

Exhibit A

**INTEGRITY AGREEMENT
BETWEEN THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
STEPHEN M. LAZARUS, M.D.**

I. PREAMBLE

Stephen M. Lazarus, M.D. (Dr. Lazarus) hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by Dr. Lazarus with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This commitment to promote compliance applies to any entity that Dr. Lazarus owns or in which Dr. Lazarus has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. Lazarus's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Dr. Lazarus is entering into a Settlement Agreement with the OIG, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The period of compliance obligations assumed by Dr. Lazarus under this Agreement shall be three years from the Effective Date of this Agreement. The Effective Date shall be the date on which the final signatory to this Agreement executes the Agreement. The one-year period beginning on the Effective Date shall be referred to as the "Reporting Period."

B. Sections VI, VII, and VIII shall expire no later than 120 days from the OIG's receipt of: (1) Dr. Lazarus's final Annual Report; or (2) any additional materials submitted by Dr. Lazarus pursuant to the OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Persons" includes:
 - a. Dr. Lazarus and any co-owners, officers, directors, and

employees;

b. All contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of Dr. Lazarus; and

c. All other individuals responsible for the provision or documentation of items or services reimbursable by Federal health care programs on behalf of Dr. Lazarus, or in the preparation of claims, reports, or other requests for reimbursement for such items or services.

III. INTEGRITY OBLIGATIONS

Dr. Lazarus shall establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days after the Effective Date, Dr. Lazarus shall designate a person to be responsible for compliance activities (Compliance Contact). The Compliance Contact shall: (1) develop and implement policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements; and (2) shall respond to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. Dr. Lazarus shall provide the name and phone number of the Compliance Contact to the OIG within 60 days after the Effective Date. In the event a new Compliance Contact is appointed during the term of this Agreement, Dr. Lazarus shall notify the OIG, in writing, within 15 days after such a change.

B. Written Policies and Procedures

Within 90 days after the Effective Date, Dr. Lazarus shall develop, implement, and make available to all Covered Persons written policies that address the following (hereafter, "Policies and Procedures"):

1. Dr. Lazarus's commitment to operate his business in full compliance with all Federal health care program requirements;

2. Dr. Lazarus's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Dr. Lazarus's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this Agreement);

3. The requirement that all of Dr. Lazarus's Covered Persons shall be expected to report to Dr. Lazarus or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Lazarus's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect;

4. The requirement that Dr. Lazarus shall not hire as employees, or engage as contractors any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Dr. Lazarus shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://hhs.oig.gov>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>). In addition to prospective checks, Dr. Lazarus shall conduct annual checks of all Covered Persons against each exclusion list;

5. The commitment by Dr. Lazarus to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the Medicare carrier related to Federal health care program requirements;

6. The proper procedures for the accurate documentation of services and the accurate preparation and submission of claims in accordance with Federal health care program requirements;

7. The proper documentation of services and billing information and the retention of such information in a readily retrievable form; and

8. The proper use and handling of drug samples in accordance with the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t), 333(c), and 353(c), and applicable Federal health care program requirements, including the requirement that drug samples not be sold or billed to any payor or any patient.

Within 90 days after the Effective Date and annually thereafter, Dr. Lazarus and each Covered Person shall certify in writing that he or she has read, understood, and shall abide by Dr. Lazarus's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within fifteen days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Dr. Lazarus shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the first Annual Report(s). Copies of any revisions to the Policies and Procedures shall be included in subsequent Annual Report(s).

C. Training and Certification

Within 90 days after the Effective Date, and at least once each year thereafter, Dr. Lazarus and Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive appropriate training on the topics outlined below from an individual or entity other than Dr. Lazarus or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, *e.g.*, the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t), 333(c), and 353(c), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

New Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for New Covered Persons may either be provided internally by Covered

Persons who have completed the required training or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new Covered Person training sessions shall cover the following topics:

1. The Policies and Procedures developed pursuant to Section III.B, above;
2. The Prescription Drug Marketing Act, the Anti-Kickback Statute, and the regulations and other guidance documents related to these statutes;
3. Applicable legal sanctions and consequences for violations of the Prescription Drug Marketing Act and the Anti-Kickback Statute; and
4. Examples of violations of the Prescription Drug Marketing Act and the Anti-Kickback Statute.

Dr. Lazarus and each Covered Person shall annually certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date received. Dr. Lazarus shall retain the certifications, along with the training course materials. The training course materials shall be provided to the OIG in the Annual Report(s).

D. Handling and Reporting of Drug Samples

This Section III.D pertains to those drugs which may be separately billed to or reimbursed by any Federal health care program or other third party payor, and specifically to samples of such drugs (hereafter “Drug Samples”). Within 90 days after the Effective Date, Dr. Lazarus shall assess his internal procedures relating to the use and financial disposition of Drug Samples. If necessary, Dr. Lazarus shall establish and implement, or revise, his internal procedures so they are reasonably designed to track the receipt, storage, inventory, use, and financial disposition of Drug Samples, and to prevent his billing of Drug Samples to patients, Federal health care programs, or third party insurers.

As part of each Annual Report, Dr. Lazarus shall describe his general procedures used to track the receipt, storage, use, inventory, and financial disposition of Drug

Samples. In addition, Dr. Lazarus shall report the following information:

1. The aggregate number of Drug Samples for each type of drug that Dr. Lazarus received during the Reporting Period;
2. The entity or individual who provided each type of Drug Sample to Dr. Lazarus;
3. The specific manner in which Dr. Lazarus used each Drug Sample. For example, if Dr. Lazarus used the Drug Samples to treat patients, Dr. Lazarus shall list the name of each patient, the source of the patient's insurance (if any), the number of Drug Sample(s) used to treat each patient, the date(s) of such use, and the manner in which the patient or any insurer was charged (if at all) for the sample. If Dr. Lazarus used Drug Samples to replace a damaged or expired product, he shall provide the number of Drug Sample(s) used in this manner, the date of the replacement, and the number of units of product, if any, returned to the manufacturer. If Dr. Lazarus used Drug Samples for training purposes, he shall identify to whom the training was provided, the date(s) on which the training was provided, and how many Drug Sample(s) were used in providing such training. If Dr. Lazarus used the Drug Samples in any other manner, he shall describe, in detail, the manner in which those Drug Samples were used; and
4. A certification by Dr. Lazarus that he did not bill any Drug Sample to any patient, Federal health care program, or other third party payor.

If, during the applicable Reporting Period, Dr. Lazarus did not receive any Drug Samples (as defined above), he shall so certify in the Annual Report. He shall also certify that he did not bill any Drug Sample to any patient, Federal health care program, or other third party payor. In such an instance, Dr. Lazarus need not report on his procedures to track the receipt, storage, use, inventory, and financial disposition of any Drug Samples, nor on the items listed in Sections III.D.1-3, above.

In the event the OIG has reason to believe that: (a) Dr. Lazarus's use and handling of Drug Samples fails to conform to the requirements of this Agreement; or (b) the Drug Sample information reported in accordance with this Section III.D is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether Dr. Lazarus's use and financial disposition of Drug Samples complies with the requirements of the

Agreement and/or the Drug Sample information reported pursuant to Section III.D is inaccurate. Prior to initiating such a review, the OIG shall notify Dr. Lazarus of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. The OIG will attempt in good faith to resolve any issues relating to the review with Dr. Lazarus prior to conducting the review. Dr. Lazarus agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is received by the OIG.

E. Notification of Government Investigations or Legal Proceedings

Within 30 days after discovery, Dr. Lazarus shall notify the OIG, in writing, of any ongoing investigation known to Dr. Lazarus or any legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Dr. Lazarus has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Dr. Lazarus shall also provide written notice to the OIG with a description of the findings and/or results of the proceedings, if any.

IV. ANNUAL REPORTS

Dr. Lazarus shall submit to the OIG Annual Reports with respect to the status of and findings regarding his compliance activities for each of the three Reporting Periods. The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by the OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. For the first Annual Report, a copy of the Policies and Procedures developed pursuant to Section III.B; for subsequent Annual Reports, if revisions were made to the Policies and Procedures, a copy of the revised Policies and Procedures;
2. A certification by Dr. Lazarus that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.B.;

3. A schedule, topic outline, and copies of the training materials for the training programs provided in accordance with Section III.C;
4. A certification signed by Dr. Lazarus indicating that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.C;
5. The Drug Sample information and/or certification required pursuant to Section III.D;
6. A certification signed by Dr. Lazarus indicating that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs;
7. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.E. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding, if available; and
8. A certification signed by Dr. Lazarus indicating that he has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

For the OIG: Administrative and Civil Remedies Branch
 Office of Counsel to the Inspector General
 Office of Inspector General
 U.S. Department of Health and Human Services
 Cohen Building, Room 5527
 330 Independence Avenue, S.W.
 Washington, DC 20201
 Telephone: (202) 619-2078
 Facsimile: (202) 205-0604

For Dr. Lazarus: Stephen M. Lazarus, M.D.
 28 Dows Lake Circle
 Dallas, TX 75230
 Telephone: (214) 693-9196

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VI. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Dr. Lazarus's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dr. Lazarus's locations for the purpose of verifying and evaluating: (1) Dr. Lazarus's compliance with the terms of this Agreement; and (2) Dr. Lazarus's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Dr. Lazarus to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Dr. Lazarus's employees,

contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. Dr. Lazarus agrees to assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Dr. Lazarus's employees may elect to be interviewed with or without a representative of Dr. Lazarus present.

VII. BREACH AND DEFAULT PROVISIONS

Dr. Lazarus is expected to fully and timely comply with all of his Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Lazarus and the OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Lazarus fails to:
 - a. have in place a Compliance Contact as required in Section III.A;
 - b. implement and make available the Policies and Procedures required in Section III.B;
 - c. require that Covered Persons attend the training required by Section III.C within the time frames contained in that Section;
 - d. if Dr. Lazarus receives Drug Samples, as defined in Section III.D, establish or maintain procedures designed to track the receipt, storage, inventory, use, and financial disposition of Drug Samples, and prevent the billing of Drug Samples to patients, Federal health care programs, or third party insurers, required in Section III.D; or
 - e. meet any of the deadlines for the submission of the Annual

Reports to the OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Dr. Lazarus employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, Dr. Lazarus's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Section VII.A.2, shall not be demanded for any time period during which Dr. Lazarus can demonstrate that he did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.B.4) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day Dr. Lazarus fails to grant access to the information or documentation as required in Section VI. (This Stipulated Penalty shall begin to accrue on the date Dr. Lazarus fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Dr. Lazarus as part of any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this Agreement.

5. A Stipulated Penalty of \$750 for each day Dr. Lazarus fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. Lazarus, the OIG shall state the specific grounds for its determination that Dr. Lazarus has failed to comply fully and adequately with the Agreement obligation(s) at issue and the steps Dr. Lazarus must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Dr. Lazarus receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this subsection 5 shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

Dr. Lazarus may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this Section, if the OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties

for failure to perform the act or file the notification or report shall not begin to accrue until one day after Dr. Lazarus fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Dr. Lazarus receives the OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by the OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Dr. Lazarus has failed to comply with any of the obligations described in Section VII.A and after determining that Stipulated Penalties are appropriate, the OIG shall notify Dr. Lazarus of: (a) Dr. Lazarus's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after receipt of the Demand Letter, Dr. Lazarus shall respond by either: (a) curing the breach to the OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to the OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section VII.E. In the event Dr. Lazarus elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Lazarus cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section VII.D below.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to Secretary of the Department of Health and Human Services, and submitted to the OIG at the address set forth in Section V.

4. *Independence from Material Breach Determination.* Except as set forth in Section VII.D.1.c below, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's decision that Dr. Lazarus has materially breached this Agreement, which decision shall be made at the OIG's discretion

and shall be governed by the provisions in Section VII.D, below.

D. Exclusion for Material Breach of this Integrity Agreement

1. *Definition of Material Breach.* A material breach of this Agreement means:

- a. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section VII.A;
- b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section VII.C; or
- c. a failure to prevent the billing of Drug Samples to patients, Federal health care programs, or private insurers.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Dr. Lazarus constitutes an independent basis for Dr. Lazarus's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Dr. Lazarus has materially breached this Agreement and that exclusion should be imposed, the OIG shall notify Dr. Lazarus of: (a) Dr. Lazarus's material breach; and (b) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Dr. Lazarus shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. Dr. Lazarus is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. Lazarus has begun to take action to cure the

material breach; (ii) he is pursuing such action with due diligence; and (iii) he has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Dr. Lazarus fails to satisfy the requirements of Section VII.D.3, the OIG may exclude Dr. Lazarus from participation in the Federal health care programs. The OIG will notify Dr. Lazarus in writing of its determination to exclude him (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section VII.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Dr. Lazarus wishes to apply for reinstatement, he must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon the OIG’s delivery to Dr. Lazarus of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Dr. Lazarus shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, the OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS administrative law judge (ALJ) and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Dr. Lazarus was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. Dr. Lazarus shall have the burden of proving his full and timely compliance and the steps taken to

cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this Agreement and orders Dr. Lazarus to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Lazarus requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of the OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

- a. whether Dr. Lazarus was in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) Dr. Lazarus had begun to take action to cure the material breach within that period; (ii) he has pursued and is pursuing such action with due diligence; and (iii) he provided to the OIG within that period a reasonable timetable for curing the material breach and has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for Dr. Lazarus, only after a DAB decision in favor of the OIG. Dr. Lazarus's election of his contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude him upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Dr. Lazarus may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. Dr. Lazarus agrees to waive his right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Dr. Lazarus, Dr. Lazarus will be reinstated effective on the date of the original

exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

VIII. EFFECTIVE AND BINDING AGREEMENT

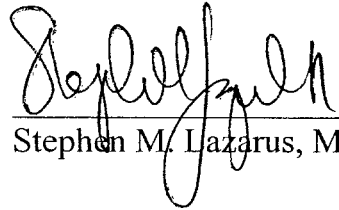
Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Dr. Lazarus and the OIG agree as follows:

- A. This Agreement shall be binding on the successors, assignees and transferees of Dr. Lazarus, including any reorganized corporation or debtor;
- B. This Agreement shall become final and binding on the date the final signature is obtained on this Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
- D. The OIG will agree to a suspension of Dr. Lazarus's obligations under this Agreement upon receipt of credible evidence from Dr. Lazarus that he has ceased his participation in the Federal health care programs. If Dr. Lazarus's obligations under this Agreement are suspended by the OIG in accordance with this provision, the suspension shall remain in effect only so long as Dr. Lazarus does not participate in the Federal health care programs. If Dr. Lazarus once again participates in any respect in Federal health care programs, the suspension of the Agreement shall be automatically lifted and Dr. Lazarus shall be responsible for all obligations under the Agreement for the remainder of its three-year term. The effective date of the lifting of the suspension shall be the date on which Dr. Lazarus again participates in Federal health care programs. In any event, Dr. Lazarus must provide the OIG with written notice within 10 days of his withdrawal or renewed participation in the Federal health care programs.
- E. The undersigned Dr. Lazarus signatory represents and warrants that he is

authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the Parties hereto affix their signatures:

FOR STEPHEN M. LAZARUS, M.D.



Stephen M. Lazarus, M.D.



Date

**FOR THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

Larry J. Goldberg

Larry J. Goldberg
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

9/15/04

Date