

SETTLEMENT AGREEMENT
BETWEEN THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ROBERT A. BERKMAN, M.D.

I. PARTIES

The Parties to this Settlement Agreement (Agreement) are the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS), and Robert A. Berkman, M.D. (Dr. Berkman).

II. RECITALS

As a preamble to this Agreement, the Parties agree to the following:

A. Dr. Berkman is a physician licensed to practice medicine in the State of Ohio and he has a practice located in Columbus, Ohio. Dr. Berkman has a specialty in urology and treats patients suffering from prostate cancer. As part of his treatment of certain patients suffering from prostate cancer, Dr. Berkman prescribed the drug Zoladex. Dr. Berkman purchased Zoladex from its manufacturer and also received samples of Zoladex at no charge from the manufacturer.

B. Pursuant to discussions between the United States of America, by and through the United States Attorney's Office for the District of Delaware, and Dr. Berkman, Dr. Berkman has agreed to waive indictment and plead guilty to a one count Information in the case captioned United States of America v. Robert A. Berkman, Criminal Action No. 03-45-JJF (the Criminal Action). The Information charges Dr. Berkman with conspiring to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(c), in violation of 18 U.S.C. § 371, by submitting claims for payment to patients and to their insurance companies for samples of Zoladex which had been provided to him free of charge. A copy of the Information is attached to this Agreement.

C. The OIG contends that from 1993 through 1999, Dr. Berkman solicited and/or received free samples of Zoladex. Dr. Berkman subsequently billed the samples of Zoladex to patients and their insurance companies, including the Medicare program. In return for these samples, Dr. Berkman prescribed Zoladex to Federal health care beneficiaries. The conduct described in this paragraph shall be referred to as the

“Covered Conduct.” The OIG contends that Dr. Berkman’s submission of claims to Federal health care programs for payment for the samples of Zoladex constitutes actionable false or fraudulent claims and subjects him to civil monetary penalties and assessments under 42 U.S.C. § 1320a-7a(a)(1)(B). The OIG further contends that Dr. Berkman’s solicitation and receipt of the samples constitutes illegal remuneration under 42 U.S.C. § 1320a-7b(b)(1), and subjects him to civil monetary penalties and damages under 42 U.S.C. § 1320a-7a(a)(7). Finally, the OIG contends that this conduct constitutes a basis for the OIG to exclude Dr. Berkman from participation in Federal health care programs pursuant to 42 U.S.C. §§ 1320a-7(b)(7) or 1320a-7a(a).

III. TERMS AND CONDITIONS

A. Pursuant to his agreement to plead guilty in the Criminal Action, and as reflected in the Memorandum of Plea Agreement (attached hereto), Dr. Berkman agrees to pay restitution of \$84,448.06 for his billings for the free samples of Zoladex. He also agrees to pay a fine of \$20,000 and a special assessment of \$100 at the time of his sentencing.

B. Dr. Berkman agrees to cooperate fully and truthfully with the United States’ investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Dr. Berkman will encourage the cooperation of, and make reasonable efforts to facilitate access to, individuals and entities not released in this Agreement. Dr. Berkman also agrees to furnish to the United States, upon reasonable request, all non-privileged documents and records in his possession, custody, or control relating to the conduct described in the Information.

C. Dr. Berkman agrees to pay to the OIG the differential between \$126,672.09 and the amount of restitution he is ordered to pay in connection with his plea in the Criminal Action (hereafter the “Settlement Amount”). Payment shall be made in the form of a certified cashier’s check, made payable to the Secretary, United States Department of Health and Human Services. Full payment is due at the time that Dr. Berkman pays restitution.

D. In consideration of Dr. Berkman’s obligations as reflected in the Memorandum of Plea Agreement and this Agreement (including the integrity obligations set forth in Sections IV through X below), and conditioned upon Dr. Berkman’s full payment of the Settlement Amount and his fulfillment of the other obligations contained in the Memorandum of Plea Agreement and this Agreement, the OIG releases Dr. Berkman from any claims or causes of action it may have against him under 42 U.S.C. §§ 1320a-7a(a)(1)(B), 1320a-7a(a)(7), and 1320a-7(b)(7) for the Covered Conduct. The OIG and HHS do not agree to waive any rights, obligations, or causes of action other than

those specifically referred to in this paragraph. This release is applicable only to Dr. Berkman and his successors, transferees, and assigns and is not applicable in any manner to any former employee or agent, or other person, partnership, corporation, or other entity.

IV. TERM OF INTEGRITY OBLIGATIONS

Dr. Berkman hereby agrees to undertake the obligations set forth in Sections IV through X of this Agreement to promote compliance 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) by Dr. Berkman. Except as otherwise provided, the period of the compliance obligations assumed by Dr. Berkman 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.

V. INTEGRITY OBLIGATIONS

Dr. Berkman hereby agrees to establish a Compliance Program that, at a minimum, includes the following elements:

A. Compliance Contact

Within 30 days after the Effective Date, Dr. Berkman shall designate a person to be the Compliance Contact for his medical practice for purposes of developing and implementing policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact shall be responsible for addressing questions and concerns regarding compliance with the integrity obligations. Dr. Berkman 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. Berkman 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. Berkman agrees to develop, implement, and make available to all affected persons written policies that address the following (hereafter, "Policies and Procedures"):

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

apply to Dr. Berkman and to any entity that Dr. Berkman owns or in which he has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity's officers, directors, employees, agents, contractors, and all others responsible for providing, documenting, or preparing claims for the reimbursement of, items or services that are reimbursed by Federal health care programs (hereafter, Dr. Berkman and any such individuals shall be collectively referred to as "Covered Persons");

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

3. The requirement that all Covered Persons shall be expected to report to Dr. Berkman or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Berkman'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. Berkman 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 non-procurement 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. Berkman 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. Berkman shall conduct annual checks of all Covered Persons against each exclusion list;

5. 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;

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

7. The federal Anti-Kickback statute, codified at 42 U.S.C. § 1320a-

7b(b), and the proper use and handling of drug samples in accordance with the Prescription Drug Marketing Act of 1987 (PDMA) and applicable Federal health care program requirements, including the requirement that drug samples not be sold or billed to any payor or any patient.

At least annually (and more frequently if appropriate), Dr. Berkman 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.

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

Copies of the Policies and Procedures shall be included in the first Annual Report. 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. Berkman 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. Berkman or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., the PDMA and the federal Anti-Kickback statute.

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 training sessions shall cover the following topics:

1. The Policies and Procedures developed pursuant to Section V.B., above;
2. The PDMA and the federal Anti-Kickback statute and the regulations and other guidance documents related to these statutes;
3. Applicable legal sanctions and consequences for violations of the PDMA and the federal Anti-Kickback statute;
4. Examples of violations of the PDMA and the federal Anti-Kickback statute.

Dr. Berkman 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. Berkman shall retain the certifications, along with the training course materials. The training course materials shall be provided to the OIG in the Annual Report.

D. Handling and Reporting of Drug Samples

This section V.D. of the Agreement pertains to those drugs for which Dr. Berkman or any Covered Person may separately bill or seek reimbursement from 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. Berkman shall assess his internal procedures relating to the use and financial disposition of any Drug Samples. If necessary, Dr. Berkman shall establish and implement, or revise, internal procedures so they are reasonably designed to track the receipt, storage, inventory, use and financial disposition of Drug Samples, and to prevent the billing of Drug Samples to patients, Federal health care programs or third party insurers.

As part of each Annual Report, Dr. Berkman shall describe the general procedures used to track the receipt, storage, use, inventory and financial disposition of Drug Samples. In addition, Dr. Berkman shall report the following information:

1. The aggregate number of Drug Samples for each type of drug received during the Reporting Period (as defined below in section VI);
2. The entity or individual who provided each type of Drug Sample;

3. The specific manner in which each Drug Sample was used. For example, if Dr. Berkman used the Drug Samples to treat patients, Dr. Berkman 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 the Drug Samples were used to replace a damaged or expired product, Dr. Berkman 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 the Drug Samples were used for training purposes, Dr. Berkman 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. Berkman uses 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. Berkman that he did not bill any Drug Sample to any patient, Federal health care program, or other third party payor.

In the event the OIG has reason to believe that: (a) Dr. Berkman'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 V.D. is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether Dr. Berkman'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 V.D. is inaccurate. Dr. Berkman 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.

VI. ANNUAL REPORTS

Dr. Berkman shall submit to the OIG Annual Reports with respect to the status of and findings regarding his compliance activities for each of the three one-year reporting periods beginning on the Effective Date. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). 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 V.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. Berkman that all Covered Persons have executed the annual Policies and Procedures certification required by Section V.B.;
3. A schedule, topic outline, and copies of the training materials for the training programs provided in accordance with Section V.C. of this Agreement;
4. A certification signed by Dr. Berkman indicating that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section V.C. of this Agreement;
5. The Drug Sample information and certification required pursuant to Section V.D.;
6. A certification signed by Dr. Berkman 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; and
7. A certification signed by Dr. Berkman 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.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, 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, SW
 Washington, DC 20201
 Telephone: (202) 619-2078
 Facsimile: (202) 205-0604

For Dr. Berkman: Robert A. Berkman, M.D.
 5969 East Broad Street
 Suite 306
 Columbus, Ohio 43213
 Telephone: (614) 866-4488

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.

VIII. 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. Berkman's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dr. Berkman's locations for the purpose of verifying and evaluating: (1) Dr. Berkman's compliance with the terms of this Agreement; and (2) Dr. Berkman'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. Berkman 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. Berkman'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. Berkman 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. Berkman's employees may elect to be interviewed with or without a representative of Dr. Berkman present.

IX. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Dr. Berkman is expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr. Berkman.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Berkman 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. Berkman fails to:
 - a. have in place a Compliance Contact as required in Section V.A.;
 - b. implement and make available the Policies and Procedures required in Section V.B.;
 - c. require that Covered Persons attend the training required by Section V.C. of the Agreement within the time frames contained in that Section;
 - 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; 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. Berkman employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, Dr. Berkman’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 paragraph shall not be demanded for any time period during which Dr. Berkman can

demonstrate that he did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section V.B.4) as to the status of the person).

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

4. A Stipulated Penalty of \$750 for each day Dr. Berkman fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. Berkman, the OIG shall state the specific grounds for its determination that Dr. Berkman has failed to comply fully and adequately with the Agreement obligation(s) at issue and the steps Dr. Berkman must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Dr. Berkman receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under subsections 1-3 of this Section.

B. Timely Written Requests for Extensions

Dr. Berkman 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. Berkman 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. Berkman 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. Berkman has failed to comply with any of the obligations described in Section IX.A. and after determining that Stipulated Penalties are appropriate, the OIG shall notify Dr. Berkman of: (a) Dr.

Berkman'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 the receipt of the Demand Letter, Dr. Berkman 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 IX.E. In the event Dr. Berkman elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Berkman 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 IX.D.

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

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

D. Exclusion for Material Breach of this 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 IX.A.;
- b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section IX.C.; or
- c. a failure to prevent the regular 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. Berkman constitutes an independent basis for Dr. Berkman's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Dr. Berkman has materially breached this Agreement and that exclusion should be imposed, the OIG shall notify Dr. Berkman of: (a) Dr. Berkman'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. Berkman shall have 30 days after the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. Dr. Berkman 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. Berkman 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. Berkman fails to satisfy the requirements of Section IX.D.3, the OIG may exclude Dr. Berkman from participation in the Federal health care programs. The OIG will notify Dr. Berkman 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 IX.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 non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Dr. Berkman 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. Berkman 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. Berkman 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 the 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. Berkman 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. Berkman 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. Berkman to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Berkman 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. Berkman 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. Berkman 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. Berkman, only after a DAB decision in favor of the OIG. Dr. Berkman'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. Berkman 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. Berkman 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. Berkman, Dr. Berkman 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.

X. EFFECTIVE AND BINDING AGREEMENT

Dr. Berkman and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assignees and transferees of Dr. Berkman, including any reorganized corporation or debtor;
2. This Agreement shall become final and binding on the date the final signature is obtained on this Agreement;
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;

4. Dr. Berkman consents to the OIG's disclosure of this Agreement and information contained herein to the public;

5. OIG may agree to a suspension of Dr. Berkman's obligations under this Agreement in the event of Dr. Berkman's cessation of participation in Federal health care programs. If Dr. Berkman withdraws from participation in Federal health care programs and is relieved from his Agreement obligations by the OIG, Dr. Berkman agrees to notify the OIG 30 days in advance of his intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the Agreement should be reactivated or modified.

6. This Agreement and the Memorandum of Plea Agreement attached hereto contain a complete description of the bargain between the Parties. All material representations, understandings, and promises of the Parties are contained solely in these Agreements. Any modification to this Agreement between the OIG and Dr. Berkman must be set forth in writing and signed by each of those Parties. Dr. Berkman represents that this Agreement is entered into with knowledge of the events described herein. Dr. Berkman further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion by the OIG or any other governmental department, agency, or entity; and

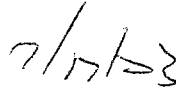
7. The undersigned Dr. Berkman signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatories represent that they are signing this Agreement in their official capacity and that they are authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:


FOR ROBERT A. BERKMAN, M.D.



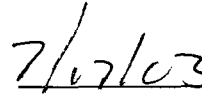
Robert A. Berkman, M.D.
5969 East Broad Street
Suite 306
Columbus, Ohio 43213



Date



Terry K. Sherman, Esq.
Counsel for Dr. Berkman



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
330 Independence Avenue, SW, Room 5527
Washington, DC 20201

July 15, 2003

Date

Mary E. Riordan

Mary E. Riordan
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW, Room 5527
Washington, DC 20201

July 15, 2003

Date