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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
ex rel. YONG WU,

CIVIL ACTION NO. 97-3396

Plaintiffs,

v.

THOMAS JEFFERSON UNIVERSITY, et al.,

Defendants.

FILED

JUN - 6 2000

MICHAEL A. WOOD, Clerk

By _____ Dep. Clerk

ORDER

AND NOW, this ^{June} 6th day of ~~May~~, 2000, upon consideration of the foregoing

Stipulation of Dismissal filed by the United States and Relator and after approval and entry of the Global Settlement Agreement and the Settlement Agreement by the Court,

IT IS HEREBY ORDERED:

The defendants are hereby dismissed from this action pursuant to and consistent with and subject to the terms of the Global Settlement Agreement and the Settlement Agreement executed by the parties. The Court shall retain jurisdiction for purposes of interpreting and enforcing the Global Settlement Agreement and Settlement Agreement.

Charles R. Wren

United States District Judge

ENTERED: _____

CLERK OF COURT

COPIES BY MAIL ON: 6/7/00

TO: *[Signature]*

COPIES BY FAX ON: _____

TO: *Hoffman*

GLOBAL SETTLEMENT AGREEMENT

I. PARTIES

This Global Settlement Agreement ("Agreement") is entered into by and between the United States of America, including the Office of Inspector General ("OIG-HHS") and the National Institutes of Health ("NIH") and the Office of Research Integrity ("ORI") of the Department of Health and Human Services ("HHS"), and the Deputy Assistant Secretary for Grants and Acquisition Management of HHS (collectively "United States") and Thomas Jefferson University ("TJU"), Carlo Croce, M.D. ("Croce"), and Jerold Glick ("Glick"), Yong Wu, M.D. ("Wu"), Lingxun Duan, M.D. ("Duan"), and Roger J. Pomerantz, M.D. ("Pomerantz") (hereinafter also referred to collectively as "the Parties"), through their authorized representatives.

II. PREAMBLE

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

A. TJU is an educational institution located in Philadelphia, Pennsylvania which, among other items, receives federal funds for research purposes including federal grants from the NIH.

1. GRANT 55541

B. In August 1994, the Office of Management Assessment of the NIH commenced a management review of TJU's accounting practices that addressed: (1) TJU's policy and practices for allocating costs to National Cancer Institute ("NCI") funded projects; (2) the adequacy of TJU's time and effort reporting system to account for NCI funds on an individual project basis; and (3) alleged improper use of grant funds on a specific cancer research grant.

C. On or about August 12, 1996, NIH issued Management Report P-95-55 which addressed the findings made by the Office of Management Assessment. The Report found alleged deficiencies in several TJU management systems, including but not limited to, cost allocation and time and effort reporting. TJU responded to the findings by promptly implementing measures to address the alleged deficiencies. In addition, during the course of the management review, alleged improper activities relating to a specific federal cancer research grant were referred by NIH representatives to OIG-HHS for investigation. OIG-HHS Audit and Investigations conducted an investigation into alleged fraudulent activity associated with the grant. TJU conducted

its own internal investigation of the allegations and cooperated fully with the United States in the government's investigation.

D. As a result of the investigation, the United States contends that TJU, Croce, (the Chairman of TJU's Department of Microbiology-Immunology ("Department")), and Glick, (the former Senior Administrator for the Department), submitted or caused to be submitted false claims for payment to the NIH and the NCI for Grant R01 CA55541, "The Role of IGF1 in Cell Proliferation" ("Grant 55541").

E. The United States contends that it has certain civil claims against TJU, Croce and Glick under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines, for engaging in the following conduct during the period from March 1992 through October 1995:

(1) applying for federal grant funds for cancer research based upon false representations to the United States, i.e., the Principal Investigator (PI) for Grant 55541 had resigned and returned to Italy at the time of the grant award yet TJU, Croce and Glick confirmed his presence for purposes of obtaining the grant award; (2) failing to advise the United States of material changes in the status of researchers responsible for performing cancer research, i.e., the PI was, in

years 2 and 3 to spend 75% of his effort on Grant 55541 when, in fact, he was in Italy and was not performing the research; (3) charging of salaries to Grant 55541 for post-doctoral fellows who had nothing to do with that research; and (4) engaging in a pattern of false representations to the United States as a means of receiving federal research funds, i.e., TJU, Croce and Glick advised NCI that the PI was in the country performing research when he, in fact, was in Italy by executing or causing to be executed Applications for Continuation of Grant 55541 and Financial Status Reports relating to Grant 55541 which contained false or fraudulent information that were then submitted to the United States. From August 1992 through October 31, 1995, a total payment in the amount of \$496,000 was made to TJU by NCI for Grant 55541. The allegations described herein are referred to as the "Grant 55541 Covered Conduct".

(2) Additionally, once the alleged fraudulent activity was uncovered, an audit of 10 federally funded grants was agreed to by TJU and the United States. This audit was performed by Arthur Andersen LLP ("Andersen Audit"), and reviewed by the HHS, OIG-Audit, and addressed the administration and management of federal grants by TJU. The Andersen Audit of the 10 federal grants are identified as follows: 5 P01 AR38923-

09, 5 P01 AR38923-08, 5 P01 AR38923-07, 5 R01 AI33810-03, 5 R01 AI33810-02, 5-U01 AI32783-03, 5 R35 CA39860-12, 5 R35 CA39860-11, 5 P30 CA56036-02A4, 1 P30 CA56036-01A4, 5 P01 CA21124-17A3, 5 P01 CA21124-16A3, 3 P50 AA07186-11, 3 P50AA07186-10, 3 P50AA07186-09, 7 R01 CA51664-04, 5 R01 NS29857-06, 5 R01 NS29857-05, 5 HD7 TI00966-02. The results of the audit and the findings of the Andersen Audit were disclosed to the United States in a report of August 22, 1997, and correspondence of February 5, 1998 and February 13, 1998, providing additional information and clarification in response to questions, and are referred to herein as the "Anderson Audit".

F. The United States also contends that it has certain administrative claims and debarment actions against TJU, Croce and Glick under the provisions for eligibility to receive federal grants and contract funds, 45 C.F.R. Part 76 and 48 C.F.R. Part 9.4 for the Grant 55541 Covered Conduct.

G. TJU, Croce and Glick do not admit the contentions of the United States as set forth in Paragraphs D, E, and F, and deny any wrongdoing or liability with respect to the allegations against them. TJU contends that the absences of the PI for personal reasons, were reported to NIH and that the "science" which was contracted to be performed under Grant 55541 was

performed by qualified personnel at TJU, and that several publications demonstrate that the research provided pursuant to Grant 55541 has been utilized in furtherance of other scientific research. NIH contends that the absences of the PI were not approved nor was a substitute PI. NIH also disputes the "science" was performed and contends that essentially no new information on the research proposed in the grant was produced. TJU further contends that OMB Circular No. A-133 audits of TJU, conducted by outside auditors for periods in question, found that TJU complied in all material respects with grant requirements.

2. GRANT 36552

H. In December of 1996, Wu, a researcher at TJU, made allegations that Duan (who was employed as a post-doctoral researcher at TJU in the Division of Infectious Diseases), engaged in scientific misconduct and that certain published articles contained false scientific information relating to research Grant 36552, which was awarded to TJU by the National Institute of Allergy and Infectious Diseases ("NIAID") of NIH in September of 1994.

I. Upon learning of these allegations, TJU pursuant to its Policy and Procedures for Responding to Alleged Misconduct

in Research convened the appropriate committees to investigate the allegations. After due deliberation and evaluation of the available relevant evidence, the Ad Hoc Investigation Committee ("Committee"), which was comprised of knowledgeable scientists, concluded that no research misconduct had been committed, but that Duan made false statements to the Committee. The Committee issued findings and recommendations in a report dated September 29, 1997, which TJU states it has implemented. The Committee's report was forwarded by TJU to ORI for oversight pursuant to 42 C.F.R. Part 50, Subpart A. ORI oversight of TJU's investigation into this matter was suspended pending resolution of a related civil action.

J. TJU subsequently learned that in May of 1997 Wu filed a qui tam lawsuit (under seal) in the United States District Court for the Eastern District of Pennsylvania (Civil Action No. 97-3396), which made allegations similar to those considered by the TJU Ad Hoc Investigation Committee, and along with Duan, named TJU and Pomerantz (Chief of the Division of Infectious Diseases at TJU and the Director of TJU's Center for Human Virology) as additional defendants. An investigation was conducted of the allegations by the United States Attorney's Office for the Eastern District of Pennsylvania, based in part

upon materials turned over by TJU from its own internal investigation of Wu's allegations.

K. The United States contends that as a result of its investigation, it has claims against Duan, TJU and Pomerantz for statements/research data contained in the initial application for Grant 36552 and subsequent applications for continuance of the grant and progress reports that were based, in part, on falsified and/or fabricated research data, or data that are non-existent that were submitted from September 1994 through May 1998. The United States further contends that had it known that the data were allegedly falsified and/or fabricated, or that data did not exist to support the findings that were made in certain publications and the grant application, NIAID would never have initially funded nor continued to fund Grant 36552. A total of \$836,712 was paid by NIAID to TJU for Grant 36552 during a four-year period. The allegations contained herein are referred to as the "Duan Covered Conduct".

L. The United States contends that it has certain civil claims against Duan, TJU, and Pomerantz under the False Claims Act, 31 U.S.C. §§3729-3733, and other federal statutes and/or common law doctrine for the Duan Covered Conduct.

M. The United States also contends that it has certain administrative claims and debarment actions against Duan, TJU, and Pomerantz under the provisions for eligibility to receive federal grants and contract funds, 45 C.F. R. Part 76 and 48 C.F.R. Part 9.4 for the Duan Covered Conduct. ORI has retained continuing oversight of the internal investigation performed by TJU regarding allegations of research misconduct that pertain solely to Duan, and not to Pomerantz and TJU.

N. Duan, TJU, and Pomerantz do not admit the contentions of the United States as set forth in Paragraphs K, L and M, and deny any wrongdoing or liability with respect to the allegations against them.

3. TJU'S COMPLIANCE EFFORTS

O. As part of its compliance efforts in the areas of scientific research and grants administration, TJU has adopted and is continuing to adopt and implement new policies and procedures for cost transfers, non-reimbursable expenditures for federally-funded programs, costing guidelines for sponsored projects, cost sharing and matching grants, emergency use of investigational drugs and biologicals, IRB review of adverse events and a Code of Conduct and conflict of interest

statements. These policies and procedures are being made available to NIH.

P. In April 1998, TJU implemented a training program for all responsible staff, including all Jefferson Medical College faculty and key administrative personnel involved in supported research, and provided instruction in the following research areas including, but not limited to: (1) risks of noncompliance; (2) rules, regulations and TJU policies and procedures governing research; (3) delineation of roles and responsibilities; (4) effort certification; and (5) signing authority. According to TJU, since April 1998 over 550 of TJU's research staff have attended presentations on this training program.

Q. On January 26, 1999, TJU and the NIH conducted a joint one day grant administration program at TJU which focused on the following areas including, but not limited to: (1) misconduct in research; (2) data stewardship; (3) authorship and mentorship; (4) ethics; and (5) conflict of interest.

R. In January 1999, TJU began implementing a new system for effort certification, led by the Assistant Compliance Officer, the Director of Research Compliance, and the Effort

Coordinator, who administers the effort certification program for sponsored projects.

4. FULL AND FINAL SETTLEMENT

S. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of the above referenced claims, the Parties have reached a full and final settlement as set forth below. This Agreement shall not be construed as an admission of any liability or wrongdoing on the part of TJU, Croce, Glick, Pomerantz and Duan, or constitute an adjudication of any issue of fact or law.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. TJU agrees to pay to the United States Two Million Six Hundred Thousand Dollars (\$2,600,000) (the "Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by United States. TJU agrees to make this electronic funds transfer upon execution of the Settlement Agreement.

2. TJU agrees to implement additional policies and procedures to improve its administration and accounting of research grants/projects funded by HHS in order to assure compliance with all federal laws and regulations pertaining to the award and receipt of federal grant funds. Upon execution of this Settlement Agreement and in order to assure compliance, TJU agrees to immediately implement an Institutional Integrity Agreement ("IIA") which is attached hereto and incorporated herein as Exhibit A.

3. TJU will also implement the following policies and procedures:

(a) TJU will make available for interview to the OIG, ORI, and the NIH and any subdivisions therein, ("Appropriate Agency of the United States"), all Principal Investigators and other key grant personnel and administrators ("Responsible Parties") in the event that any of these federal entities has reason to believe that falsification, fabrication, plagiarism or other types of misrepresentation of data or other information pertinent to a grant award has occurred--such interview to occur at a reasonable time and place. TJU will encourage such interviews as part of its IIA. However, if a Responsible Party, consistent with the rights and privileges of such individual,

refuses to be interviewed based upon an individual decision and/or advice of counsel, TJU will not be in breach of this Agreement and/or the IIA if the interview does not occur. In the event that the interview with the Responsible Party requires the presence of an individual with scientific knowledge, as determined by the United States, a representative of the United States that is knowledgeable and conversant with any science that is the subject of the research grant will be present during any such interview. Counsel for TJU may be present during the interview if TJU counsel is representing the Responsible Party.

(b) TJU will appoint the grants administrator for the Department of Microbiology-Immunology as a member of the Compliance Committee and TJU agrees to make that individual available for interview by the United States upon request by the United States.

(c) TJU agrees to adopt a policy as part of the IIA on manuscript authorship in accordance with Exhibit B, attached hereto and incorporated herein.

Nothing in this paragraph 3 shall obligate the United States to notify TJU of any allegations, inquiry, civil and/or criminal investigations, or qui tam filings related to falsification, fabrication, plagiarism or other types of

misrepresentation of data or other information pertinent to a grant award or misrepresentation of data. Nothing in this paragraph shall relieve TJU of its responsibility to comply with all federal laws, regulations and published policies governing investigations into scientific misconduct and/or grant administration. Any requirements found in this Agreement and/or the IIA are in addition to existing federal requirements.

4. TJU has represented to the NIH that it is taking appropriate corrective actions to establish and maintain a grants management and administration program satisfactory to the NIH as required by the October 3, 1996 letter from Geoffrey E. Grant, Acting Director, Office of Policy for Extramural Research Administration, NIH, to Paul C. Brucker, M.D., President, TJU, and the November 21, 1996 letter from Mr. Grant to Alan B. Kelly, Esquire, TJU. TJU shall report to NIH on the implementation of its corrective actions as required by these letters. Both TJU and NIH are committed to a continuing collaborative relationship whereby NIH will provide technical assistance to TJU in connection with the development and implementation of TJU's corrective action plan. Because TJU was designated by NIH as an Exceptional Organization pursuant to 45 C.F.R. §74.14, a primary objective of TJU's corrective action

plan is the prompt removal of said designation. Accordingly, the following process and standards will be used by NIH to remove the Exceptional Organization designation:

(a) To the extent TJU has not done so, TJU will develop and implement policies, procedures and other materials consistent with the laws, regulations and NIH published policies governing sponsored programs in the areas addressed in the above-referenced letters.

(b) TJU will submit all applicable policies, procedures and other materials to NIH. Within 180 days of TJU's final submission, and notification by TJU of such final submission, NIH will review all applicable policies, procedures and materials submitted by TJU for compliance with applicable law, regulations and NIH published policies and provide TJU specific comments identifying critical revisions to the policies, procedures and materials. All policies, procedures, and materials submitted by TJU, including critical revisions identified by NIH, will be considered TJU's corrective actions.

(c) Subsequent to TJU's implementation of corrective actions under paragraph (b), and no earlier than the completion of the first annual audit required by the Institutional Integrity Agreement and subsequent review by an Independent

Review Organization ("IRO"), at TJU's request NIH will conduct an Effectiveness Site Visit at a scheduled time mutually convenient for both TJU and NIH, using their best efforts to commence the Effectiveness Site Visit no later than 90 days following TJU's request.

(d) Within 90 days of the Effectiveness Site Visit, NIH will determine, in its sole discretion, and notify TJU of the following: (1) Based on its assessment, whether TJU has implemented appropriate corrective actions that are operating effectively at a demonstrated level of substantial compliance with TJU's policy and procedures, including critical revisions; and (2) NIH's decision on removing TJU's designation as an Exceptional Organization, consistent with 45 C.F.R. §74.14.

(e) NIH may extend the time frames in this paragraph 4 up to an additional 60 days with notification to TJU and only for good cause.

5. The United States and TJU agree that the statement attached as Exhibit C hereto is a true and accurate summary of the current state of the science with respect to the scientific matters at issue relating to Grant 35662.

6. The United States and TJU and Pomerantz shall make a good faith effort to obtain publication of the correction

statement attached as Exhibit C by all journals that previously published the results of the research performed at TJU. The United States will not seek to require any further correction or any retraction of the previously published work related to Grant 36552 by TJU, and agrees that any publication of the correction statement by any journal should only be identified as a correction.

7. Promptly after this Agreement is executed, and after payment in full of the Settlement Amount, the United States will notify the Court in the Civil Action, simultaneously, that (a) the United States is intervening in Civil Action No. 97-3396 for the purposes of joining with the Relator Wu in stipulating to a dismissal with prejudice of this action and that (b) notwithstanding such intervention, all parties have reached a settlement, and pursuant to this settlement, all parties have stipulated that the claims in Civil Action No. 97-3396 are dismissed with prejudice.

8. Subject to the terms of this Agreement and upon receipt of the payment described in paragraph 1, the United States agrees to fully and finally release TJU and its current and former directors and officers, employees and agents, Croce and Glick, from civil or administrative monetary claims the

United States has asserted or may assert, under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Grant 55541 Covered Conduct and for the Anderson Audit described above.

9. Subject to the terms of this Agreement and upon receipt of payment described in paragraph 1, the United States agrees to fully and finally release TJU and its current and former directors and officers, employees and agents, Pomerantz and Duan from civil or administrative monetary claims the United States has asserted or may assert, under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§3801-3812; or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Duan Covered Conduct.

10. In consideration of the obligations of TJU, Croce, Glick, Pomerantz and Duan set forth in this Agreement and the IIA, and conditioned upon TJU's payment in full of the Settlement Amount as set forth in paragraph 1, HHS agrees to release and refrain from instituting, directing or maintaining any debarment action under 45 C.F.R. Part 76 and 48 C.F.R.

Part 9.4 or administrative claim against TJU, Croce, and Glick for the Grant 55541 Covered Conduct and for the Anderson Audit; and against TJU, Pomerantz and Duan for the Duan Covered Conduct, except as reserved in Paragraph 11 below.

11. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person are the following:

- (1) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
- (2) Any criminal liability;
- (3) Except as set forth in the Covered Conduct described above and released, any administrative liability;
- (4) Any liability to the United States (or its agencies) for any conduct except as set forth in the Covered Conduct described above and released;
- (5) Any claims based upon such obligations as are created by this Agreement;
- (6) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by TJU;

(7) Any claims for personal injury or property damage or for other consequential damages except as set forth in the Covered Conduct described above and released; and

(8) Any claims based on a failure to deliver items or services due, except as set forth in the Covered Conduct described above and released.

(9) Any findings made or administrative action taken by the United States, resulting from ORI's continuing oversight in ORI 97-07 of the investigation of allegations of research misconduct against Duan, except as to the publication of any journal correction which shall be in accordance with paragraph 6.

12. TJU, Croce, Glick, Pomerantz and Duan fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which TJU, Croce, Glick, Pomerantz and Duan have asserted, or may assert against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct described above and the United States' investigation and prosecution thereof.

13. TJU, Pomerantz and Duan fully and finally release Relator Wu from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which TJU, Pomerantz and Duan have asserted, or may have asserted against Wu, including but not limited to the litigation captioned Thomas Jefferson University v. Yong Wu, Civil Action No. 00-923 (Eastern District of Pennsylvania) (petition for removal) and the case captioned Thomas Jefferson University v. Yong Wu, July Term, 1999, No. 3772 (Philadelphia Court of Common Pleas).

14. Wu fully and finally releases TJU, its current and former directors and officers, employees and agents, Pomerantz and Duan from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Wu has asserted, or may have asserted against TJU, Pomerantz and Duan relating to the Duan Covered Conduct as well as any retaliation claim against TJU, its current and former directors and officers, employees and agents.

15. TJU, Croce, Glick, Pomerantz and Duan agree that all costs (as defined in 45 C.F.R. § 74.27, 45 C.F.R. Part 74 and 45 C.F.R. Part 92), whether direct or indirect incurred by or on behalf of TJU, Croce, Glick, Pomerantz and Duan or their agents, employees, or former employees in connection with: (1) the

matters covered by this Agreement, (2) the Government's audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement, (3) TJU's investigation, defense, and corrective actions undertaken in response to the Government's audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees) and the IIA, including the obligations undertaken pursuant to the IIA incorporated into this Settlement Agreement, to the extent undertaken in response to the government's audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement, including attorney's fees; (4) the negotiation of this Agreement, and (5) the payment made pursuant to this Agreement, are unallowable costs under the cost principles applicable to government grants, contracts, cooperative agreements, and other agreements to which 45 C.F.R. Part 74 and 45 C.F.R. Part 92 applies (hereafter, "unallowable costs"). These unallowable costs will be separately estimated and accounted for by TJU and TJU will not charge such unallowable costs directly or indirectly to any grants, contracts, cooperative agreements, or other agreements with the United States or seek payment for such unallowable costs through any cost report, cost statement, information

statement or payment request submitted by TJU or any of its departments or agencies. The parties agree that nothing in this Agreement shall constitute a waiver of any rights the United States may have under 45 C.F.R. § 74.27, 45 C.F.R. Part 74 and 45 C.F.R. Part 92. TJU, Croce, Glick, Pomerantz and Duan further agree that within 60 days of the effective date of this Agreement they will identify to applicable United States grantors any unallowable costs (as defined above in this paragraph as (1) through (5)) included in payments previously sought from the United States, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by TJU, any of its departments, Croce, Glick, Pomerantz or Duan, and will request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. TJU, Croce, Glick, Pomerantz and Duan agree that the United States will be entitled to recoup from each of them any overpayment as a result of the inclusion of such unallowable costs on previously-submitted costs reports, information reports, cost statements or requests for payment. Any payments due after the adjustments have been

made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by TJU, any of its departments, Croce, Glick, Pomerantz or Duan on the effect of inclusion of unallowable costs (as defined above in this paragraph as (1) through (5)) on any of their cost reports, cost statements or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

16. In the event that TJU, Croce, Glick, Pomerantz and/or Duan fail to comply in good faith with any of the terms of this Agreement, or should any of TJU, Glick, Croce, Pomerantz or Duan's representations or warrants be materially false ("Alleged Breach"), the United States may, at its sole discretion, exercise one or more of the following rights against the defaulting party:

(1) seek specific performance of this Agreement and in addition, recover reasonable attorney's fees and costs;

(2) impose any remedy contained in the IIA in accordance with the procedures set forth therein;

(3) exercise any other right granted by law, including debarment from participation in federal programs or exercise any right granted or cognizable at common law or equity, including injunctive relief. The United States agrees that it will first give written notice of any Alleged Breach, specifying the circumstances of the Alleged Breach, and provide the alleged defaulting party an opportunity to cure any Alleged Breach within thirty (30) days of receipt of such written notice. In the event the United States elects to rescind the Agreement, the Parties do not waive any defenses, claims or causes of action which were available as of the date of execution of this Agreement by the Parties.

17. TJU, Croce, Glick, Pomerantz and Duan agree not to intimidate or take any retaliatory action against any individual or individuals who cooperated with the investigations and/or who cooperate(s) with the United States throughout the pendency of this Agreement and the IIA.

18. This Agreement is intended to be for the benefit of the Parties, their successors and assigns, and by this instrument the Parties do not release any claims against any other person or entity.

19. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. TJU, Croce, Glick, Pomerantz and Duan represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Eastern District of Pennsylvania, except any dispute under the IIA shall be subject to the dispute resolution provisions therein, and any dispute with NIH shall be subject to the administrative process of NIH as set forth in paragraph 4 of this Agreement which shall be resolved in good faith by TJU and NIH. Nothing in this Agreement shall be construed to create or denigrate any rights to administrative and/or judicial review otherwise available to the Parties to the extent allowed by law.

22. This Agreement and the Exhibits constitute the complete agreement between the Parties. There are no restrictions, promises, representations, warranties, covenants, or undertakings other than those expressly set forth or referred

to in this Agreement and the Exhibits. This Agreement, together with the Exhibits, supersedes any and all prior agreements and understandings between the Parties with respect to this subject matter. This Agreement may not be amended except by written consent of the Parties, except that only TJU and OIG-HHS must agree in writing to modification of the IIA, pursuant to the terms set forth in the IIA.

23. The undersigned individuals signing this Agreement on behalf of the United States, TJU, Croce, Glick, Pomerantz, Duan and Wu represent and warrant that they are authorized by the United States, TJU, Croce, Glick, Pomerantz, Duan and Wu to execute this Agreement.

24. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA:

THOMAS JEFFERSON UNIVERSITY:

Michael R. Stiles 5/19/00
MICHAEL R. STILES Date
United States Attorney

Date

James G. Sheehan 5/19/00
JAMES G. SHEEHAN Date
Assistant United States Attorney
Chief, Civil Division

CARLO CROCE, M.D.:

Date

David R. Hoffman 5/19/00
DAVID R. HOFFMAN Date
Assistant United States Attorney

JEROLD GLICK:

Date

ROGER POMERANTZ, M.D.

LEWIS MORRIS Date
Assistant Inspector General
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department
of Health and Human Services

Date

Terrence J. Tychan Date
Deputy Assistant Secretary for
Grants and Acquisition Management

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA:

THOMAS JEFFERSON UNIVERSITY:

MICHAEL R. STILES Date
United States Attorney

Paul C. Brucker 5/18/00
PAUL C. BRUCKER, MD Date
PRESIDENT

JAMES G. SHEEHAN Date
Assistant United States Attorney
Chief, Civil Division

CARLO GROCE, M.D.:
[Signature]

Date

DAVID R. HOFFMAN Date
Assistant United States Attorney

JEROLD GLICK:
[Signature] 5/18/00

Date

LEWIS MORRIS Date
Assistant Inspector General
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department
of Health and Human Services

ROGER POMERANTZ, M.D.
[Signature] 5/18/00

Date

Terrence J. Tychan Date
Deputy Assistant Secretary for
Grants and Acquisition Management

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA:

THOMAS JEFFERSON UNIVERSITY:

MICHAEL R. STILES Date
United States Attorney

_____ Date

JAMES G. SHEEHAN Date
Assistant United States Attorney
Chief, Civil Division

CARLO CROCE, M.D.:

_____ Date

DAVID R. HOFFMAN Date
Assistant United States Attorney

JEROLD GLICK:

_____ Date

Lewis Morris Date
LEWIS MORRIS
Assistant Inspector General
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department
of Health and Human Services

ROGER POMERANTZ, M.D.

_____ Date

for Charles Gale Date
Terrence J. Tychan
Deputy Assistant Secretary for
Grants and Acquisition Management

YONG WU, M.D.

LINGKUN DUAN, M.D.


Date

5-17-00

Date

Approved and So Ordered

United States District Court Judge

YONG WU, M.D.

LINGXUN DUAN, M.D.

Date



Date 5/19/06

Approved and So Ordered

United States District Court Judge