UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

UNITED STATES OF AMERICA ex rel.)
BERNARD LISITZA, STATE OF ILLINOIS ex)
rel. BERNARD LISITZA, STATE OF)
CALIFORNIA ex rel. BERNARD LISITZA,)
STATE OF DELAWARE ex rel. BERNARD)
LISITZA, DISTRICT OF COLUMBIA ex rel.) No. 03 C 742
BERNARD LISITZA, STATE OF FLORIDA ex)
rel. BERNARD LISITZA, STATE OF HAWAII) CHIEF JUDGE HOLDERMAN
ex rel. BERNARD LISITZA, STATE OF)
LOUISIANA <i>ex rel</i> . BERNARD LISITZA,) FILED UNDER SEAL
STATE OF MASSACHUSETTS ex rel.)
BERNARD LISITZA, STATE OF NEVADA ex)
rel. BERNARD LISITZA, STATE OF)
TENNESSEE <i>ex rel</i> . BERNARD LISITZA,)
STATE OF TEXAS ex rel. BERNARD)
LISITZA, STATE OF VIRGINIA ex rel.)
BERNARD LISITZA, and BERNARD)
LISITZA, individually,)
)
Plaintiffs,)
)
V.)
)
CVS CAREMARK CORPORATION,)
)
Defendant.	

SETTLEMENT AGREEMENT

I. Parties

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively the "United States"); defendant CVS Caremark Corporation ("CVS"); and Bernard

Lisitza ("Relator") acting through their authorized representatives. Collectively, all of the above will be referred to as "the Parties".

II. Preamble

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

- A. CVS is a Delaware corporation that owns and/or operates approximately 6,000 retail pharmacies throughout the United States.
- B. Relator is an individual resident of the State of Illinois. On January 31, 2003, Relator filed a *qui tam* action in the United States District Court for the Northern District of Illinois captioned *United States ex rel. Bernard Lisitza et al.*, v. CVS Corporation, No. 03 C 742 (hereinafter "the Civil Action"). The United States has intervened in the Civil Action, simultaneous with the execution of this Agreement.
- C. The United States contends that CVS submitted or caused to be submitted claims for payment to the Medicaid Programs (Medicaid), 42 U.S.C. §§ 1396-1396v in the states in which CVS pharmacies were located.
- D. The United States contends that it has certain civil claims, as specified in Paragraphs 2, 3, and 4, below, against CVS for engaging in the following conduct (hereinafter referred to as the "Covered Conduct"): From April 1, 1999 through December 31, 2006 CVS improperly caused its pharmacies to switch Medicaid patients who were prescribed ranitidine (generic Zantac) 150 mg or 300 mg tablets to the capsule form of the drug. This switch occurred because the Centers for Medicare and Medicaid Services ("CMS") had imposed a Federal Upper Limit ("FUL") price on the tablet form of ranitidine. As a result of this improper substitution, CVS received reimbursement amounts from various state Medicaid programs that were higher than it was entitled to receive.

- E. The United States also contends that it has certain administrative claims, as specified in Paragraph 2, 3, and 4 below, against CVS for engaging in the Covered Conduct.
- F. This Agreement is made in compromise of disputed claims. CVS expressly denies each and every one of the contentions and claims of the United States that are set forth in Paragraph D above, the allegations of the Relator in the Civil Action, and the civil and administrative claims specified in Paragraphs 2, 3, and 4 below, and expressly denies that it has engaged in any wrongful conduct in connection with the Covered Conduct or that it is liable under the False Claims Act, 31 U.S.C. §§ 3729-3733, or any other civil, administrative or criminal cause of action with regard to such contentions or allegations. Nothing in this Agreement, or any obligation herein, or the fact of the settlement shall constitute, be construed to be, or be understood as an admission by CVS that it has violated or breached any act, law, regulation, obligation or contract or has engaged in any wrongdoing.
- G. Contemporaneously herewith, CVS is entering into separate settlement agreements with the states listed on Exhibit A attached (hereinafter referred to as the "Medicaid Participating States") which will be receiving settlement funds from CVS pursuant to Paragraph 1b below for the Covered Conduct described in Paragraph D above.
- H. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. Terms and Conditions

1. CVS agrees to pay to the United States and the Medicaid Participating States, collectively thirty-six million, seven hundred thousand dollars (\$36,700,000) (the "Settlement

Amount"). The Settlement Amount is to be paid to the United States and the Medicaid Participating States as follows:

- a. CVS and the United States agree that the sum of twenty-one million, sixty thousand, five hundred thirty-five dollars and fifty-four cents (\$21,060,535.54) represents the Federal Share (the "Federal Settlement Amount"). CVS agrees to pay the Federal Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the U.S. Attorney's Office for the Northern District of Illinois. CVS agrees to make this electronic funds transfer no later than ten (10) business days from the Effective Date of this Agreement.
- b. CVS and the Medicaid Participating States agree that the sum of fifteen million six hundred thirty-nine thousand four hundred sixty-four dollars and forty-six cents (\$15,639,464.46) represents the Medicaid Participating States' share (the "State Settlement Amount") under terms and conditions agreed upon by CVS and the Medicaid Participating States (the "State Settlement Agreements"). The State Settlement Amount shall be paid to an account designated by the Negotiating Team of the National Association of Medicaid Fraud Control Units ("NAMFCU") no later than ten (10) business days from the Effective Date of this Agreement for distribution to the Medicaid participating States by NAMFCU.
- c. Contingent upon the United States receiving the Federal Settlement Amount from CVS and as soon as feasible after receipt, the United States agrees to pay \$3,580,291 to Relator by electronic funds transfer pursuant to instructions provided by Michael I. Behn, of Behn & Wyetzner, Chartered ("Counsel for Relator").
- d. Contingent upon the Medicaid Participating States receiving the State Settlement Amount from CVS and as soon as feasible after receipt, the Medicaid Participating States agree to pay \$729,039.73 to Relator by electronic funds transfer pursuant to instructions provided by Counsel for Relator.

- e. CVS further agrees to pay Counsel for the Relator for expenses and attorney's fees and costs pursuant to instructions provided by Counsel for Relator in accordance with the terms of a separate agreement between CVS and the Relator. CVS agrees to make this electronic funds transfer no later than 10 days from the Effective Date of this Agreement.
- 2. Subject to the exceptions in Paragraph 5, below, in consideration of the obligations of CVS in this Agreement, conditioned upon CVS's full payment of the Federal and State Settlement Amounts, the United States (on behalf of itself, its officers, agents, employees, servants, agencies, and departments) fully and finally releases CVS, its parents, divisions, subsidiaries, predecessors, successors, assignees, transferees, employees, agents, and affiliates (collectively the "CVS Released Parties") from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, against the CVS Released Parties, or the common law theories of payment by mistake, unjust enrichment, and fraud. The CVS parents, divisions, subsidiaries, predecessors, successors, assignees, transferees, and affiliates included in the CVS Released Parties are listed on Exhibit A attached.
- 3. Subject to the exceptions in Paragraph 5, below, in consideration of the obligations of CVS in this Agreement, conditioned upon CVS's full payment of the Federal and State Settlement Amounts, and the expenses, fees and costs referenced in paragraph 1e above, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release the CVS Released Parties from any civil monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 against the CVS Released Parties.
- 4. In consideration of the obligations of CVS in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and CVS, conditioned upon CVS's full

payment of the Federal and State Settlement Amounts, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against CVS, its parents, divisions, subsidiaries, predecessors, successors, assignees, transferees, or affiliates under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 5, below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude CVS from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below.

- 5. 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 CVS and Relator) are the following claims of the United States:
- a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - e. Any liability based upon such obligations as are created by this Agreement;

- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services; and
 - g. Any liability for failure to deliver goods or services due.
- 6. Relator and his heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and, conditioned upon receipt of Relator's share, Relator, for himself individually, and for his heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730 in the Civil Action; from any claims arising from the filing of the Civil Action; and from any other claims for a share of the Federal and State Settlement Amounts; and in full settlement of any claims Relator may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.
- 7. a. Conditioned upon receipt of the payments described in Paragraph 1c, d, and e, Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, agrees to release the CVS Released Parties, and its current and former officers, directors, agents, and employees, from any liability to Relator arising from the Covered Conduct against the CVS Released Parties, and under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs. Relator consents to the disclosure of this Agreement, and information about this Agreement, to the public.
- b. CVS, its current and former officers, directors, agents, and employees, agree to release Relator, his heirs, successors, attorneys, agents, and assigns, from any liability arising from the Covered Conduct, and under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.

- 8. CVS waives and shall not assert any defenses CVS may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. CVS is specifically not waiving any other defenses it may have. Nothing in this Paragraph or any other provision of this 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.
- 9. CVS fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that CVS has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, or any state payer, related to the Covered Conduct; and CVS shall not resubmit to any Medicare carrier or intermediary, or any state payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.
 - 11. CVS agrees to the following:
- a. <u>Unallowable Costs Defined</u>: if applicable, that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of CVS, its present or former officers,

directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and/or criminal investigation(s) of the matters covered by this Agreement;
- (3) CVS's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and/or any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
 - (4) the negotiation and performance of this Agreement;
- (5) the payment CVS makes to the United States pursuant to this Agreement and any payments that CVS may make to Relator, including costs and attorneys fees; and
 - (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
- (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
 - (ii) prepare and submit reports to the OIG-HHS.

However, nothing in this Paragraph 11a(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to CVS. (All costs described or set forth in this Paragraph 11a are hereafter "unallowable costs.")

b. <u>Future Treatment of Unallowable Costs</u>: If applicable, these unallowable costs shall be separately determined and accounted for by CVS, and CVS shall not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information

statement, or payment request submitted by CVS or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, CVS further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by CVS or any of its subsidiaries or affiliates, and shall 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. CVS agrees that the United States, at a minimum, shall be entitled to recoup from CVS any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

If applicable, 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 CVS or any of its subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this Paragraph) on CVS or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine CVS's books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this Paragraph.

- 12. CVS agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, CVS shall encourage, and agrees not to impair the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. CVS agrees to furnish to the United States complete and unredacted copies of all documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by its counsel or other agent, unless such material is covered by a valid claim of privilege.
- 13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 14, below.
- 14. CVS waives and shall not seek payment for any of the health care billings covered by this Agreement from any Medicaid beneficiary or said beneficiary's parents, sponsors, legally responsible individuals or third party payors based upon the claims defined as Covered Conduct.
- 15. CVS warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to CVS, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are

intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to that CVS was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

- 16. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 17. CVS represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 18. Relator represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 19. 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 is the United States District Court for the Northern District of Illinois, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.
- 20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- Upon receipt of the payments described in Paragraph 1a- e above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal with prejudice of the Civil Action and waiving all rights of appeal and costs pursuant to the terms of the Agreement.
- 22. The individuals signing this Agreement on behalf of CVS represent and warrant that they are authorized by CVS to execute this Agreement. The individual signing this Agreement on behalf of Relator represents and warrants that he is authorized by Relator to execute this Agreement.

The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

- 23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 24. This Agreement is binding on CVS's parents, divisions, subsidiaries, predecessors, successors, assignees, transferees, and affiliates (listed on Exhibit A, attached).
 - 25. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.
- 26. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 27. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

Exhibit A

CVS Caremark Corporation and CVS Pharmacy, Inc., a Rhode Island corporation, on its own behalf and on behalf of each of its subsidiaries and affiliates that operated stores in the jurisdictions listed below during the period from April 1, 1999 to December 31, 2006, including those CVS Pharmacy, Inc. subsidiaries operating under the ProCare or PharmaCare Pharmacy names. Specifically excluded from the CVS Released Parties are those store locations in the states of Indiana and Illinois acquired from Albertson's, Inc. on June 2, 2006.

Alabama

Connecticut

Washington, DC

Florida

Georgia

Illinois

Indiana

Kentucky

Maine

Maryland

Massachusetts

Michigan

New Hampshire

New Jersey

New York

North Carolina

Ohio

Pennsylvania

Rhode Island

South Carolina

Tennessee

Vermont

Virginia

West Virginia

THE UNITED STATES OF AMERICA

DATED: 3/18/08	BY	LINDA A. WAWZENSKI Assistant United States Attorney Northern District of Illinois 219 South Dearborn Street Chicago, Illinois 60604
DATED:	BY:	GREGORY E. DEMSKE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED:	BY:	
And committee control and a department of the control and a control and		LINDA A. WAWZENSKI
		Assistant United States Attorney
		Northern District of Illinois
		219 South Dearborn Street
		Chicago, Illinois 60604
2/14/08	70.0	
DATED: 5/19/48	BY:	GREGORY E. DEMSKE
		Assistant Inspector General for Legal Affairs
		Office of Counsel to the Inspector General
		Office of Inspector General
		*
		United States Department of Health
		and Human Services

CVS Caremark Corporation - DEFENDANT

DATED: n/6/07	BY:	DOUGLAS A. SGARRO Executive Vice President and Chief Legal Officer CVS Caremark Corporation One CVS Drive Woonsocket RI 02895

DATED: 12 107

BY:

MICHAEL S. GARDENER

Counsel for CVS Caremark Corporation

Mintz Levin Cohn Ferris Glovsky and Popeo, P.C.

One Financial Center Boston, MA 02111

Bernard Lisitza - RELATOR

DATED:_	January 29, 2008	BY:	BERNARD LYSITZA
DATED:_	January 29, 2008	BY:	MICHAEL I. BEHN Counsel for Bernard Lisitza
			Behn & Wyetzner, Chartered 500 N. Michigan Avenue, Suite 850 Chicago, Illinois 60611