



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



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

Issued: April 6, 2022

Posted: April 11, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-06

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 the provision of free genetic testing and genetic counseling services to individuals who meet specified clinical criteria (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 you 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 prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the 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) although the Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, the OIG will not impose sanctions on Requestor in connection with the Arrangement 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 person¹ 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 Disease

[Redacted] is a disorder characterized by [description redacted] (the “Disorder”). The Disorder can present in different forms, distinguished by their symptoms and the body systems they affect. One form of the Disorder, [redacted] (the “Disease”), affects the heart and can lead to heart failure and death. The Disease can be an inherited condition, known as the hereditary form, or it can occur spontaneously, known as the [redacted] form. Requestor, a biopharmaceutical company, manufactures and markets two forms of the drug [redacted], [redacted] and [redacted] (collectively, the “Medications”), which are each approved by the U.S. Food and Drug Administration for the treatment of both the [redacted] and the hereditary forms of the Disease in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. Other than the Medications, Requestor does not manufacture, market, promote, or otherwise have a financial interest in any items or services that are used to treat or diagnose the Disease or the Disorder.

Requestor stated that diagnosis of the Disease requires an objective clinical assessment consisting of: (i) diagnostic testing (either a heart biopsy or non-invasive testing, such as nuclear scintigraphy) confirming [description redacted] in the heart; and (ii) testing to rule out [description redacted]. According to Requestor, because the Disease is rare and its symptoms are nonspecific, patients with the Disease often do not receive a correct diagnosis until many years after Disease onset. As a result of these delays, patients may be erroneously treated for other cardiac conditions, and these treatments may be ineffective or harmful to the patient.

B. Genetic Testing

The [redacted] gene provides instructions for producing [redacted], and there are more than 120 mutations in this gene that are known to be associated with the Disorder (the “Gene Mutations”). Genetic testing to identify the Gene Mutations cannot diagnose the Disease, but it nonetheless may have potential value for certain categories of patients. First, for patients who have been diagnosed with the Disease, genetic testing for the Gene Mutations can reveal whether the patient has the hereditary or [redacted] form, which, according to Requestor, may provide information regarding expected Disease progression because the Disease may progress more

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.

quickly in those with the hereditary form. Second, for patients who have signs and symptoms, but who have not been diagnosed with the Disease, a physician may order genetic testing in parallel with diagnostic testing to enable the physician to efficiently establish which variant of the Disease the patient has in the event the diagnostic testing leads to a confirmed diagnosis of the Disease. Third, for patients who do not have symptoms, but who are related to someone who has the hereditary form of the Disease, Requestor stated that an awareness that a patient has one of the Gene Mutations may increase the likelihood that the patient will be monitored by a cardiologist for signs and symptoms of cardiac disease.²

In the United States, the majority of hereditary cases of the Disease are caused by a specific mutation in the [redacted] gene called [redacted], and Requestor estimates, based on available data, that approximately 10-20 percent of patients with this particular gene mutation will develop the Disease, which means that many patients who test positive for one of the Gene Mutations will never develop the Disease.

The presence of one of the Gene Mutations, without a diagnosis of the Disease, is not a basis for prescribing the Medications. Requestor certified that there is no data to support use of the Medications for the treatment of patients who have not been diagnosed with the Disease (irrespective of whether any of the Gene Mutations are present), including for the prevention of the Disease, and it would not be medically appropriate or within the standard of care for a physician to prescribe either of the Medications for patients who have not been diagnosed with the Disease. Requestor further certified that it does not promote use of the Medications for patients who have not been diagnosed with the Disease.

Where a patient with one of the Gene Mutations does develop the Disease, the presence of one of the Gene Mutations does not have any bearing on whether a physician would prescribe one of the Medications for the patient, or if prescribed, which of the Medications would be prescribed, because the Medications are indicated for both the hereditary form and the [redacted] form of the Disease.

C. The Arrangement

Under the Arrangement, Requestor offers a free genetic test to screen for the Gene Mutations (the “Genetic Test”) and free genetic counseling services (the “Counseling Services”) to certain individuals. The Genetic Test only tests for the Gene Mutations and does not include testing for

² According to Requestor, there are no established guidelines regarding genetic testing or clinical evaluation of family members of patients who have the hereditary form of the Disease, but there is evidence that screening for the Gene Mutations can shorten the time to diagnosis from onset of symptoms of the Disease (in situations where the Disease is diagnosed at all), and earlier diagnosis may potentially allow the patient to avoid ineffective or harmful treatments. According to Requestor, there is also data that suggests the greatest benefit of the Medications may occur in patients who begin treatment during the early stages of the Disease.

genetic mutations that are not associated with the Disorder.³ To be eligible for the Genetic Test and Counseling Services under the Arrangement, an individual must be 18 years or older, reside in the United States, and meet one of the following clinical criteria: (i) the individual has been diagnosed with the Disease; (ii) the individual’s physician suspects the individual has the Disease based on clinical evidence but has not yet made a diagnosis; or (iii) the individual has not been diagnosed with the Disease, but a family member has a confirmed diagnosis of the hereditary form of the Disease (each an “Eligible Patient”).

Requestor entered into a contract with a third-party laboratory company that specializes in genetic diagnostic analyses of rare inherited diseases (the “Testing Vendor”) to develop and produce customized specimen collection kits and conduct the Genetic Tests for the Arrangement.⁴ Requestor’s contract with the Testing Vendor requires the Testing Vendor to maintain all professional licenses, consents, authorizations, permits, and certificates required by law for its performance of the genetic testing services, and it prohibits the Testing Vendor from promoting its other services to any physician who orders a Genetic Test through the Arrangement or to any patient who receives a free Genetic Test as part of the Arrangement. The Genetic Test, and any subsequent tests furnished by the Testing Vendor, require a physician order. Requestor does not pay for any tests furnished outside of the Arrangement.

Any physician may order a Genetic Test through the Arrangement for any Eligible Patient. Requestor certified that it does not require or otherwise incentivize physicians who order a Genetic Test through the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor. When physicians order a Genetic Test through the Arrangement, they must make certain attestations—provided directly to the Testing Vendor—relating to the patient’s eligibility, including clinical evidence of the Disease, familial relationship with a patient with a confirmed diagnosis of the hereditary form of the Disease, or both. For all patients, ordering physicians must also attest that they believe that the Genetic Test is clinically appropriate for the patient.

Blood samples are collected in the ordering physician’s office, a similar practice setting, or an associated laboratory. In most instances, a blood sample for the Genetic Test is collected via venipuncture, but in some instances it may be collected by finger stick. Requestor does not provide any payment for specimen collection in connection with the Arrangement. It is possible

³ Requestor asserted that testing for only Gene Mutations associated with the Disease, instead of all Gene Mutations associated with the Disorder, would under-report pathogenic variants, which could result in an individual who has the hereditary form of the Disease being misdiagnosed. In addition, according to Requestor, testing only a subset of the Gene Mutations would provide patients who are suspected of having the Disease and their family members with incomplete information about their potential risk of developing the Disorder, including the Disease, undermining the ability of their physicians to provide appropriate monitoring for individuals who carry one or more of the Gene Mutations.

⁴ The Testing Vendor is not a party to this advisory opinion. We have not been asked to opine on, and express no opinion regarding, any arrangement between Requestor and the Testing Vendor.

that, in at least some circumstances, the specimen collection may be covered by a Federal health care program.

Eligible Patients who receive a Genetic Test through the Arrangement have the option to obtain free Counseling Services before and after the results of the Genetic Test are available for a total of 90 minutes of counseling if requested by the ordering physician. The Counseling Services provided as part of the Arrangement are furnished by licensed genetic counselors through a separate, third-party vendor under contract with Requestor (the “Counseling Vendor”).⁵ The Testing Vendor provides patient information to the Counseling Vendor; at no time does Requestor receive individually identifiable health information related to patients who received the Genetic Test. Following the genetic counseling session(s), the Counseling Vendor provides a report to the patient’s physician, and the patient is referred back to their physician to address any questions regarding medical management, follow up, or potential treatment options. The terms of the contract between Requestor and the Counseling Vendor prohibit the genetic counselors from discussing treatment options with patients or their family members. According to Requestor, some physicians who order a Genetic Test through the Arrangement may choose to offer genetic counseling directly to their patients, outside of the Arrangement. These genetic counseling services may be offered by physicians as part of a reimbursable evaluation and management service; Requestor does not pay the ordering physician for these services.

The Testing Vendor provides monthly reports about the Arrangement to Requestor to enable Requestor to track participation. Requestor certified that the data it receives from the Testing Vendor and the Counseling Vendor does not include individually identifiable health information because it meets the standards for de-identification set forth in 42 C.F.R. § 164.514(b)(2), and consequently, Requestor does not have sufficient information to identify patients who receive a Genetic Test through the Arrangement. Requestor further certified that the data it receives from the Testing Vendor and the Counseling Vendor does not include sufficient information to enable Requestor to identify specific providers who order Genetic Tests through the Arrangement. Although it is possible that Requestor may learn that a provider has ordered a Genetic Test if the provider (or provider’s personnel) voluntarily disclose this information, Requestor’s policies prohibit Requestor’s personnel, including its sales representatives, from soliciting this information from providers or their staff. Finally, Requestor certified that it does not allow its sales force to access any data that Requestor receives from the Testing Vendor or the Counseling Vendor, and Requestor does not use such data for sales and marketing activities, including sales targeting or incentives.

Requestor’s contracts with the Testing Vendor and the Counseling Vendor both specify that neither the Testing Vendor nor the Counseling Vendor may bill any third-party (other than Requestor), including any insurer or patient, for the testing and counseling services furnished pursuant to the Arrangement.

⁵ The Counseling Vendor is not a party to this advisory opinion. We have not been asked to opine on, and express no opinion regarding, any arrangement between Requestor and the Counseling Vendor.

D. Marketing

Requestor’s sales representatives distribute materials about the Arrangement and specimen collection kits for the Genetic Test to cardiologists whom Requestor has identified as being likely to diagnose and treat patients with the Disease. Requestor does not provide any data about utilization of the Arrangement to its sales representatives, and sales representatives do not distribute materials about the Arrangement or specimen collection kits in a manner that takes into account physicians’ usage of the Arrangement or their history prescribing the Medications or any other therapy used for the Disease. Requestor also limits the number of specimen collection kits a sales representative may provide to any individual physician, although physicians may order additional specimen collection kits directly from the Testing Vendor. In addition, any physician, regardless of specialty, may order the Genetic Test for any Eligible Patient directly from the Testing Vendor under the Arrangement.

Requestor does not proactively provide information about the Arrangement directly to patients or potential patients. However, Requestor’s patient support program for the Medications may reactively provide information about the Arrangement to a patient prescribed one of the Medications for the Disease. Requestor also provides information about the Arrangement to patient advocacy groups who request information about patient support programs. The terms of the contract between the Testing Vendor and Requestor prohibit the Testing Vendor from promoting the Arrangement to providers or patients. The terms of the contract between Requestor and the Counseling Vendor prohibit the genetic counselors from promoting the Medications (or any other Requestor product) to patients, their family members, providers, or payors.

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.

⁶ Section 1128B(b) of the Act.

⁷ Id.

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 Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The 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. The 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 because it results in remuneration to Eligible Patients and their physicians that may induce Eligible Patients to purchase, or their physicians to prescribe, the Medications or other products manufactured by Requestor. With respect to Eligible Patients, the free Genetic Test and Counseling Services provided through the Arrangement are inherently valuable. With respect to Eligible Patients' physicians, the Arrangement confers value by enabling them to offer a service, at no cost to them or their patients, that may create an opportunity for physicians to bill for other services, such as evaluation and management services involving genetic counseling, patient monitoring services, or other, unrelated services in the future. However, for the combination of the reasons discussed below, we conclude that the Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

First, several features of the Arrangement make it unlikely to lead to overutilization or inappropriate utilization. Perhaps most significantly, the Genetic Test results indicate only if a patient carries one of the Gene Mutations. The presence of one of the Gene Mutations does not determine whether a patient has, or will develop, the Disease and is not, standing alone, a

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).

sufficient basis to prescribe one of the Medications for a patient. In reaching our conclusion that the Arrangement is unlikely to lead to overutilization or inappropriate utilization, we rely on Requestor's certifications that: (i) there is no data to support use of the Medications for the treatment of patients who have not been diagnosed with the Disease (irrespective of whether one of the Gene Mutations is present), including, but not limited to, for the prevention of the Disease; (ii) it is not medically appropriate or within the standard of care for a physician to prescribe either of the Medications for patients who have not been diagnosed with the Disease (which requires a separate, objective clinical assessment); (iii) Requestor does not promote the use of the Medications for patients who have not been diagnosed with the Disease; and (iv) Requestor does not manufacture, market, promote, or otherwise have a financial interest in any other items or services that are used to treat or diagnose the Disease or the Disorder. Based on these facts, the nexus between the remuneration offered and exchanged under the Arrangement and ordering or purchasing Requestor's products is attenuated. We caution that we would likely reach a different conclusion with respect to the risk presented by this type of arrangement if any of these facts were different and there were a more direct nexus between the remuneration and ordering or purchasing the manufacturer's products.

In addition, even where a patient has a diagnosis of the Disease, the Genetic Test result has no bearing on whether the physician would prescribe one of the Medications (or which of the Medications the physician would prescribe) because the Medications are indicated for both the [redacted] and hereditary forms of the Disease. We also note that the Arrangement incorporates clear, objective patient eligibility criteria, and the ordering physician must sign an attestation regarding the patient's eligibility and the clinical appropriateness of the test for the patient. Requestor's contracts with the Testing Vendor and the Counseling Vendor also both specify that neither may bill any third-party (other than Requestor) for the testing and counseling services furnished pursuant to the Arrangement, which reduces the risk of potential double billing.

We acknowledge that it is possible, if not likely, that the Arrangement may increase costs to Federal health care programs because it will lead to, in at least some instances, certain covered services that otherwise might not have been furnished, such as patient monitoring. However, based on the specific facts presented here, the potential for increased utilization does not raise significant fraud and abuse concerns. Among other things, there are various safeguards in place to prevent use of the Arrangement as a marketing or sales tool to induce physicians to order additional items and services, including further testing. We also note that the Arrangement covers only genetic testing for the Gene Mutations, which has limited utility, rather than testing for a broader range of potential genetic mutations not associated with the Disorder, and that Requestor does not manufacture, market, promote, or otherwise have a financial interest in items or services used to diagnose or monitor for the Disease or Disorder. Depending on the circumstances, free genetic testing that covers a wider range of genetic mutations may present a higher risk of overutilization or inappropriate utilization.

Second, the Arrangement is unlikely to skew clinical decision making or raise concerns regarding patient safety or quality of care. Requestor does not require or otherwise incentivize providers who order Genetic Tests through the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor. In addition, based on Requestor's certifications, the Genetic Test may help to improve patient safety and quality of care by

shortening the time to diagnosis of the Disease from onset of symptoms, which may allow patients to avoid inappropriate or harmful treatments and obtain the greatest benefit from the Medications by starting treatment during the early stages of the Disease.

Third, there are various safeguards in place to prevent use of the Arrangement as a marketing or sales tool to induce physicians to order additional items and services, including further testing or Requestor's products, or to induce beneficiaries to purchase the Medications. In particular, Requestor certified that its sales representatives do not distribute materials or specimen collection kits in a manner that takes into account a physician's usage of the Arrangement or the physician's history prescribing the Medications or any other therapy used for the Disease, and Requestor limits the number of kits a sales representative may provide to any individual physician.

There are also various limitations on the exchange of data relating to the Arrangement that constrain the potential for Requestor to use the Arrangement to target specific providers or patients for further testing or to encourage prescribing or purchasing the Medications. Specifically, neither the Testing Vendor nor the Counseling Vendor provide Requestor with any individually identifiable health information regarding patients who receive a Genetic Test or any data that would enable Requestor to identify providers who order Genetic Tests through the Arrangement. Requestor's policies also prohibit Requestor's personnel, including its sales representatives, from soliciting information from providers regarding whether they have ordered any Genetic Tests. In addition, Requestor does not allow its sales force to access any data that Requestor receives from the Testing Vendor or the Counseling Vendor, and Requestor does not use data from the Testing Vendor or the Counseling Vendor for sales and marketing activities, including sales targeting or incentives.

The terms of the contract between the Testing Vendor and Requestor also prohibit the Testing Vendor from promoting the Arrangement to providers or patients, and the terms of the contract between Requestor and the Counseling Vendor prohibit the Counseling Vendor from discussing treatment options with patients or their family members or promoting the Medications (or any other Requestor product) to patients, their family members, providers, or payors. Finally, Requestor certified that it does not proactively provide information about the Arrangement directly to patients.

2. Beneficiary Inducements CMP

Although Requestor is a biopharmaceutical manufacturer and therefore not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP, an offer of remuneration by a biopharmaceutical manufacturer to a beneficiary that is likely to influence the beneficiary to select a particular provider, practitioner, or supplier would implicate the Beneficiary Inducements CMP. Here, the Arrangement implicates the Beneficiary Inducements CMP because, for example, the Arrangement could influence a beneficiary to seek follow-up care from the physician who ordered the Genetic Test. However, for the reasons stated above with respect to the Federal anti-kickback statute, we conclude that we would not impose administrative sanctions under the Beneficiary Inducements CMP in connection with Requestor's provision of the Genetic Test and Counseling Services to Eligible Patients.

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 prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the 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) although the Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, the OIG will not impose sanctions on Requestor in connection with the Arrangement 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 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.

The 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. The 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, the 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 the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs