

SETTLEMENT AGREEMENT

The parties agree as follows:

1. This Settlement Agreement (Settlement Agreement) is entered into between the United States of America, acting through the United States Department of Justice, the United States Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively the United States); the Board of Regents of the University of Minnesota that governs the University through its President, Officers, Deans, and faculty (past and present) (altogether, the University); and Dr. James F. Zissler (Relator), through their authorized representatives in order to resolve all claims stated in the Amended Complaint of the United States in United States ex rel. Zissler v. Board of Regents of the University of Minnesota, No. 3-95-168 (D. Minn.).

2. On February 21, 1995, Relator filed the original complaint against the University in United States ex rel. Zissler v. Board of Regents of the University of Minnesota, No. 3-95-168 (D. Minn.), on behalf of himself and the United States, pursuant to 31 U.S.C. §3730(b)(1).

3. On December 19, 1996, the United States intervened in United States ex rel. Zissler v. Board of Regents of the University of Minnesota, No. 3-95-168 (D. Minn.), and on February 12, 1998, the United States filed its Amended Complaint (Amended Complaint) in this matter.

4. The United States has alleged legal and equitable civil claims against the University for conduct described in the United States' Amended Complaint.

5. Except as indicated in its Answer to the United States' Amended Complaint, the University has not and does not admit the contentions of the United States as set forth in the Amended Complaint.

6. The University agrees to pay the United States the Settlement Amounts as follows:

(a) \$20,000,000, to be paid by electronic funds transfer pursuant to written instructions from the United States. The University agrees to make this electronic funds transfer by no later than three (3) days after the effective date of this Settlement Agreement;

(b) \$8,000,000, to be paid by electronic funds transfer or transfers pursuant to written instructions by the United States. This \$8,000,000, and any interest payable consistent with this sub-paragraph, is to be paid by the University, in installments if necessary, within thirty (30) days of receipt of any social security tax refund it receives from the United States in accordance with the decision of the United States Court of Appeals for the Eighth Circuit in State of Minnesota v. Apfel, Case No. 97-3141 (8th Cir. 1998). The University has represented to the United States that on these refund claims it is entitled to an amount exceeding \$8,000,000. From the date of this Settlement Agreement to the date of payment to the United States under this sub-paragraph, interest shall accrue on this \$8,000,000, or any portion of it that remains unpaid after installment payment(s), at the same rate and in the same manner of compounding, as interest paid to the University by the United States on these same funds. If, however, the Internal Revenue Service issues a final determination that the University is entitled to less than \$8,000,000 on

these social security tax refund claims, then, within thirty (30) days, the University shall pay to the United States the remainder of that \$8,000,000, plus interest, dating from the effective date of this Settlement Agreement, at a rate determined pursuant to 28 U.S.C. § 1961(c)(2) (post judgment interest).

(c) \$4,000,000, to be paid over a period of three (3) years, by paying offsets against NIH research grant awards made to the University. This provision will be implemented as follows:

- i. On notice of a grant award, NIH will identify, in its sole discretion, an amount that otherwise would have been funded by NIH under that grant, the amount to be paid by NIH and the amount for which the University shall assume complete financial responsibility.
- ii. Selection of the grant or grants that the University shall be responsible to fund in whole or in part under this Settlement Agreement shall be determined before or after the grant award at the sole discretion of NIH .
- iii. The University shall conduct annual audits of its payments against such grant award(s) to assure that the portions of the grants for which the University is financially responsible are fully funded and provide to NIH a certified copy of each annual audit.
- iv. The University shall report to NIH any shortfall in such payments along with a proposal for rectifying such shortfall within a

reasonable period; acceptance of any University proposal shall be at the sole discretion of NIH.

- v. Paragraph 15 of this Settlement Agreement shall not preclude NIH from enforcing all laws and regulations and terms and conditions of grants with regard to the offsets made under this subparagraph.
- vi. NIH will notify the University of its intention to offset and then will, at the University's request, discuss the offsets provided for in sub-paragraph 6(c) on any particular grant award.

7. Effective upon filing the joint stipulation pursuant to paragraph 12, the United States releases the University and its current and former Regents, officers, employees, and agents from any civil, equitable, or monetary administrative claim the United States has or may have for the transactions or occurrences that are the subject matter of the United States' claims in the Amended Complaint.

8. As between the United States and Relator Dr. James Zissler, only, the United States will pay Dr. Zissler \$1,500,000 of the Settlement Amount pursuant to 31 U.S.C. § 3730(d), in satisfaction of all claims the relator has against the United States under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and all claims against the United States arising from Relator's Complaint and Relator's Amended Complaint. The Relator releases the United States and the University from all claims he may have arising from the Complaint and Amended Complaint and under 31 U.S.C. § 3730 for transactions or occurrences that are the subject matter of the claims in the Amended Complaint. The Relator agrees that the settlement is fair, adequate and reasonable and that he will not challenge this Settlement Agreement pursuant to 31 U.S.C. §

3730(c)(2)(B). The Relator will join in any stipulation dismissing the Amended Complaint and the Relator's Amended Complaint with prejudice.

9. As between the University and Relator, only, Relator expressly and unconditionally reserves his claim for attorneys' fees and costs against the University pursuant to 31 U.S.C. § 3730(d)(1) and any employment, employment benefits, employment retaliation, and retaliation claims, if any, including any claims pursuant to 31 U.S.C. § 3730(h). The University and the relator will continue discussion toward settlement of those matters. In the event that those matters are not settled, the Relator shall be free to present his fees and costs by petition to the Court, and to present in the appropriate forum, his employment, employment benefits, employment retaliation, and retaliation claims, if any, including any claims pursuant to 31 U.S.C. § 3730(h), which may be opposed by the University. The University reserves all defenses to the Relator's claim for attorneys' fees and costs and to Relator's employment, employment benefits, employment retaliation, and retaliation claims, if any, including defenses to any claims brought pursuant to 31 U.S.C. § 3730(h).

10. The University shall, within three (3) days of the effective date of this Settlement Agreement, dismiss its appeal, with prejudice, in Board of Regents of the University of Minnesota v. Shalala, Case No. 97-3587, currently pending before the United States Court of Appeals for the Eighth Circuit.

11. The University shall, within three (3) days of the effective date of this Settlement Agreement, withdraw its petition for rehearing and rehearing en banc currently pending before the United States Court of Appeals for the Eighth Circuit in United States ex rel. Zissler v. Regents of the University of Minnesota, Case No. 97-4099.

12. Within one business day of the United States' receipt of the University's payment pursuant to paragraph 6(a), the Parties will file a joint stipulation (in the form attached as Exhibit A) seeking dismissal with prejudice of this action.

13. Effective upon filing the joint stipulation pursuant to paragraph 12, the OIG-HHS agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against the University under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the transactions or occurrences that are the subject matter of the United States' claims in the Amended Complaint. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude the University from the Medicare, Medicaid or other federal health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based on those transactions and occurrences.

14. Effective upon filing the joint stipulation pursuant to paragraph 12, HHS agrees to release and refrain from instituting, directing or maintaining any administrative action seeking suspension or debarment of the University for the transactions or occurrences that are the subject matter of the United States' claims in the Amended Complaint.

15. Exclusive jurisdiction and venue for any dispute arising between and among the parties to this Settlement Agreement concerning the obligations created by this Settlement Agreement will be in the United States District Court for the District of Minnesota, except as set forth in paragraph 6(c) to this Settlement Agreement.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including the University) are any and all of the following:

- (a) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by the University;
- (c) Any claims for contribution or indemnification for personal injury or property damage or for other consequential damages arising from any conduct other than that included in the Amended Complaint;
- (d) Any non-monetary administrative claims and remedies against any individuals, including officers and employees; and
- (e) the NIH action initiated pursuant to the letter from Geoffrey Grant to Mark Brenner dated August 14, 1995; provided, however, the NIH will not seek to suspend or debar the University based on transactions or occurrences that are the subject matter of the United States' claims in the Amended Complaint.

17. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

18. The University agrees that all costs incurred by or on behalf of the University, its agents, officers, employees, or former employees in connection with the investigation, litigation,

settlement, and corrective actions that bear a direct relationship to the transactions or occurrences that are the subject matter of the United States' claims in the Amended Complaint are unallowable costs for all purposes on all United States' contracts, grants, and other programs.

19. This Settlement Agreement is intended to be for the benefit of the United States, the University and the Relator (the Parties) only as set forth herein, and by this instrument the Parties do not release any claims against any other person or entity.

20. The United States and the University will bear their own legal and other costs incurred in connection with this matter including the preparation and performance of this Settlement Agreement.

21. The Parties represent that this agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

22. This Settlement Agreement is governed by the laws of the United States.

23. This Settlement Agreement constitutes the complete agreement between the Parties. This Settlement Agreement may not be amended except by written consent of the Parties.

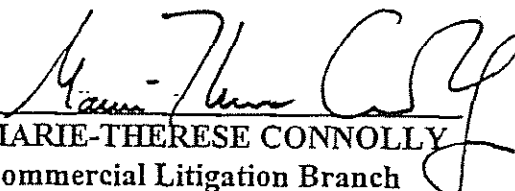
24. Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is duly authorized to do so.

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


26. This Settlement Agreement is effective on the date of signature of the last signatory to the Settlement Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

On behalf of the UNITED STATES OF AMERICA.

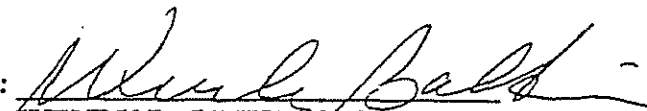
DATED: 11/16/98

BY: 
MARIE-THERESE CONNOLLY
Commercial Litigation Branch
Civil Division
U.S. Department of Justice

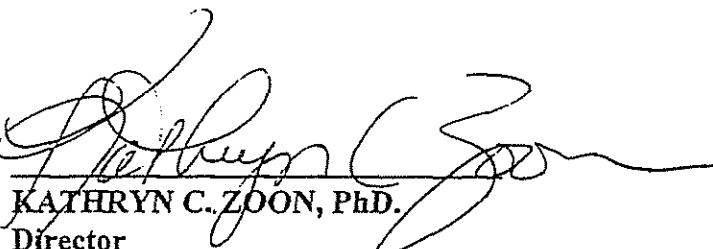
DATED: 11/16/98

BY: 
HARRIET S. RABB
General Counsel
U.S. Department of Health and Human Services

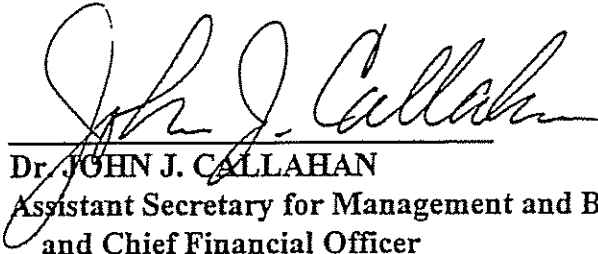
DATED: 11/16/98

BY: 
WENDY BALDWIN, PhD.
Deputy Director for Extramural Research
National Institutes of Health
U.S. Department of Health and Human Services

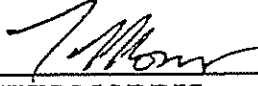
DATED: 11/16/98

BY: 
KATHRYN C. ZOON, PhD.
Director
Center for Biologics Evaluation and Review
Food and Drug Administration
U.S. Department of Health and Human Services

DATED: 11/16/98

BY: 
Dr. JOHN J. CALLAHAN
Assistant Secretary for Management and Budget
and Chief Financial Officer
U.S. Department of Health and Human Services

DATED: 11/16/98

BY: 
LEWIS MORRIS
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

On behalf of the REGENTS OF THE UNIVERSITY OF MINNESOTA

DATED: _____

BY: _____
MARK YUDOF
President
University of Minnesota

DATED: _____

BY: _____
MARK ROTENBERG
General Counsel
Regents of the University of Minnesota

DATED: _____

BY: _____
THOMAS TINKHAM
Dorsey & Whitney L.L.P.
Counsel to the University of Minnesota

DATED: _____

BY: _____

TERRENCE J. TYCHAN
Deputy Assistant Secretary
Grants and Acquisition Management
U.S. Department of Health and Human Services

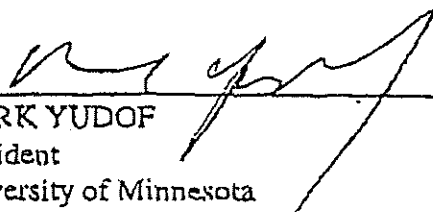
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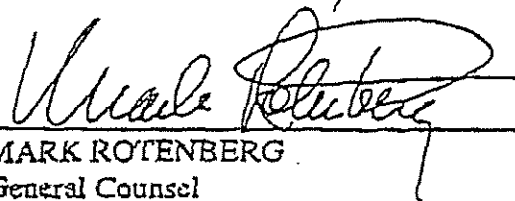
LEWIS MORRIS
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

On behalf of the REGENTS OF THE UNIVERSITY OF MINNESOTA

DATED: 11/16/98

BY: 
MARK YUDOF
President
University of Minnesota

DATED: 11/16/98

BY: 
MARK ROTENBERG
General Counsel
Regents of the University of Minnesota

DATED: _____

BY: _____
THOMAS TINKHAM
Dorsey & Whitney L.L.P.
Counsel to the University of Minnesota

DATED: _____

BY: _____

TERRENCE J. TYCHAN
Deputy Assistant Secretary
Grants and Acquisition Management
U.S. Department of Health and Human Services

DATED: _____

BY: _____

LEWIS MORRIS
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

On behalf of the REGENTS OF THE UNIVERSITY OF MINNESOTA

DATED: _____

BY: _____

MARK YUDOF
President
University of Minnesota

DATED: _____

BY: _____

MARK ROTENBERG
General Counsel
Regents of the University of Minnesota

DATED: November 16, 1998 BY: _____



THOMAS TINKHAM
Dorsey & Whitney L.L.P.
Counsel to the University of Minnesota

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GARY A WEISSMAN

PAGE 11

FROM : ELLEN ZISSLER

PHONE NO. :

Nov. 14 1998 11:29AM P1

11/13/1998 17:39 6123381771

GARY A WEISSMAN
612-974-9615

NOV 14 1998
11:29 AM
P1

DRAFT: 11/13/98 4:00 EST

On behalf of the debtor DE. JAMES ZISSLER, by his attorney

DATED: 11/17/98

BY:


GARY A. WEISSMAN
Attorney for Debtor

On behalf of the debtor DE. JAMES ZISSLER, by himself

DATED: 11/14/98

BY:



JAMES F. ZISSLER, Ph.D.
Debtor

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,
ex rel. JAMES ZISSLER,

Civ. No. 3-95-168

Plaintiff,

**JOINT NOTICE OF SETTLEMENT
AND STIPULATION OF DISMISSAL**

v.

REGENTS OF THE UNIVERSITY
OF MINNESOTA,

Defendant.

The United States, relator James F. Zissler, and the Regents of the University of Minnesota (University) have reached an agreement to settle this litigation. (A copy of the parties' Settlement Agreement is attached.) Pursuant to Rule 41(a)(1) of the Federal Rules of Civil Procedure and the False Claims Act, 31 U.S.C §3730(b)(1), the United States, by its undersigned attorneys, relator James F. Zissler, by his undersigned attorney, and the University, by its undersigned attorney, stipulate that the amended complaint be dismissed with prejudice. The parties stipulate that Court shall retain jurisdiction over any and all disputes concerning enforcement of that Settlement Agreement.

Respectfully submitted,

FRANK HUNGER
Assistant Attorney General
U.S. Department of Justice

ROBERT M. SMALL
Acting United States Attorney
District of Minnesota

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MARIE-THERESE CONNOLLY
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University of Minnesota

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333 City Boulevard West
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Orange, California 92868
(714) 634-4534
Counsel for James F. Zissler

Date: November __, 1998.

IT IS SO ORDERED:

Dated: November __, 1998.

U.S. DISTRICT JUDGE