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

Issued: February 5, 2008

Posted: February 12, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-04

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal to offer a free trial prescription program to hemophilia A patients who are Federal health care program beneficiaries (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act"), or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of

Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] ("Requestor") manufactures health care products and pharmaceuticals, including [drug name redacted] (the "Medication"), a recombinant antihemophilic factor VIII product indicated for the control and prevention of hemorrhagic episodes and for surgical and short-term routine prophylaxis in patients with hemophilia A. The Medication is reimbursed under Medicare Part B under the average sales price ("ASP") methodology. As with other Part B benefits, Medicare beneficiaries must pay a cost-sharing amount equal to 20% of the allowable Medicare benefit.[1] The Medication, when covered by Medicaid, is reimbursed in accordance with the methods specific to the relevant state.

Patients with hemophilia A can choose between the Medication, competing recombinant factor VIII products manufactured by other companies, and plasma-derived products. The Medication costs about the same as the competing recombinant factor VIII products,[2] while plasma-derived products are generally less expensive than recombinant products.[3] Requestor has certified that the risk of transferring human blood-borne pathogens associated with plasma-derived factor VIII products is greater than the risk associated with recombinant factor VIII products. In general, there are no barriers to switching between different recombinant factor VIII products or between recombinant factor VIII products and plasma products.

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[1] The Medication is not reimbursed under Medicare Part D.

[2] Requestor has certified that Medicare Part B currently reimburses for all recombinant factor VIII products, including the Medication, using the same HCPCS code. Reimbursement for products covered under Part B are subject to change each quarter based on the ASP submitted by the manufacturer. In the case of recombinant factor VIII products that share a HCPCS code, the ASP is calculated as a weighted average of all of the products in that code.

[3] Requestor has certified that plasma-derived products have been historically less expensive than recombinant factor VIII products as demonstrated by List Price published by First Data Bank.

Under the Proposed Arrangement, Requestor would give one complimentary trial supply of the Medication to hemophilia A patients, including Medicare and Medicaid beneficiaries (the "Program").[4] The Requestor would offer a limited number of Program enrollment forms at hemophilia treatment centers ("HTCs") and hemophilia/oncology physician practices (for ease of reference we use the term "physicians" to include physicians at HTCs as well as physicians at hemophilia/oncology practices). The number of enrollment forms available to each HTC and physician practice would be based on ten percent of U.S. hemophilia A patients served by that HTC or physician practice with a further limitation that no one HTC or physician practice would receive more than twenty total enrollment forms per year. Patients would not be permitted to enroll in the Program more than once, and patients currently on the Medication would not be eligible for the Program.

A patient would receive the free Medication under the Program as follows. First, a physician would elect to participate in the Program by identifying patients that can benefit from the Medication and filling out enrollment forms for such patients. The physician would then write a prescription for the Medication. The patient would complete the patient information portion of the enrollment form and a patient authorization form, then send the forms and the prescription to the Program administrator. The Program administrator is a licensed pharmacy contracting with Requestor that does not commercially distribute hemophilia products. The Program administrator then would fill the prescription and ship the Medication directly to the patient. Physicians would not take possession of the Medication provided under the Program. Finally, the Program administrator would confirm with the patient that the Medication was received. According to Requestor, the Medication would be sent directly to the patient as a safeguard to ensure that the physician would not bill for the Medication and that it would not be resold. The Requestor would not compensate the physicians directly or indirectly for their participation in the Program. Requestor has certified that the Program would comply with the Prescription Drug Marketing Act of 1987 ("PDMA") at 21 U.S.C. § 353.

The amount of the Medication that a particular patient would be eligible to receive under the Program would be based upon ten doses for the average patient size for three age ranges: 0 to 5 years of age (5,000 IU of Medication); 6 to 11 years of age (10,000 IU of Medication); and 12 years of age and older (20,000 IU of Medication). According to Requestor, the amounts will approximate on average the minimum amount necessary to permit a fair trial of the Medication's efficacy for the patient. Under the Program, physicians would not be able to prescribe the free Medication for more than the trial quantity established per age tier. The Medication would likely last from approximately one

[4] Patients who are not recipients of Medicare or Medicaid are currently eligible to participate in the Program.

to ten weeks depending on several factors, including the patient's weight, severity of illness, and level of activity.[5] The total value of the Medication sample per patient could range from approximately $5,000 to approximately $20,000.

Under the Program, the Medication would be provided to patients free of charge. No third-party payers, including Federal health care programs, would be billed for the Medication dispensed under the Program. Physicians would sign a statement on the Program enrollment form acknowledging that the Medication is complimentary, is provided at no cost, and neither may be billed to third-party payers nor resold. Patients would sign a similar statement acknowledging that the Medication provided through the Program is complimentary. The Program administrator would contractually acknowledge that the Medication is complimentary and provided to patients at no cost to the patient or health care provider. The Program administrator would further warrant that it would not resell the Medication or bill any third-party payer for it. Patients would also be informed that there is no obligation to purchase the Medication in the future in order to participate in the Program.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also

[5] Provided the patient does not experience any unusual bleeds, the Medication will likely last for about 3 to 4 weeks for patients using a prophylactic regimen, and about 5 to 10 weeks for patients using an "on demand" regimen.

initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

As a prefatory matter, in our Compliance Program Guidance for Pharmaceutical Manufacturers (68 F.R. 23731, 23739 (May 5, 2003)) (the "CPG") we said the following with respect to drug samples: "Failure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (e.g., a physician) and are used to treat [F]ederal health care program beneficiaries, the improper use of samples may also trigger liability under… the anti-kickback statute." Here, Requestor has fashioned the Proposed Arrangement so that physicians never take possession of the Medication, thereby reducing the risk OIG identified in the CPG, i.e., the improper resale or billing of samples. While this feature of the Proposed Arrangement is responsive to the specific risk outlined in the CPG, it is not dispositive with respect to fraud and abuse risk. Moreover, we note that neither the CPG nor PDMA requires sampling programs to be structured to avoid physicians taking possession of samples.

The Proposed Arrangement raises two potential kickback concerns: first, that the Proposed Arrangement amounts to a kickback from Requestor to the physicians participating in the Program; and second, that patients participating in the Program would receive remuneration in the form of relief of cost-sharing amounts for the trial supply of the Medication as an inducement to get them to self-refer to the Medication in the future. We address these two issues in turn, and, for a combination of the following reasons, conclude that the Proposed Arrangement presents a low risk of fraud and abuse.

With respect to whether the Proposed Arrangement entails an offer of remuneration from Requestor to physicians participating in the Program, we conclude that there is no direct or indirect monetary or economic remuneration to the physicians, nor do we discern any other benefit to the physicians of the type that we would subject to administrative sanctions. Requestor has included safeguards in the Proposed Arrangement to eliminate any opportunity for physicians to take possession of and sell the Medication samples dispensed under the Program. Specifically, the Program administrator would directly dispense the Medication to patients so participating physicians never actually have possession of it, which precludes unscrupulous physicians from reselling or billing for a sample. Furthermore, physicians would sign a statement on the Program enrollment form acknowledging that the Medication is complimentary, provided at no cost, and neither may be resold nor may be billed to third-party payers.

With respect to whether patients would be receiving remuneration in the form of the free one-time trial supply of the Medication as an inducement to self-refer to the Medication in the future, we conclude that this risk is low based on the following considerations. First, the Proposed Arrangement entails no cost to Federal health care programs. Neither the

Program administrator nor prescribing physicians will bill for the trial supply of Medication, and all such parties will be required to sign statements acknowledging that condition.

Second, the risk of steering associated with starting patients on a particular course of treatment is reduced in the Proposed Arrangement. Medicare patients who choose to stay on the Medication after the one-time trial supply will still be responsible for substantial cost-sharing amounts, so the Proposed Arrangement offers no ongoing financial incentive to use the Medication. According to Requestor, there are no clinical barriers to switching between competing treatments, so patients can opt to use an alternative treatment after the trial supply is exhausted. Furthermore, patients cannot self-enroll in the Program; rather, physicians would identify patients who they believe would be good candidates for the Medication.

Third, the Proposed Arrangement is not likely to result in overutilization of the Medication. As a threshold matter, the Medication is not prone to overutilization inasmuch as it is indicated for patients requiring treatment for the control and prevention of hemorrhagic episodes and for surgical and short-term routine prophylaxis in patients with hemophilia A. Patients would not be permitted to enroll in the Program more than once, and patients currently on the Medication would not be eligible for the Program. Moreover, as discussed above, when dispensed to Medicare beneficiaries the Medication carries with it a 20% cost-sharing amount, which imposes discipline on beneficiaries' utilization.[6]

Fourth, the Program has a number of additional safeguards. Physicians do not take possession of the Medication, and both they and the Program administrator will sign statements acknowledging that the Medication is complimentary, is provided at no cost, and neither may be resold nor billed to third-party payers. HTCs and physician practices will receive a limited number of enrollment forms each year. In addition, patients would be informed that there is no obligation to purchase the Medication in the future in order to participate in the Program. Finally, Requestor has certified that the Program would comply with the PDMA.

The Proposed Arrangement is distinct from problematic programs that offer free goods or other remuneration to prescribers as a means to "seed" or introduce new products into the marketplace. Moreover, the specific facts and circumstances of the Proposed Arrangement readily distinguish it from riskier programs targeted at patients that are designed to create consumer demand on physicians to prescribe medications. We might have reached a different conclusion on different facts or with a non-PDMA compliant sampling program.[7]

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[6] The Medication, when covered by Medicaid, is reimbursed in accordance with the methods specific to the relevant state.

[7] We note that section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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

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care program, including Medicaid, beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program, including Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. With respect to the selection of the Medication, the Program does not implicate section 1128A(a)(5) of the Act, because Requestor is a pharmaceutical company that manufactures, but does not bill Medicare or Medicaid for, the Medication, and thus does not constitute "a particular provider, practitioner, or supplier" within the meaning of section 1128A(a)(5) of the Act. With respect to any potential inducement to select a participating physician, for the reasons noted above, we also would not impose administrative sanctions under section 1128A(a)(5).

Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

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

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party 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 [name redacted] 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. 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 [name redacted] with respect to any action 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General