	X	X	X
Fund #10	X	X	X	X
Fund #11	X	X	X	X
Fund #12	X	X		X

1. Cost-Sharing Subsidies

Each of the Disease Funds provides cost-sharing subsidies for items and services associated with treating the particular disease, including, but not limited to, drugs prescribed for treatment of the disease, symptoms of the disease, and side effects of treatment. Requestor does not limit its assistance to any particular drug or to expensive or specialty drugs. Cost-sharing subsidies represent the largest category of aggregate spending across the Disease Funds, totaling nearly $2 million in expenditures in 2021, or approximately 41 percent of overall spending. Prescription drug cost-sharing subsidies, in particular, represent approximately 31 percent of overall spending of the Disease Funds. In 2021, none of the Disease Funds spent more than 35 percent of their overall expenditures on cost-sharing subsidies for donors' drugs.

2. Medical Assistance

Eleven of the Disease Funds provide medical assistance that covers a wide range of medically necessary items and services for eligible patients who are either uninsured or who are insured but for whom insurance coverage has been denied for such items and services. Such items and services could include medical consults or office visits, infusion services, infusion supplies, durable medical equipment, prescription drugs, radiology services, a medical alert subscription

representative of typical spending by the Disease Funds. Although Requestor stated that it could not predict how these trends could shift in the future, the legal analysis and conclusions reached in this opinion assume that the 2021 data will continue to be generally representative of the relative proportion of different categories of financial support in the Disease Funds during the Effective Period. If those proportions materially change, this opinion will be without force and effect.

service, and medical foods. Under this category, Requestor also pays for travel and lodging expenses associated with treatment of the patient's disease. After cost-sharing subsidies, payments for medical assistance comprise the second largest category of expenses under the Arrangement, representing more than $1.8 million in spending in 2021, or approximately 39 percent of overall spending.

Requestor imposes certain safeguards with respect to its medical assistance expenditures. For example, when possible, Requestor distributes funds directly to the person or entity furnishing the item or service rather than to the patient. In addition, Requestor imposes annual per-patient caps on medical assistance that vary by Disease Fund and depend on the availability of funding and other spending priorities within each fund. With respect to travel and lodging expenses, Requestor employs a number of additional limitations and safeguards aimed at utilizing the least expensive travel and lodging option that meets the needs of the patient. For example, before covering any travel expense, Requestor requires proof of a medical appointment from the health care provider with whom the appointment is scheduled.

3. Premium Assistance

In addition to other categories of support, eight of the Disease Funds under the Arrangement provide premium assistance for patients unable to afford insurance premiums, including premiums for certain Federal health care programs, such as Medicare Advantage plans or Medicare Part D plans. In 2021, Requestor spent more than $800,000 on premium assistance, representing approximately 18 percent of overall spending under the Arrangement.

4. Emergency Relief

Under the Arrangement, eight of the Disease Funds offer various forms of emergency relief to enrolled patients. Emergency relief represented less than 2 percent of Requestor's overall spending on the Disease Funds in 2021, or approximately $90,000. Requestor's emergency relief payments provide short-term, limited financial assistance associated with essential, non-medical expenses that arise unexpectedly or in an emergency situation. As an example, when a patient whose medication required refrigeration was temporarily displaced due to a major hurricane, Requestor purchased a compact, portable refrigerator to keep the patient's medication cold. According to Requestor, the types of expenses that could be covered by this category include: (i) utility costs; (ii) electrical generators; (iii) repair or replacement of an automobile, major home appliance, or other home repair; (iv) rent or mortgage payments; (v) lodging assistance not directly related to medical appointments; and (vi) dental care.

Requestor imposes the same safeguards with respect to emergency relief payments as it does for medical assistance, as described above. In addition, Requestor imposes annual per-patient caps on emergency relief that vary by Disease Fund and depend on the availability of funding and other spending priorities within each fund.

C. Requestor's Relationships with Donors

Requestor enters into a written agreement with each of its donors, which specifies that the donor will not exert, directly or through any affiliate, any influence or control over the identification,

delineation, establishment, or modification of any specific disease funds operated by Requestor. In addition, Requestor does not establish, delineate, or modify disease funds at the request or suggestion of donors or potential donors (or their affiliates). Requestor certified that it makes decisions about which Disease Funds to create and what categories of assistance to provide within each Disease Fund based on the needs of patients and without influence by donors or potential donors. Requestor does not notify patients or providers of the identity of any donor supporting a patient's Disease Fund. Requestor does not allow donors to specify that funds may be used only for prescription drug cost-sharing subsidies. Moreover, donors are not allowed to influence what type of drugs or other items or services their contributions will be used to support.

Requestor limits the information that it provides to donors and never relays any individualized information about recipients of assistance. In addition, Requestor does not provide its donors with information about how funds from a particular Disease Fund are spent, including how much money is spent on any particular drug (or on drugs in general as opposed to other categories of expenses). Requestor's reports to donors do not contain information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the Disease Fund.

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.[6] 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.[7] 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.[8] 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

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

[7] Id.

[8] 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).

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 Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

1. OIG's Guidance on Independent Charity Patient Assistance Programs

OIG has long recognized that patient assistance programs ("PAPs"), including programs sponsored predominantly by drug manufacturers, can provide important safety net assistance to patients, especially patients who cannot afford their cost-sharing obligations for prescription drugs.[9] OIG also recognizes that prescription drug costs have increased dramatically in recent years, exacerbating this financial challenge for some patients.[10] OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws. PAPs organized by purportedly independent charitable organizations, which OIG has in the past referred to as "independent charity PAPs," can provide meaningful and important

[9] See, e.g., OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf (hereinafter the "2014 Bulletin"); OIG, Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf (hereinafter the "2005 Bulletin").

[10] See, e.g., Arielle Bosworth et al., Price Increases for Prescription Drugs, 2016-2022, ASPE Issue Brief (Sept. 30, 2022), https://aspe.hhs.gov/sites/default/files/documents/e9d5bb190056eb94483b774b53d512b4/price-tracking-brief.pdf; Juliette Cubanski & Tricia Neuman, Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020 (Feb. 25, 2022), https://www.kff.org/medicare/issue-brief/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020/.

safety net assistance to patients with financial need. Nevertheless, independent charity PAPs that rely heavily on donations from pharmaceutical manufacturers present significant fraud and abuse risks. OIG has consistently warned that, in order to reduce fraud and abuse risks, independent charity PAPs should be independent of pharmaceutical manufacturer influence and "not function as a conduit for payments by the pharmaceutical manufacturer to patients."[11]

In recent years, OIG's substantial enforcement experience, various OIG appraisals of the administration of the Medicare Part D program, increasing drug prices, and recent peer-reviewed economic analyses have amplified our understanding of how these PAPs operate and the risks they pose to Federal health care programs. Our enforcement experience involving the "independent charity PAP" model reinforces that the model both implicates the Federal anti-kickback statute and is susceptible to abuse. The risks OIG has identified in connection with cost-sharing subsidies funded by manufacturers include: the potential for improperly increased drug prices, which could result in improperly increased costs to Federal health care programs and certain patients; the possible steering of Part D enrollees to certain drugs, which could result in enrollees taking drugs that are not as safe and efficacious for them as other drugs; and the prospect of anti-competitive effects.

2. The Effective Period

Before embarking upon our analysis of the Arrangement, we note that, during the course of our review of the Arrangement, Congress enacted legislation that restructures the cost sharing imposed on Medicare Part D enrollees. The new law eliminates Medicare Part D enrollees' 5-percent cost sharing in the catastrophic phase beginning in 2024 and also caps enrollees' annual out-of-pocket costs for Part D drugs at $2,000 beginning in 2025 (with the cap updated annually thereafter). This reduction in cost-sharing obligations could ease demand for the type of cost-sharing subsidies provided under the Arrangement. This could lead, in turn, to potential changes in the amounts or types of donations Requestor receives, changes in the relative proportion of funding each Disease Fund spends on different categories of expenses, and the number of patients who meet financial need criteria. As a result, these changes also could alter our assessment of the balance of benefits and risks under the Arrangement. Because we are uncertain whether our analysis and conclusions will remain the same after full implementation of the out-of-pocket caps and potential changes to the Arrangement as a result, this opinion will terminate—and the prospective immunity it confers will expire—at the end of the Effective Period, on January 1, 2027, 2 years after full implementation of the $2,000 out-of-pocket cap on Part D cost-sharing obligations. Requestor may submit a new advisory opinion request or a request for modification of this opinion. OIG has extended the Effective Period to 2 years after the full implementation of the modifications to the Part D cost-sharing obligations to ensure that Requestor has sufficient time and data to submit a new advisory opinion request or request for modification of this opinion (as desired).

[11] 2005 Bulletin, 70 Fed. Reg. at 70,627; 2014 Bulletin, 79 Fed. Reg. at 31,121.

3. Evaluation of the Arrangement

Because this opinion is effective only for the Effective Period, we provide the following analysis of the Arrangement as it operates under the current Part D cost-sharing structure (i.e., before implementation of the out-of-pocket caps). As a threshold matter, the Arrangement implicates the Federal anti-kickback statute. Under the Arrangement, drug manufacturers, through Requestor, provide various categories of remuneration to patients, including Federal health care program beneficiaries, who have been diagnosed with a disease that can be treated by a drug the donor manufactures. With respect to the Federal anti-kickback statute, that remuneration could induce the purchasing or ordering, or the arranging for the purchase or order, of a prescription drug reimbursable by a Federal health care program.

By contrast, the Arrangement does not implicate the Beneficiary Inducements CMP. Requestor certified that a patient's eligibility is not contingent on the selection of a particular treating physician or pharmacy. Because the Arrangement does not influence an enrollee'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, the Arrangement does not implicate the Beneficiary Inducements CMP.

For the combination of reasons described below and in an exercise of our enforcement discretion, OIG will not impose administrative sanctions on Requestor related to the Federal anti-kickback statute in connection with the Arrangement during the Effective Period.

First, the Disease Funds vary substantially in the proportion of funds spent to support the purchase of the donors' drugs. Disease Funds that spend a larger proportion of their contributions to support their donors' own drugs present a greater risk of fraud and abuse because the Disease Funds are more likely to function as conduits between their donors and patients taking their donors' drugs. Taken as a whole, however, the Arrangement includes many of the features OIG has highlighted in the past as reducing fraud and abuse risk in independent charity PAPs, including: (i) defining Disease Funds based on established disease states; (ii) awarding assistance without regard to the treatment regimen prescribed for a particular patient; (iii) limitations on the sharing of information with donors; and (iv) application of a financial eligibility process.

Second, Requestor's Disease Funds provide assistance to financially needy patients with rare disorders. Given the increasing cost of prescription drugs generally, Requestor's Disease Funds provide assistance that could be highly impactful for those patients. In addition, while less than one-third of funds spent under the Arrangement support the purchase of the drugs manufactured by donors through cost-sharing subsidies, more than two-thirds of the funds spent under the Arrangement are in the form of other categories of assistance, including cost sharing for other items and services (i.e., not drugs), medical assistance, premium support, and emergency relief.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, during the Effective Period, (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent

were present, 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 or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in 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 is in force and effect only during the Effective Period. Beginning January 1, 2027, this advisory opinion will no longer be in force and effect and the prospective immunity provided through this favorable advisory opinion will no longer apply.

- 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.

During the Effective Period, 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 prior to the end of the Effective Period. 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 during the Effective Period 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