

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,  
ex rel. ROBERT RUDOLF

Plaintiff

v.

ELI LILLY AND COMPANY

Defendant

CIVIL ACTION NO. 03-943

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UNITED STATES OF AMERICA,  
ex rel. JOSEPH FALTAOUS

Plaintiff

v.

ELI LILLY AND COMPANY.

Defendants

CIVIL ACTION NO. 06-2909

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UNITED STATES OF AMERICA  
ex rel. STEVEN WOODWARD

Plaintiff

v.

CIVIL ACTION NO. 06-5526

ELI LILLY AND COMPANY :  
:   
Defendant :

UNITED STATES OF AMERICA, :  
ex rel. JAYDEEN VICENTE :  
:   
Plaintiff :

v. : CIVIL ACTION NO. 07-1791

ELI LILLY AND COMPANY. :  
:   
Defendant :

UNITED STATES NOTICE OF INTERVENTION FOR PURPOSES OF SETTLEMENT

The United States of America, by and through its undersigned attorneys, provides this written notice to the Court that it is intervening in the following counts of the designated Complaints in the above actions pursuant to 31 U.S.C. § 3730(b) for the purposes of settlement and dismissal:

1. Count I of Relator Rudolf's Second Amended Complaint filed on August 29, 2008 in Civil Action No. 03-943, Docket No. 38, as to the allegations involving Zyprexa only;

B. Count I of Relator Faltaous's Second Amended Complaint filed on July 3, 2006 in Civil Action No. 06-0411, Docket No. 8 ;

C. Count I of Relator Woodward's Complaint filed on December 19, 2006 in Civil Action No. 07-0076, Docket No. 1 as to defendant Eli Lilly and Company only;

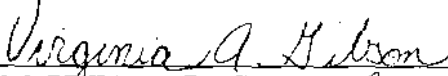
D. Count I of Relator Vicente's Complaint filed on May 3, 2007 in the


Eastern District of Pennsylvania in Civil Action No. 07-1791, Docket No. 1.

The United States, relators and defendant, Eli Lilly and Company, have reached an amicable resolution of these matters. A copy of the Settlement Agreement incorporating the terms of this resolution is attached hereto as Exhibit A. The parties agree that, upon payment of the Federal Settlement Amount and compliance with III 1(b)(i) with respect to the Medicaid State Settlement Amount as defined in the Settlement Agreement, the United States and relators will file Stipulations of Dismissal in accordance with the terms of the Settlement Agreement.

Respectfully submitted,

LAURIE MAGID  
Acting United States Attorney

  
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VIRGINIA A. GIBSON *MLH*  
Assistant United States Attorney  
Chief, Civil Division

  
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JOSEPH TRAUTWEIN  
Assistant United States Attorney

Dated: 1/15/09

CERTIFICATE OF SERVICE

I hereby certify that on this 14<sup>th</sup> day of January, 2009, I caused a copy of the foregoing United States Notice of Intervention for Purposes of Settlement to be served by first class mail, postage prepaid, upon:

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JOSEPII TRAUTWEIN  
Assistant United States Attorney

# **EXHIBIT “A”**

## 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, Civil Division, and the United States Attorney's Office for the Eastern District of Pennsylvania, the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), TRICARE Management Activity (“TMA”) and the United States Office of Personnel Management (“OPM”) (collectively the “United States”); the Relators as identified in Paragraphs B through E of the Preamble to this Agreement (“Relators”); and Eli Lilly and Company (“Eli Lilly”). 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. At all relevant times, Eli Lilly, an Indiana corporation headquartered in Indianapolis, Indiana, distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Zyprexa.

The qui tam actions identified in Paragraphs (B) through (E) will be referred to collectively as the “Civil Actions.”

B. Robert Rudolph (“Rudolph”), Hector Rosado (“Rosado”), and Robert Evan Daywitt (“Daywitt”) filed a qui tam action in the United States District Court for the Eastern

District of Pennsylvania captioned United States of America ex rel. Robert Rudolph, et al., v. Eli Lilly and Company, Civil Action No. 03-943. On August 13, 2003, Rudolph, Rosado and Daywitt filed a first amended complaint, adding relators Bradley Lutz (“Lutz”) and James Wetta (“Wetta”). A second amended complaint was filed on September 27, 2007, adding relator William Lofing (“Lofing”).

C. Joseph Faltaous (“Faltaous”) filed a qui tam action in the United States District Court for the Eastern District of New York captioned United States of America ex rel. Joseph Faltaous v. Eli Lilly and Company, Civil Action No. 05-1471. That action was transferred to the Eastern District of Pennsylvania as Civil Action No. 06-2909.

D. Steven Woodward (“Woodward”) filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States ex rel. Steven Woodward v. Dr. George B. Jerusalem, Tesse Jerusalem, Bay Psychiatric Services, and Eli Lilly, Civil Action No. 06-5526.

E. Jaydeen Vicente (“Vicente”) filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. Jaydeen Vicente v. Eli Lilly and Company, Civil Action No. 07-1791.

F. Eli Lilly has entered into a plea agreement with the United States Attorney for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Department of Justice and has agreed to plead guilty, pursuant to Fed.R.Crim.P. 11 to specific conduct described in a plea agreement to be filed in United States v. Eli Lilly and Company (the “Federal Criminal Action”).

G. Eli Lilly will be entering into separate settlement agreements, described in

Paragraph III.1(b) below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Eli Lilly executes a Medicaid State Settlement Agreement in the form to which Eli Lilly and the National Association of Medicaid Fraud Control Units ("NAMFCU") have agreed, or in a form otherwise agreed to by Eli Lilly and an individual State, shall be defined as "Medicaid Participating States."

H. The United States and the Medicaid Participating States allege that Eli Lilly caused claims for payment for Zyprexa to be submitted to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("the Medicaid Program").

I. The United States further alleges that Eli Lilly caused claims for payment for Zyprexa to be submitted to the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; and caused purchases of Zyprexa by the Department of Veterans Affairs ("DVA"), the Bureau of Prisons ("BOP"), the Department of Defense, the Department of Labor, and the Public Health Service Entities.

J. The United States contends that it has certain civil claims against Eli Lilly, as specified in Paragraph III.2 below, for engaging in the following conduct concerning the marketing, promotion and sale of Zyprexa between September 1999 and December 31, 2005 (hereinafter referred to as the "Covered Conduct"):



Eli Lilly knowingly promoted the sale and use of Zyprexa to psychiatrists, other physicians (including primary care physicians), and other health care professionals (collectively, "Health Care Professionals") for certain uses for which the Food and Drug Administration had not approved (i.e. "unapproved uses"); Eli Lilly implemented a marketing strategy to promote Zyprexa to Health Care Professionals, who treated patients of all ages, for unapproved uses; Eli Lilly also promoted Zyprexa to Health Care Professionals treating patients in long term care facilities for unapproved uses; Eli Lilly encouraged Health Care Professionals to prescribe Zyprexa in higher amounts than the recommended dose; the promotion of Zyprexa for these unapproved uses violated the Food Drug and Cosmetic Act, 21 U.S.C. § 331(a) and 21 U.S.C. § 352(f); Eli Lilly, in connection with its marketing and promotional efforts for Zyprexa, provided remuneration and other things of value to Health Care Professionals; and these unapproved uses were not medically accepted indications for which the United States and State Medicaid programs provided coverage.

As a result of the foregoing alleged conduct, the United States contends that Eli Lilly knowingly caused false and/or fraudulent claims to be submitted to the United States and the Medicaid programs and caused TRICARE, the FEIIBP, the Department of Veterans Affairs, the Bureau of Prisons, the Department of Defense, the Department of Labor, and Public Health Service Entities to purchase Zyprexa for these unapproved uses.

K. The United States also contends that it has certain administrative claims against Eli Lilly as specified in Paragraphs III.4-6 below, for engaging in the Covered Conduct.

L. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Eli Lilly nor a concession by the United States that its

claims are not well-founded. With the exception of the specific conduct for which Eli Lilly is pleading guilty as described in the plea agreement filed in connection with the Federal Criminal action, Eli Lilly expressly denies the allegations of the United States and the Relators as set forth herein and in the Civil Actions and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct. Neither this agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting upon the merits of the dispute by Eli Lilly.

M. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. TERMS AND CONDITIONS

1. Subject to the terms and procedures set forth below, Eli Lilly agrees to pay to the United States the sum of Four Hundred Thirty Eight Million, One Hundred Seventy One Thousand, Five Hundred Forty Three Dollars and Fifty Eight Cents (\$438,171,543.58) plus accrued interest in an amount of 3% per annum from October 20, 2008 and continuing until and including the day of payment (the "Federal Settlement Amount"), and – pursuant to the terms of Paragraph III.1.b – agrees to pay to all of the States and the District of Columbia (which shall be defined, for purposes of this Agreement, as a State) Three Hundred Sixty One Million, Eight Hundred Twenty Eight Thousand, Four Hundred Fifty Six Dollars and Forty Two Cents (\$361,828,456.42) plus accrued interest in the amount described in sub-paragraph III.1.b(ii)

below, of which One Million, Four Hundred Thirty Three Thousand, Six Hundred Forty Two Dollars and Ninety Six Cents (\$1,433,642.96) has already been paid to the State of Alaska pursuant to a separate settlement agreement. The amount of Three Hundred Sixty Million, Three Hundred Ninety Four Thousand, Eight Hundred Thirteen Dollars and Forty Six Cents (\$360,394,813.46) shall be defined as the "Medicaid State Settlement Amount".

(a) The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions to be provided by the United States. Eli Lilly agrees to make this electronic funds transfer no later than ten (10) business days after the date on which the Court accepts Eli Lilly's guilty plea in connection with the Federal Criminal Action and imposes the agreed-upon sentence.

(b) Eli Lilly shall pay the States according to the following terms:

(i) No later than ten (10) business days following the date on which the Court accepts Eli Lilly's guilty plea in connection with the Federal Criminal Action and imposes the agreed-upon sentence (the "Account Establishment Date"), Eli Lilly shall deposit the Medicaid State Settlement Amount plus accrued interest in the amount of 3% per annum earned on that amount from October 20, 2008 to the Account Establishment Date into one or more interest-bearing money market or bank accounts that are held in the name of Eli Lilly but segregated from other Eli Lilly accounts (the "State Settlement Accounts").

(ii) From the State Settlement Accounts, Eli Lilly shall pay (through the mechanism described below involving the New York State Attorney General's National Global Settlement Account (the "NY State Account")) to each State (with the exception of Alaska, with which Eli Lilly has reached a separate agreement including this matter) that

becomes a Medicaid Participating State (as that term is defined above) within the time limits established in subparagraph III.1.b(iv) below, that State's share of the Medicaid State Settlement Amount (as set forth in a communication from NAMFCU to Eli Lilly counsel on January 13, 2009) (the "Individual State Share") plus accrued interest on that Individual State Share in the amount of 3% per annum from October 20, 2008 to the Account Establishment Date plus that State's pro rata share of interest accrued in the State Settlement Accounts from the day following the Account Establishment Date until the date that payment is made to the NY State Account. Eli Lilly shall execute a Medicaid State Settlement Agreement with any State that executes such an agreement; provided, however, that Eli Lilly reserves the right not to execute a Medicaid State Settlement Agreement with any State that is engaged in litigation with Eli Lilly in a matter relating to Zyprexa. Eli Lilly shall pay the aggregate amount that it owes to the States that become Medicaid Participating States within 60 days following the Account Establishment Date to the NY State Account, pursuant to written wire instructions provided by NAMFCU, on the 70<sup>th</sup> day following the Account Establishment Date or within two (2) business days following receipt by Eli Lilly of the written wire instructions, whichever is later.

(iii) Eli Lilly may, at its sole discretion, waive any rights that it has reserved in sub-paragraph III.1.b(ii) with respect to the payment of any of the Individual State Shares.

(iv) Except as otherwise provided in this sub-paragraph, absent Lilly's consent, no State may become a Medicaid Participating State if it has not executed a Medicaid State Settlement Agreement within 60 days following the Account Establishment Date. (A Medicaid Participating State shall be deemed to have become a Medicaid Participating State on

the date on which it executed a Medicaid State Settlement Agreement.) If, on the 60<sup>th</sup> day following the Account Establishment Date, Eli Lilly is obligated pursuant to the terms of sub-paragraph III.1.b(ii) to pay to the NY State Account an aggregate amount less than the Medicaid State Settlement Amount, Eli Lilly shall be entitled to retain any such difference, commingle it with any other corporate funds, and use it for any purpose, and no State shall be entitled to any portion of that difference pursuant to the terms of this Agreement. In the event that there are twenty five (25) or more Medicaid Participating States by the 60<sup>th</sup> day following the Account Establishment Date, the deadline for becoming a Medicaid Participating State shall be extended by 30 days, and Eli Lilly's rights pursuant to this sub-paragraph III.1.b(iv) shall accrue on the 90<sup>th</sup> day following the Account Establishment Date. In the event that the immediately foregoing clause is triggered, Eli Lilly shall pay the aggregate amount that it owes to the States that become Medicaid Participating States in the period from 61-90 days following the Account Establishment Date to the NY State Account, pursuant to written wire instructions provided by NAMFCU, on the 100<sup>th</sup> day following the Account Establishment Date or within two (2) business days following receipt by Eli Lilly of the written wire instructions, whichever is later.

(c) Subject to the terms of this paragraph, Eli Lilly shall mail checks to affected Public Health Service entities the aggregate sum of Seven Hundred Fifty One Thousand, Five Hundred and Forty Three Dollars and Eighty Eight Cents (\$751,543.88, plus interest accrued thereon at a rate of 3% per annum from October 20, 2008, continuing until and including the day before checks are mailed pursuant to this paragraph (the "Public Health Settlement Amount"). Within 60 days of the date on which the Court accepts Eli Lilly's guilty plea in connection with the Federal Criminal Action and imposes the agreed-upon sentence, Eli

Lilly shall distribute to each affected Public Health Service entity a check in the amount of its proportionate share of the Public Health Settlement Amount along with a cover letter referencing this Agreement and providing that, by cashing the check, the entity is releasing Eli Lilly and its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from liability for the Covered Conduct.

(d) Contingent upon the United States receiving the Federal Settlement Amount from Eli Lilly, the United States agrees to pay, as soon as feasible after receipt, to Relator Rudolph \$78,870,877.84 plus the pro rata share of the actual accrued interest paid to the United States by Eli Lilly on the amount set forth in Paragraph III.1.a above (“Relator’s Share”).

(e) Relators have entered into a separate agreement concerning the allocation of the Relators’ Share among themselves.

2. Subject to the exceptions in Paragraph 7 below (concerning excluded claims), in consideration of the obligations of Eli Lilly in this Agreement, conditioned upon Eli Lilly’s full payment of the Federal Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Eli Lilly, its predecessors, current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, 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 Program Fraud Civil

Remedies Act, 31 U.S.C. §§ 3801-12; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, Section 0.45(D) (1999) or the common law theories of payment by mistake, unjust enrichment, fraud, disgorgement of illegal profits, and, if applicable, breach of contract.

Subject to the exceptions in Paragraph 7 below (concerning excluded claims), in consideration of the obligations of Eli Lilly in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Eli Lilly, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from any claim the United States has or may have for the Covered Conduct under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a.

3. In consideration of the obligations of Eli Lilly in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, Relators Faltaous, Woodward, Vicente, Rudolph, Rosado, Daywitt, Bradley Lutz, Wetta, and Lofing, for themselves and for their heirs, successors, transferees, attorneys, agents, and assigns, agree to dismiss with prejudice any currently pending claims against Eli Lilly and release Eli Lilly, its predecessors and current and

former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, employees, agents, servants, representatives, attorneys, consultants, successors, heirs, executors, administrators, and assigns, individually and collectively, from all liability, claims, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation or that they otherwise would have standing to bring, except that they expressly reserve any claims arising under the *qui tam* provisions of the False Claims Act of any State with which Eli Lilly does not execute a Medicaid State Settlement Agreement pursuant to the terms of this Agreement.

4. In consideration of the obligations of Eli Lilly set forth in this Agreement and the Corporate Integrity Agreement (“CIA”) entered into between OIG-HHS and Eli Lilly, conditioned on Eli Lilly’s payment in full of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Eli Lilly and Lilly USA, LLC 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 or other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Section.



In consideration of the obligations of Eli Lilly set forth in this Agreement and the CIA entered into between OIG-HHS and Eli Lilly, conditioned on Eli Lilly's payment in full of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), 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 Eli Lilly under 42 U.S.C. § 1320a-7(b)(1) (permissive exclusion for conviction relating to fraud) based on the Federal Criminal Action referenced in Paragraph F, except as reserved in paragraph 7 (concerning excluded claims) below, and as reserved in this Section.

The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Eli Lilly from the Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct or the Federal Criminal Action. Nothing in this Section precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

5. In consideration of the obligations of Eli Lilly set forth in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from

instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Eli Lilly, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims) below, and as reserved in this Paragraph. TMA expressly reserves its authority to exclude Eli Lilly under 32 C.F.R. § 199.9(f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of Eli Lilly set forth in this Agreement and conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action against Eli Lilly, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, under 5 U.S.C. § 8902a(b) or 5 C.F.R. Part 919 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims) below, and except if required by 5 U.S.C. § 8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or

persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. 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 Eli Lilly and Relators) are the following claims of the United States:

(a) Any criminal, civil, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any criminal liability except as set forth in the Plea Agreement resolving the Federal Criminal Action;

(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 and services, including quality of goods and services;

(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and

(h) Any liability for failure to deliver items or services due.

8. Relators, their 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). Conditioned upon Relator Rudolph's receipt of the Relators' Share, Relators, for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge the United States, its officers, agents, and employees from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of the Civil Actions identified in Paragraphs II (B) through II (E); from any other claims for a share of the Settlement Amount; and in full settlement of any claims Relators 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 Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. Eli Lilly waives and shall not assert any defenses it may have to criminal prosecution or administrative action relating to the Covered Conduct based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution, or the Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. 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.

10. Eli Lilly fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Eli Lilly has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants,

and agents, related to or arising from the Covered Conduct and the United States' investigation and prosecution of the Covered Conduct and the Civil Actions identified in Paragraphs II (B) through (E).

11. Neither the Federal Settlement Amount nor the Medicaid State Settlement Amount shall be decreased as a result of the denial of claims for payment now being withheld from payment by any State or Federal payer, related to the Covered Conduct; and Eli Lilly shall not resubmit to any State or Federal payer any previously denied claims, which denials were based on the Covered Conduct, and shall not appeal or cause the appeal of any such denials of claims.

12. Eli Lilly agrees to the following:

(a) Unallowable Costs Defined. All costs (as defined in the Federal Acquisition Regulation ("FAR"), 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Eli Lilly, its predecessors, parents, divisions, subsidiaries, or affiliates, and its present or former officers, directors, employees, and agents in connection with the following shall be "unallowable costs" on Government contracts: (1) the matters covered by this Agreement; (2) the United States' audit and civil and criminal investigation relating to matters covered by this Agreement; (3) Eli Lilly's investigation, defense, and any corrective actions undertaken in response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement and the Medicaid State Settlement Agreements and any agreement(s) with Relators concerning

fees and costs; (5) the payments made to the United States or any State pursuant to this Agreement or the Medicaid State Settlement Agreements and any payments that Eli Lilly may make to any qui tam plaintiffs; and (6) the negotiation of and obligations undertaken pursuant to the CIA to: (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to OIG-HHS. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to Eli Lilly. (All costs described or set forth in this Paragraph are hereafter, “Unallowable Costs”).

(b) Future Treatment of Unallowable Costs. If applicable, these Unallowable Costs shall be separately estimated and accounted for by Eli Lilly and Eli Lilly 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 Eli Lilly, its predecessors, parents, divisions, subsidiaries, or affiliates to any government program.

(c) Treatment of Unallowable Costs Previously Submitted for Payment. If applicable, Eli Lilly 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, DVA, BOP, 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 Eli Lilly, its predecessors, parents, divisions, 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. Eli Lilly agrees that the United States, at a minimum, shall be entitled to recoup from Eli Lilly 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. 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 of the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Eli Lilly, its predecessors, parents, divisions, subsidiaries or affiliates on the effect of inclusion of Unallowable Costs on Eli Lilly's or its predecessors', parents', divisions', 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 examine or re-examine Eli Lilly's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

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 (Waiver for Beneficiaries paragraph), below.

14. Eli Lilly shall not seek payment for any of the claims for reimbursement covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

15. Eli Lilly warrants that it has reviewed its financial situation and that it is currently 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 of the Federal Settlement Amount and compliance with subparagraphs III.1.b(i), (ii), and (iv) of this Agreement. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Eli Lilly, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded 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 that Eli Lilly 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. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, Eli Lilly commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Eli Lilly's debts, or seeking to adjudicate Eli Lilly as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Eli Lilly or for all or any substantial part of Eli Lilly's assets, Eli Lilly agrees as follows, to the extent consistent with applicable law:

(a) Eli Lilly's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Eli Lilly shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Eli Lilly's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Eli Lilly was insolvent at the time this Agreement was entered into, or



became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Eli Lilly.

(b) In the event that Eli Lilly's obligations hereunder are avoided for any reason, including, but not limited to, the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Eli Lilly for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, Eli Lilly agrees that, for purposes only of any case, action, or proceeding referenced in the first clause of this Paragraph, (i) any such claims, actions or proceedings brought by the United States (including any proceedings to exclude Eli Lilly from participation in Medicare, Medicaid, or other federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. Section 362(a) as a result of the action, case or proceeding described in the first clause of this Paragraph, and that Eli Lilly will not argue or otherwise contend that the United States' claims, actions or proceedings are subject to an automatic stay; (ii) that Eli Lilly will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings which are brought by the United States within 30 calendar days of written notification to Eli Lilly that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before February 21, 2003; and (iii) the United States and the Medicaid Participating States have valid claims against Eli Lilly in the aggregate amount of at least \$800,000,000 plus applicable multipliers and

penalties, and they may pursue their claims, inter alia, in the case, action or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

(c) Eli Lilly acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

17. The United States shall file a Notice of Partial Intervention as to all Federal Counts in the Civil Actions that pertain to the Covered Conduct, along with an executed copy of this Agreement. Within five business days after payment of the Federal Settlement Amount and Eli Lilly's compliance with sub-paragraph III.1.b(i) of this Agreement, the United States and the Relators shall file Stipulations of Dismissal With Prejudice as to all Federal Counts in the Civil Actions that pertain to the Covered Conduct pursuant to the terms of this Agreement.

18. 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.

19. Eli Lilly represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

20. Relators 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 shall be the United States District Court for the Eastern District of

Pennsylvania, except that disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

22. For purposes of construction, this Agreement shall be deemed to have been drafted by all parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

24. The individuals signing this Agreement on behalf of Eli Lilly represent and warrant that they are authorized by Eli Lilly to execute this Agreement. The individual(s) signing this Agreement on behalf of Relators represent and warrant that they are authorized by that 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.

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

26. This Agreement is binding on Eli Lilly's successors, transferees, heirs, and assigns.

27. This Agreement is binding on Relators' successors, transferees, heirs, attorneys, agents, and assigns.

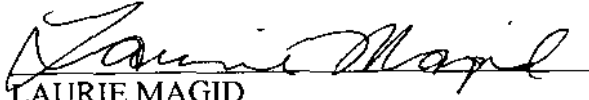
28. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "Effective Date"). Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

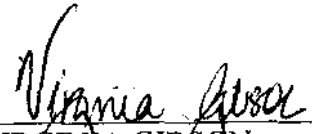
30. Notwithstanding any other provision of this Agreement, if the guilty plea referenced in Paragraph II.F is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Eli Lilly. If either the United States or Eli Lilly exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within 5 business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If the Agreement is rescinded, Eli Lilly waives any affirmative defenses based in whole or in part on the running of the statute of limitations during the period from the Effective Date of this Agreement through 30 days after the effective date of the rescission.

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UNITED STATES OF AMERICA

By:   
LAURIE MAGID  
Acting United States Attorney  
United States Attorney's Office  
Eastern District of Pennsylvania


Dated: 1/14/09

By:   
VIRGINIA GIBSON  
Chief, Civil Division  
United States Attorney's Office  
Eastern District of Pennsylvania

Dated: 1/14/09

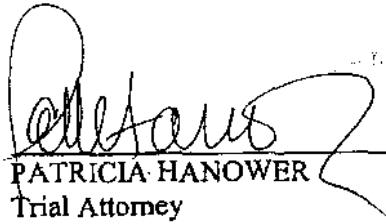
By:   
MARGARET L. HUTCHINSON  
Deputy Chief, Civil Division  
United States Attorney's Office  
Eastern District of Pennsylvania

Dated: 1/14/09

By:   
JOSEPH TRAUTWEIN  
Assistant U.S. Attorney  
United States Attorney's Office  
Eastern District of Pennsylvania


Dated: 1/14/09

By:

  
\_\_\_\_\_  
PATRICIA HANOWER  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

Dated: *January 14, 2009*

By: \_\_\_\_\_


  
**GREGORY E. DEMSKE**  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

Dated:

1/14/09



By:



LAUREL C. GILLESPE

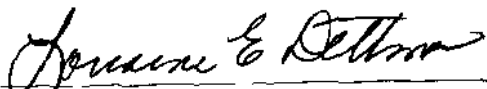
Deputy General Counsel

TRICARE Management Activity


United States Department of Defense

Dated: 12 Jun 2009

Eli Lilly Settlement Agreement

By:   
LORRAINE E. DETTMAN  
Assistant Director  
for Insurance Services Programs  
United States Office of Personnel Management


Dated: 1/12/09

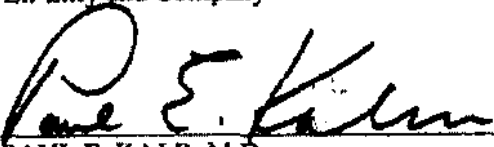
By:   
J. DAVID COPE  
Assistant Inspector General for Legal Affairs  
United States Office of Personnel Management

Dated: 1/13/2009

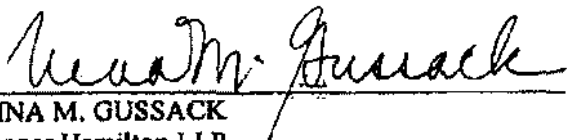
On behalf of the Federal Employees Health Benefits Program

ELI LILLY AND COMPANY

By:  Dated: 1/14/09  
ROBERT A. ARMITAGE  
Senior Vice President and General Counsel  
Eli Lilly and Company

By:  Dated: 1/14/09  
PAUL E. KALB, M.D.  
Sidley Austin LLP  
Counsel for Eli Lilly and Company

By:  Dated: 1/17/09  
BRADFORD A. BERENSON  
Sidley Austin LLP  
Counsel for Eli Lilly and Company

By:  Dated: 1/14/09  
NINA M. GUSSACK  
Pepper Hamilton LLP  
Counsel for Eli Lilly and Company

By:  Dated: 1/14/09  
THOMAS M. GALLAGHER  
Pepper Hamilton LLP  
Counsel for Eli Lilly and Company

RELATORS

By: Robert Rudolph / MUM Dated: 1/14/09  
ROBERT RUDOLPH

By: Hector Rosado / MUM Dated: 1/14/09  
HECTOR ROSADO

By: Robert Evan Daywitt / MUM Dated: 1/14/09  
ROBERT EVAN DAYWITT

By: Bradley Lutz / MUM Dated: 1/14/09  
BRADLEY LUTZ

By: James Wetta / MUM Dated: 1/14/09  
JAMES WETTA

By: William Lofing / MUM Dated: 1/14/09  
WILLIAM LOFING

By: Michael M. Mustokoff  
MICHAEL M. MUSTOKOFF  
Duane Morris, LLP

Dated: 1/14/09

By: Stephen A. Sheller /mmw  
STEPHEN A. SHELDER

Dated: 1/14/09

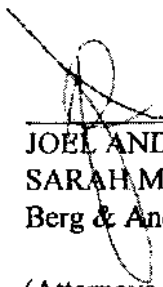
By: Gary M. Farmer /mmw  
GARY M. FARMER, JR.  
Rothstein Rosenfeldt Adler

Dated: 1/14/09

(Attorneys for Robert Rudolph, Hector Rosado, Robert Evan Daywitt, Bradley Lutz,  
James Wetta and William Lofing)

By:   
JOSEPH FALTAOUS

Dated: 1-14-09

By:   
JOEL ANDROPHY  
SARAH M. FRAZIER  
Berg & Androphy

Dated: 1-14-09

(Attorneys for Joseph Faltaous)

By: Steven Woodward Dated: 1/13/2009  
STEVEN WOODWARD

By: Brian P. Kenney Dated: 1/14/09  
BRIAN P. KENNEY  
Kenney Egan McCafferty & Young

(Attorneys for Steven Woodward)

By: Jaydeen Vicente Dated: 01/13/09  
JAYDEEN VICENTE

By: Brian P. Kenney Dated: 1/14/09  
BRIAN P. KENNEY  
Kenney Egan McCafferty & Young

By: Mark Burton Dated: 1/14/09  
MARK BURTON  
Hersh & Hersh

(Attorneys for Jaydeen Vicente)