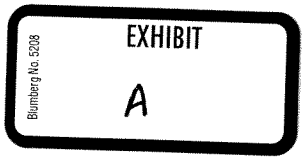
EXHIBIT A



42 U.S.C.A. § 1396r-8

United States Code Annotated Currentness
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XIX. Grants to States for Medical Assistance Programs (Refs & Annos)
§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title or under part B of subchapter XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date

Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d) of this section, or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on

November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities

(A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

(B) Covered entity defined

In this subsection, the term "covered entity" means an entity described in section 256b(a)(4) of this title and a children's hospital described in section 1395ww(d)(1)(B)(iii) of this title which meets the requirements of clauses (i) and (iii) of section 340B(b)(4)(L) of the Public Health Service Act [FN1] and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this subchapter.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

(ii) State agency

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) of this section with respect to such a drug.

(D) Effect of subsequent amendments

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(E) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies

(A) In general

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of Title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of Title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(C) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of Title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(7) Requirement for submission of utilization data for certain physician administered drugs

(A) Single source drugs

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a single source drug that is physician administered under this subchapter (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this subchapter.

(B) Multiple source drugs

(i) Identification of most frequently physician administered multiple source drugs

Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this subchapter. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) Requirement

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) Use of NDC codes

Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and

(B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) Hardship waiver

The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(C) Special rule for increased minimum rebate percentage

(i) In general

In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1396b(a) of this title in the manner specified in clause (ii), in an amount equal to the product of--

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) Manner of payment reduction

The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this subchapter to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1396b(d)(2) of this title. Such a disallowance is not subject to a reconsideration under section 1316(d) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary--

(i) not later than 30 days after the last day of each rebate period under the agreement--

(I) on the average manufacturer price (as defined in subsection (k)(1) of this section) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(c)]); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C) of this section) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990 [FN2] for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)--

(I) the manufacturer's average sales price (as defined in section 1395w-3a(c) of this title) and the total number of units specified under section 1395w-3a(b)(2)(A) of this title;

(II) if required to make payment under section 1395w-3a of this title, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1395w-3a(c)(2)(B) of this title;

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1395u(o)(1) of this title or section 1395rr(b)(13)(A)(ii) of this title, and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).

(B) Verification surveys of average manufacturer price and manufacturer's average sales price

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a-7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(C) Penalties

(i) Failure to provide timely information

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section (other than the wholesale acquisition cost for purposes of carrying out section 1395w-3a of this title) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except--

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1395w-3a of this title (including the determination and implementation of the payment amount), or to carry out section 1395w-3b of this title,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this subchapter, and

(v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.

The previous sentence shall also apply to information disclosed under section 1395w-102(d)(2) or 1395w-104(c)(2)(E) of this title and drug pricing data reported under the first sentence of section 1395w-141(i)(1) of this title.

(4) Length of agreement

(A) In general

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer

A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this title and master agreements described in section 8126(a) of Title 38.

(C) Delay before reentry

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of--

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of--

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning--

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010 [FN2] is 15.1 percent; and

(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.

(ii) Temporary limitation on maximum rebate amount

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning--

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) Minimum rebate percentage for certain drugs

(I) In general

In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) Drug described

For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1395u(o)(5) of this title and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) Best price defined

For purposes of this section--

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding--

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w-141 of this title; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII, by an MA-PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1395w-132(a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A of subchapter XVIII or enrolled under part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section

1395w-114a of this title.

(ii) Special rules

The term "best price"--

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) Application of auditing and recordkeeping requirements

With respect to a covered entity described in section 256b(a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 256b(a)(5)(C) of this title.

(D) Limitation on sales at a nominal price

(i) In general

For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III) of this section, only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 256b(a)(4) of this title.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that--

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act [FN3] or is State-owned or operated; and

(bb) would be a covered entity described in section 340(B)(a)(4) of the Public Health Service Act [FN4] insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 300(a) of this title.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors

described in clause (ii).

(ii) Factors

The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) Nonapplication

Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of Title 38.

(iv) Rule of construction

Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 300a-6 of this title.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of--

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which--

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(C) Treatment of new formulations

In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of--

(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term "line extension" means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.

(D) Maximum rebate amount

In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.

(3) Rebate for other drugs

(A) In general

The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of--

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) Applicable percentage defined

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning--

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent; and

(iii) after December 31, 2009, is 13 percent.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of this title, agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval--

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(e) Treatment of pharmacy reimbursement limits

(1) In general

During the period beginning on January 1, 1991, and ending on December 31, 1994--

(A) a State may not reduce the payment limits established by regulation under this subchapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule

If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

(4) Establishment of upper payment limits

Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more (or, effective January 1, 2007, two or more) products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) Use of AMP in upper payment limits

Effective January 1, 2007, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.

(f) Survey of retail prices; State payment and utilization rates; and performance rankings

(1) Survey of retail prices

(A) Use of vendor

The Secretary may contract services for--

(i) the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) Secretary response to notification of availability of multiple source products

If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in

subsection (e)(4) of this section.

(C) Use of competitive bidding

In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in--

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Additional provisions

A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) Availability of information to States

Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1396a(a)(5) of this title with responsibility for the administration or supervision of the administration of the State plan under this subchapter of the retail survey price determined under this paragraph.

(2) Annual State report

Each State shall annually report to the Secretary information on--

(A) the payment rates under the State plan under this subchapter for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) Annual State performance rankings

(A) Comparative analysis

The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with

data on prices under this subchapter for each such drug for each State.

(B) Availability of information

The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) Appropriation

Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(IV) Repealed. Pub.L. 108-173, Title I, § 101(e)(9)(B), Dec. 8, 2003, 117 Stat. 2152.

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for

the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection [FN5] (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * * [FN6] licensed and actively practicing pharmacists.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section [FN5] (2)(B).

(ii) Application of standards as defined in section [FN5] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management

(1) In general

In accordance with chapter 35 of Title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement

In order to carry out paragraph (1)--

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive

procurement for advance [FN7] planning and implementation documents otherwise required.

(i) Omitted

(j) Exemption of organized health care settings

(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are--

(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1396b(m) of this title; and

(B) subject to discounts under section 256b of this title.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c) of this section.

(k) Definitions

In this section--

(1) Average manufacturer price

(A) In general

Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

(B) Exclusion of customary prompt pay discounts extended to wholesalers

The average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers.

(C) Inclusion of section 505(c) drugs

In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(c)], such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means--

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355 or 357] or which is

approved under section 505(j) of such Act [21 U.S.C.A. § 355(j)];

(ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug; and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C.A. § 331, 332(a), or 334 (a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C.A. § 352(f) or 355(a)]; or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which--

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 356].

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological [FN8] used for a

medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in--

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there [FN9] at least 1 other drug product which--

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that was originally

marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception

Subparagraph (A)(1)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(1)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph--

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) Rebate period

The term "rebate period" means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XIX, § 1927, as added Nov. 5, 1990, Pub.L. 101-508, Title IV, § 4401(a)(3), 104 Stat. 1388-143, and amended Nov. 4, 1992, Pub.L. 102-585, Title VI, § 601(a) to (c), 106 Stat. 4962 to 4964; Apr. 12, 1993, Pub.L. 103-18, § 2(a), 107 Stat. 54; Aug. 10, 1993, Pub.L. 103-66, Title XIII, § 13602(a), 107 Stat. 613; Aug. 5, 1997, Pub.L. 105-33 Title IV, §§ 4701(b)(2)(A)(x), 4756, 111 Stat. 493, 527; Nov. 29, 1999, Pub.L. 106-113, Div. B, § 1000(a)(6) [Title VI, §§ 606(a), 608(u)], 113 Stat. 1536, 1501A-396, 1501A-398; Dec. 8, 2003, Pub.L. 108-173, Title I, §§ 101(e)(4), (9), 103(e)(1), 105(b), Title III, § 303(i)(4), Title IX, § 900(e)(1)(K), (L), Title X, § 1002, 117

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

UNITED STATES OF AMERICA, ex rel. Law Project for Psychiatric Rights, Plaintiff, vs. OSAMU H. MATSUTANI, et al., Defendants.	Case No. 3:09-cv-0080-TMB
UNITED STATES OF AMERICA, ex rel. Daniel I Griffin, Plaintiff, vs. RONALD A. MARTINO, MD, FAMILY CENTERED SERVICES OF ALASKA, INC., an Alaska corporation, and SAFEWAY, INC., a Delaware corporation, et al., Defendants.	Case No. 3:09-cv-0246-TMB

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS UNDER RULE 12(b)(1) (DKTS. 89 & 141)

These are two related *qui tam* actions under the False Claims Act ("FCA").[1] In the first action, Relator Law Project for Psychiatric Rights ("PsychRights") alleges that the Defendants - consisting of various medical service providers, pharmacies, state officials, and a pharmaceutical data publisher - caused the submission of false claims for reimbursement for psychiatric drugs prescribed to minors under the federal Medicaid program and Children's Health Insurance Program (the "Matsutani Action").[2] In the second action, Relator Daniel I. Griffin alleges that his former medical and pharmaceutical providers caused the submission of false claims for reimbursement for

[1] 31 U.S.C. § 3729-3732.

[2] *See* Dkt. 107 (hereinafter, "Am. Compl.").

psychiatric drugs prescribed to him when he was a minor under the Medicaid program (the "Martino Action").[3] Both actions were consolidated under Docket 3:09-cv-0080-TMB.[4]

Currently before the Court are: (a) the Matsutani Action Defendants' motion to dismiss under Rules 12(b)(1) and 12(h)(3);[5] (b) the Matsutani Action Defendants' motion to dismiss under Rule 12(b)(6);[6] (c) Defendants William Hogan, Steve McComb, Tammy Sandoval, and William Streur's (the "State Official Defendants") motion to dismiss under Rule 12(b)(6) in the Matsutani Action;[7] (d) the Matsutani Action Defendants' motion to dismiss under Rule 9(b);[8] (e) Defendant Safeway, Inc.'s ("Safeway") motion to dismiss in the Martino Action;[9] (f) Defendant Family Centered Services of Alaska, Inc.'s ("FCSA") motion to dismiss in the Martino Action;[10] and (g) PsychRights' motion for a preliminary injunction in the Matsutani Action.[11] The Parties have also requested oral argument on the various motions before the Court.[12] Because the Court concludes that it lacks subject matter jurisdiction over these actions under the FCA, it GRANTS the Defendants' motions to dismiss under Rule 12(b)(1), (Docket Nos. 89 and 141) DENIES the remaining motions as moot,[13] and DISMISSES both actions with prejudice.

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[3] *See* Dkt. 1 in Case No. 3:09-cv-0246-TMB (hereinafter, "Griffin Compl.").

[4] Dkt. 23 in Case No. 3:09-cv-0246-TMB.

[5] Dkt. 89.

[6] Dkt. 92.

[7] Dkt. 90.

[8] Dkt. 83.

[9] Dkt. 141.

[10] Dkt. 143.

[11] Dkt. 113.

[12] Dkts. 122, 133 & 156.

[13] The Relators recently requested leave to file supplemental materials in opposition to the Defendants' 12(b)(6) motions and the Defendants similarly requested leave to file supplemental authority in further support of their Rule 9(b) motion. *See* Dkts. 160 & 162. Because the Court does

I. BACKGROUND

A. Allegations

The Relators allege that the Defendants are knowingly or recklessly participating in a wide-ranging scheme to defraud the federal government by submitting, or causing the submission of, false claims for Medicaid and Children's Health Insurance Program ("CHIP") reimbursement.[14] The Relators' allegations are based on the Defendants' involvement in Medicaid and CHIP claims submitted for psychotropic drugs prescribed to minors. The Relators allege that pharmaceutical companies have promoted "off-label" use of psychotropic drugs for minors through a variety of means, such as suppressing negative research and paying "Key Opinion Leaders" to support it.[15] The Relators contend that the "off-label" uses of these drugs are not properly reimbursable under Medicaid and CHIP because they do not fall within "medically accepted indications" approved by the Food and Drug Administration ("FDA") or supported in statutorily specified "compendia."[16] In essence, the Relators contend that the Defendants are involved in presenting false reimbursement claims while intentionally or recklessly "ignor[ing] information contradicting [the] drug company false statements."[17]

Although the Relators allege that pharmaceutical companies are ultimately responsible for the conduct at issue, those companies are not defendants in this action.[18] The Defendants here consist of: (a) psychiatrists who prescribe psychotropic drugs to minors; (b) mental health service providers that employ the psychiatrists; (c) pharmacies who fill the prescriptions; (d) the State Official Defendants, who "are responsible for authorizing reimbursement" of the claims; and (e)

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not reach those issues, it also denies these requests as moot.

[14] Am. Compl. ¶¶ 5-7, 183; Griffin Compl. ¶¶ 22-28. Alaska's CHIP program "has adopted Medicaid for its benefits package." Am. Compl. ¶ 165; *see also* Alaska Admin. Code. Tit. 7 §§ 100.300-06, 100.310-16 (2010).

[15] Am. Compl. ¶¶ 5, 67-84.

[16] *See id.* ¶¶ 5-6, 156-68; Griffin Compl. ¶¶ 15, 22-26.

[17] Am. Compl. ¶ 179; *see also* Griffin Compl. ¶¶ 22, 24-25.

[18] *See* Am. Compl. ¶¶ 46-84.

Thomson Reuters (Healthcare), Inc., a pharmaceutical data publisher that the Relators allege made false statements while promoting the use of psychotropic drugs for minors.[19] The Matsutani Action focuses on the activities of a wide variety of individuals and entities in the Alaska mental healthcare community allegedly involved in the psychiatric treatment of minors,[20] while the Martino Action focuses on several specific parties allegedly involved in obtaining reimbursement for drugs prescribed to Griffin.[21]

B. Prior Disclosures

The Defendants identify several prior disclosures of allegations that they claim are substantially the same as the Relators allegations here and accordingly, bar the Relators' claims under the FCA. These include disclosures in: (1) correspondence between the State of Utah and the Department of Health and Human Services' Centers for Medicare and Medicaid Services ("Utah/CMS Correspondence"); (2) PsychRights previously-filed case against the State of Alaska, *Law Project for Psychiatric Rights, Inc. v. Alaska*, No. 3AN 08-10115CI (the "State Case"); (3) other publicly-filed cases; and (4) media reports and other publicly distributed information.

1. Utah/CMS Correspondence

The Defendants contend that the Utah/CMS Correspondence is "about precisely the same issue raised by" the Relators.[22] The first letter, from Utah to the Centers for Medicare and Medicaid Services ("CMS"), indicates that Utah was concerned that "many state Medicaid programs are liberally reimbursing - and presumably receiving Federal Financial Participation . . . - for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia."[23] CMS replied that the relevant law "does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue

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[19] *Id.* ¶¶ 7, 10-41; *see also* Griffin Compl. ¶¶ 7-9.

[20] Am. Compl. ¶¶ 10-41.

[21] Griffin Compl. ¶¶ 7-9.

[22] Dkt. 91 at 6, 13-14; Dkt. 91-4.

[23] Dkt. 91-4 at 1.

in implementing federal regulations." Accordingly, CMS explained, the law "authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication . . . however, it does not explicitly require them to do so."[24]

Utah responded on December 17, 2007, claiming that the "unambiguous statutory" language precludes states from providing coverage for off-label uses that are not medically accepted.[25] Utah's representative elaborated as follows, specifically invoking reimbursement for off-label uses of psychotropic drugs prescribed to minors:

> A "poster child" example of exactly why this issue is important not only for cost considerations, but also for patient safety, is the atypical antipsychotic drug Zyprexa manufactured by Eli Lilly. For about 10 years it has been at or near the highest dollar volume drug reimbursed by Medicaid nationwide. It is only approved for schizophrenia and bipolar disorder in adults, a very narrow segment of the population. It has been widely reported that approximately 50% of utilization is off-label, including for infants and toddlers. Based on recent lawsuit settlements totaling over a billion dollars and involving thousands of Zyprexa users, the drug causes substantial weight gain and diabetes in a significant percentage of cases. In other words, Medicaid is not only paying for a very expensive drug for uses that are not "medically accepted indications," but its reimbursement of this drug is resulting in many Medicaid recipients developing diabetes, a life-threatening condition with many adverse health complications for the individuals and a significant cost burden on taxpayers for treating these complications.[26]

In response, CMS "confirm[ed] that [its] previous response . . . [was] correct."[27]

2. PsychRights' State Case

The Defendants also contend that PsychRights' filings in the State Case disclosed the same allegations that the Relators assert in these cases.[28] In the State Case, PsychRights is seeking declaratory and injunctive relief against Alaska and various state officials to prohibit them from

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[24] *Id.* at 6. The Defendants suggest that this is consistent with the position that CMS has taken elsewhere. *See* Dkt. 91 at 4 n.6 (citing Dkt. 91-5).

[25] Dkt. 91-4 at 3.

[26] *Id.* at 4.

[27] *Id.* at 5.

[28] Dkt. 91 at 6-7, 14; *see also* Dkt. 91-7.

participating in the administration of psychotropic drugs to minors absent certain precautions.[29] The State Official Defendants here are also defendants in the State Case.[30] The Defendants note that on November 24, 2008, PsychRights moved to amend its complaint in the State Case to include a new paragraph alleging:

> 22. It is unlawful for the State to use Medicaid to pay for outpatient drug prescriptions except when medically necessary and for indications approved by the Food and Drug Administration (FDA) or included in the following compendia:
> (a) American Hospital Formulary Service Drug Information,
> (b) United States Pharmacopeia-Drug Information (or its successor publications), or
> (c) DRUGDEX Information System.[31]

Additionally, on April 3, 2009, just before commencing the Matsutani Action, PsychRights moved amend its State Case complaint to include the following additional paragraph:

> 236. The State approves and applies for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:
> (a) are not medically necessary, or
> (b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (I) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or
> (c) both.[32]

The Defendants also note that PsychRights' complaint in the State Case describes what they contend are other prior public disclosures, including PsychRights' prior efforts to persuade Alaska to adopt its proposed reforms and a program favored by PsychRights which it contends will help "to give guidance to people making decisions regarding authorizing the administration of psychotropic drugs to children and youth."[33]

3. Other Court Cases

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[29] Dkt. 91-7 at 6.

[30] *Id.* at 8-9.

[31] Dkt. 91-8 at 1.

[32] *Id.* at 2; *see also* Dkt. 91-7 at 53-56.

[33] Dkt. 91 at 7-8 (citing Dkt. 91-7 at 11-17).

The Defendants further argue that prior "cases have also included allegations that allegedly false claims for off-label, non-compendium drug prescriptions have been paid by Medicaid."[34] The Defendants cite one FCA case, *United States ex rel. Franklin v. Parke-Davis*,[35] which involved allegations that Medicaid claims for the drug Neurontin were fraudulent because they were ineligible for reimbursement. The Defendants note that Neurontin is one of the drugs that PsychRights mentions in its pleading.[36] Responding to the Defendants' argument, PsychRights additionally refers to *United States ex rel. Rost v. Pfizer*,[37] which involved alleged false claims submitted to Medicaid for off-label non-compendium uses for the drug Genotropin.[38]

4. Media Reports

The Defendants also refer to numerous media articles and other publicly available documents dating from 1999 through 2008.[39] These articles generally discuss the use of psychotropic drugs for minors, noting that some are Medicaid patients.[40] Some, however, more specifically state that Medicaid pays for psychotropic drugs prescribed to minors that are being used for off-label purposes.[41] One document - a white paper prepared by a group not unlike PsychRights - specifically discussing prescriptions of psychotropic drugs to minors, states that "most off-label prescriptions for children may not be covered under Medicaid and such reimbursements constitute Medicaid fraud."[42] Some of the articles also discuss government investigations, including an

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[34] *Id.* at 8.

[35] No. 96-11651-PBS, 2003 U.S. Dist. LEXIS, at *1-2 (D. Mass. Aug. 22, 2003).

[36] Dkt. 91 at 8; *see also* Am. Compl. ¶ 167(q).

[37] Dkt. 111 at 2-3 (citing 253 F.R.D. 11 (D. Mass. 2008)).

[38] *Rost*, 253 F.R.D. at 12-15.

[39] Dkt. 91 at 9-10.

[40] *See id.*

[41] *See id.* at 10.

[42] *See id.* (quoting Dkt. 91-12 at 11).

investigation by the former Texas Comptroller suggesting that reimbursement claims for psychotropic drugs prescribed to minors constitute Medicaid fraud.[43]

C. Procedural History

PsychRights commenced the Matsutani Action under seal on April 27, 2009.[44] Griffin commenced the Martino Action under seal on December 14, 2009.[45] PsychRights moved to unseal the Matsutani Action on June 28, 2009, submitting the Utah/CMS Correspondence in support of its motion.[46] After the Government declined to intervene,[47] the Court unsealed each action.[48]

The Matsutani Action Defendants moved to dismiss under Rule 12(b)(1) and 12(h)(3) on April 5, 2010.[49] They also moved to dismiss under Rules 12(b)(6) and 9(b).[50] PsychRights filed an Amended Complaint in response to Defendants' motions to dismiss on May 6, 2010,[51] and filed its opposition papers on May 10, 2010.[52] PsychRights' Amended Complaint substantially repeats the

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[43] Dkts. 91-15, 91-16 (indicating that the Texas Health and Human Services Commissions had stated that it was "reviewing the use of Medicaid drug claims and psychotropic drug use in children"), 91-7, & 91-8.

[44] Dkts. 1-2.

[45] *See* Griffin Compl.

[46] Dkt. 3.

[47] Dkt. 14; Dkt. 9 in Case No. 3:09-cv-0246-TMB; *see also* 31 U.S.C. § 3730(b).

[48] Dkt. 16; Dkt. 10 in Case No. 3:09-cv-0246-TMB.

[49] Dkt. 89.

[50] Dkts. 83, 90, & 92.

[51] Am. Compl.

[52] Dkt. 111.

allegations in its original Complaint, but contains additional allegations regarding specific drugs and transactions.[53] The Defendants filed a reply on May 25, 2010.[54]

In the Martino Action, Safeway moved to dismiss under Rules 12(b)(1), 9(b), and 12(b)(6) on July 27, 2010.[55] Safeway explicitly adopted the arguments in the Matsutani Action Defendants' 12(b)(1) motion papers.[56] The other Martino Action Defendants later joined in Safeway's motion.[57] Griffin filed an opposition on August 16, 2010,[58] adopting PsychRights' opposition to the Matsutani Action Defendants' 12(b)(1) motion.[59] Safeway filed a reply on August 30, 2010,[60] in which Defendant Martino joined.[61]

On September 21, 2010, the Defendants submitted supplemental authority to the Court,[62] and requested leave to present materials that had previously been maintained under seal in further support of their 12(b)(1) motion.[63]

II. LEGAL STANDARD

Where the defendants bring a "factual" motion to dismiss for lack of subject matter jurisdiction based on extrinsic evidence, the court may look "beyond the complaint without having

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[53] *See* Am. Compl. ¶¶ 183-84, 187-88, 190-95, 201-04, 206-11; *cf.* Dkt. 1.

[54] Dkt. 119.

[55] Dkt. 142.

[56] *Id.* at 5.

[57] Dkts. 146 & 149. FCSA also explicitly joined in the Matsutani Action Defendants' motion to dismiss under Rule 12(b)(1). Dkt. 145.

[58] Dkt. 151.

[59] *Id.* at 13.

[60] Dkt. 154.

[61] Dkt. 157.

[62] Dkt. 159.

[63] Dkt. 161.

to convert the motion to dismiss into a motion for summary judgment."[64] The court "may resolve factual disputes based on the evidence presented where the jurisdiction issue is separable from the merits of the case,"[65] as it is here. The proponents of subject-matter jurisdiction bear the burden of establishing its existence by a preponderance of the evidence.[66]

III. DISCUSSION

The FCA provides that a private person may bring an action on behalf of the United States by filing a complaint under seal.[67] The purpose of the FCA is to return fraudulently divested funds to the federal treasury.[68] Congress revised the FCA in 1986 in order to encourage insiders with knowledge of fraudulent activity to "blow the whistle."[69] The statute accordingly provides a relator with a right to share in the recovery as an incentive to bring FCA claims.[70] The primary purpose of the revisions was thus to "alert the government as early as possible to fraud that is being committed against it and to encourage insiders to come forward with such information where they would otherwise have little incentive to do so."[71]

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[64] *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (citation omitted); *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1200 n.2 (9th Cir. 2009) (citing *Safe Air*). Courts may consider public records as extrinsic evidence. *See Gemtel Corp. v. Community Redev. Agency of L.A.*, 23 F.3d 1542, 1544 n.1 (9th Cir. 1994).

[65] *United States ex rel. Alfatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 521 (9th Cir. 1999) (citation omitted).

[66] *United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1018 (9th Cir. 1999).

[67] 31 U.S.C. § 3730(b)(2).

[68] *See United States ex rel. Green v. Northrop Corp.*, 59 F.3d 953, 968 (9th Cir. 1995).

[69] *See id.* at 963. *Accord United States ex rel. Zaretsky v. Johnson Controls, Inc.*, 457 F.3d 1009, 1017 (9th Cir. 2006) (stating that Congress sought to "encourage private individuals who are aware of fraud being perpetrated against the Government to bring such information forward" (citation omitted)).

[70] *See Green*, 59 F.3d at 963-64 (citing 31 U.S.C.A. § 3730(d) (West Supp. 1994)).

[71] *United States ex rel. Biddle v. Board of Trustees of the Leland Stanford, Jr., Univ.*, 161 F.3d 533, 538-39 (9th Cir. 1997).

Congress, however, also "sought to discourage 'parasitic' suits brought by individuals with no information of their own to contribute to the suit."[72] A relator who merely "echoes" previously disclosed fraud is not assisting the Government in its effort to expose fraud, but is rather opportunistically seeking to share in the Government's recovery of funds from the defrauding party at the Government's expense.[73] Accordingly, the FCA bars relators from asserting claims where the information has been previously "public[ly] disclosed" unless the relator is the "original source" of the information (the "Public Disclosure Bar").[74]

The Public Disclosure Bar involves a two-part inquiry.[75] A court must first determine whether "there has been a prior public disclosure of the allegations or transactions underlying the *qui tam* suit."[76] If there has been a prior public disclosure, the court must then determine "whether the relator is an original source within the meaning of" the statute.[77] Before engaging in either of those inquiries, however, this Court must first determine whether the recently amended version or prior version of the FCA Public Disclosure Bar controls the analysis here. As explained below, the Court concludes that the prior version of the statute controls, that the allegations at issue here have

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[72] *Zaretsky*, 457 F.3d at 1017 (citation omitted). Relator argues for a narrow reading of the FCA's Public Disclosure Bar, quoting a passage from the First Circuit's decision in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 27-28 (1st Cir. 2009), where that court "question[ed] th[e] conclusion" that FCA suits brought after a public disclosure are "parasitic." Dkt. 111 at 13-14. In a more recent decision, however, that court has reaffirmed the principle that the Public Disclosure Bar "is designed to preclude parasitic *qui tam* actions." *See United States ex rel. Poteet v. Bahler Med., Inc.*, __ F.3d __, No. 09-1728, 2010 WL 3491159, at *6 (1st Cir. Sept. 8, 2010). In any event, while there may well be policy reasons for expanding the reach of the FCA, this Court is compelled to evaluate the Relators' claims in light of the statutory text and controlling authority in this Circuit.

[73] *See United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999); *Seal 1 v. Seal A*, 255 F.3d 1154, 1158, 1161 (9th Cir. 2001).

[74] *See* 31 U.S.C. § 3130(e)(4) (2006).

[75] *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009).

[76] *Id.* (citation omitted).

[77] *Id.* (citation omitted).

been "publicly disclosed" within the meaning of the prior version of the FCA, and that the Relators are not an "original source" of the disclosures.

A. Controlling Text

Congress amended the language of FCA's Public Disclosure Bar on March 23, 2010.[78] The primary difference between the old version and the amended statute, for the purposes of this case, is that the new language narrows the categories of "public disclosure[s]."[79] The Supreme Court has found that the recent amendments to the FCA do not apply retroactively to pending actions.[80]

The Relators argue that the new version of the statute "probably" applies to the Matsutani Action because PsychRights filed its Amended Complaint on May 6, 2010 - i.e., after the FCA amendment.[81] Therefore, they argue that the Matsutani Action - as it is currently constituted - was not "pending" on the date of the FCA amendment and the Supreme Court's recent ruling does not apply to it.[82] In support of their argument, the Relators rely on *Rockwell Int'l Corp. v. United States*, for the proposition that "courts look to the amended complaint to determine jurisdiction."[83] In *Rockwell*, the Supreme Court held that courts should examine the allegations in an amended complaint when determining whether the Public Disclosure Bar applies.[84]

The Relators misconstrue this authority. Although it is true that a court should look to an amended pleading when examining the allegations forming the alleged basis for jurisdiction, that

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[78] Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 § 10104(j)(2) (2010).

[79] *Compare id. with* 31 U.S.C. § 3130(e)(4) (2006). The new version of the statute also omits the prior text's reference to "jurisdiction" suggesting that a prior public disclosure is no longer a jurisdictional defect, although the statute still compels courts to "dismiss" cases involving prior public disclosures. *See* Pub. L. 111-148, 124 Stat. 119 § 10104(j)(2) (2010).

[80] *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010).

[81] Dkt. 111 at 6-8.

[82] *Id.*

[83] *Id.* at 6 (citing 549 U.S. 457, 474 (2007)).

[84] 549 U.S. at 473-74.

does not mean that a party may erase the entire procedural history of a case for all purposes by amending its pleading.[85] Indeed, Rule 15(c) provides that "[a]n amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out - or attempted to be set out - in the original pleading."[86] PsychRights' Amended Complaint includes some additional detail about the drugs and transactions at issue but asserts essentially the same claims against the same parties based on the same conduct as its original Complaint. These relatively minor amendments do not change the fact that the Matsutani Action was "pending" when Congress revised the FCA. *Rockwell* and the rest of the authority cited by the Relators are not to the contrary.[87] The Relators essentially concede this point later in their opposition brief when they argue that information disclosed on PsychRights' website *after* it filed the Matsutani Action Complaint but *before* it filed the Amended Complaint "cannot trigger the public disclosure bar because . . . it *post dates the filing of this action*[.]"[88] Thus, both actions were "pending" on the date of the FCA amendment and the Supreme Court's recent ruling controls this Court's analysis. Under that precedent, the pre-amendment version of the Public Disclosure Bar applies to these consolidated actions.

B. Public Disclosures

Prior to the recent amendment, the FCA's Public Disclosure Bar provided:

> No court shall have jurisdiction over an action brought under this section based upon the public disclosure of allegations or transactions [1] in a criminal, civil, or administrative hearing, [2] in a congressional, administrative, or Government Accounting Office [GAO] report, hearing, audit, or investigation, or [3] from the news

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[85] *Stubbs v. de Simone*, No. 04Civ. 5755(RJH)(GWG), 2005 WL 2429913, at *3 (S.D.N.Y. 2005) ("Plaintiff's amended complaint may supplant the original complaint, but it does not delete the procedural history of the case").

[86] Fed. R. Civ. P. 15(c).

[87] *Cf. Desai v. Deutsche Bank Secs. Ltd.*, 573 F.3d 931, 936 (9th Cir. 2009) (discussing a district court's failure to consider a recently amended pleading when denying a motion for class certification); *Ferdik v. Bonzelet*, 963 F.2d 1258, 1262 (9th Cir. 1992) (finding that the names of defendants included in earlier complaints could not be used to "fill[] in" the names of defendants included in a later pleading omitting the names in favor of the phrase "et al.").

[88] Dkt. 111 at 17 n.32.

> media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.[89]

The public disclosure inquiry involves two "distinct but related determinations."[90] First, whether the disclosure "originated in one of the sources enumerated in the statute."[91] Second, whether the present action is "based upon" the prior disclosure.[92]

Here, the Defendants invoke disclosures made in: (1) the Utah/CMS Correspondence; (2) the State Case; (3) prior cases involving Medicaid fraud allegations based on off-label prescriptions; and (4) various media reports.[93] Section 3730(e)(4)(A)'s first category undoubtedly includes a state proceeding, such as the State Case[94] or the other cases cited by the Defendants involving Medicaid fraud allegations.[95] Similarly, the second category encompasses the Utah/CMS Correspondence.[96]

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[89] *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1401-02 (2010) (quoting § 3730(e)(4)).

[90] *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009).

[91] *Id.* (citation omitted).

[92] *See id.* (citations omitted).

[93] The Relators do not suggest that any of this information is not "public" for the purposes of the FCA. *Cf. Seal 1 v. Seal A*, 225 F.3d 1154, 1162 (9th Cir. 2001) (indicating that allegations or transactions are "public[ly] disclosed" where they are provided "to one member of the public, when that persons seeks to take advantage of that information by filing an FCA action").

[94] *See Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1404-05 (2010).

[95] *See United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1020 (9th Cir. 1999). Disclosures filed in the context of litigation may be encompassed by the statute even if they are not the subject of a hearing. *Id.* Additionally, the fact that the court has not ruled on the issue does not matter. *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1474 (9th Cir. 1996) ("An issue need not be decided in prior litigation for the public disclosure bar to be triggered; rather, its mere disclosure suffices.").

[96] The Relators argue, without any analysis, that the Utah/CMS Correspondence does not constitute an "investigation" under either version of the statute. Dkt. 111 at 11. Under the FCA, however, the term "investigation" is extremely broad, encompassing "any kind of government investigation - civil, criminal, administrative, or any other kind." *Seal 1 v. Seal A*, 225 F.3d 1154,

The Relators do not dispute that the media reports fall squarely within the third category.[97] Accordingly, the disclosures identified by the Defendants all qualify as "public disclosure[s]" for the purposes of the statute.

The Court must still determine, however, whether the allegations or transactions at issue are "based upon" the public disclosures identified by the Defendants.[98] The Parties devote most of their argument to this issue.

In the Ninth Circuit, the relevant inquiry is whether the relator's allegations, "fairly characterized," repeat what the public already knows.[99] The "publicly disclosed facts need not be identical with, but only substantially similar to," the relator's allegations to invoke the Public Disclosure Bar.[100] Thus, simply adding a "few factual assertions never before publicly disclosed" will not change the character of allegations that were otherwise known to the public.[101] Allegations that "rest on the same foundation" as other claims that have been previously disclosed do not

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1161 (9th Cir. 2001). Thus, while an act such as responding to a FOIA request that merely requires duplicating records might not qualify as an "investigation" or "report," acts that involve creating "independent work product" by analyzing findings or conducting "leg-work" do qualify. *See United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1153 (9th Cir. 2006). Here, the Utah/CMS Correspondence plainly involved analysis and "leg-work" on the part of both parties involved. Additionally, the version of the statute that applies here does include *state* investigations. *See Graham Cty.*, 130 S. Ct. at 1400. Even if the second category were limited to *federal* investigations as it is under the revised statute, *see* 31 U.S.C.A. § 3130(e)(4) (West 2010), the correspondence would still qualify as a federal investigation because of CMS's role in it.

[97] Dkt. 111 at 18.

[98] Courts may consider multiple sources as a whole when determining whether the allegations or transactions have been "publicly disclosed." *See United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 n.1 (9th Cir. 2006) (noting that transactions do not have to be disclosed in "a single document" in order to constitute a public disclosure; the court may analyze multiple documents or hearings to determine whether the allegations or transactions have been publicly disclosed).

[99] *United States ex rel. Biddle v. Board of Trustees of the Leland Stanford, Jr., Univ.*, 161 F.3d 533, 537 (9th Cir. 1997) (quoting *Wang v. FMC Corp.*, 975 F.2d 1412,1417 (9th Cir. 1992))..

[100] *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009).

[101] *Biddle*, 161 F.3d at 537 (quoting *Wang*, 975 F.2d at 1417).

provide a basis for jurisdiction.[102] Mere disclosure of allegations - as opposed to *proof* of the allegations - invokes the Public Disclosure Bar.[103] Moreover, allegations do not have to be specifically "derived from" a public disclosure in order to be "based upon" the disclosure.[104]

Thus, where the "broad categories" of fraud have been disclosed and the relator merely fills in details, the allegations have been publicly disclosed where they are sufficient "to enable the government to pursue an investigation."[105] Similarly, the fact that the specific defendants in an FCA action were not named in a prior disclosure does not preclude a finding that the action was "based upon" the same allegations as the disclosure.[106] Indeed, the specific identity of the defendants is less of a concern where the government could easily identify those committing the fraud.[107]

Nor do the allegations need to mention the FCA or fraud to constitute a public disclosure.[108] Where "transactions" as opposed to "allegations" are at issue and the "material elements of the allegedly fraudulent 'transaction' are disclosed in the public domain" the transaction has been

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[102] *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1475 (9th Cir. 1996).

[103] *Wang v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992).

[104] *Biddle*, 161 F.3d at 536-40.

[105] *United States ex rel. Longstaffe v. Litton Indus., Inc.*, 296 F. Supp. 2d 1187, 1193-94 (C.D. Cal. 2003). *Accord United States ex rel. Poteet v. Bahler Med., Inc.*, __ F.3d __, No. 09-1728, 2010 WL 3491159, at *8-9 (1st Cir. Sept. 8, 2010) (finding that allegations that include additional details that add "color" but that "target[] the same fraudulent scheme" as prior disclosures will trigger the Public Disclosure Bar); *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1219 (E.D. Cal. 2002) (stating that "a relator's ability to reveal specific instances of fraud where the general practice has already been publicly disclosed is insufficient to prevent operation of the jurisdictional bar.").

[106] *United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999).

[107] *Id.* at 1019.

[108] *Id.* at 1019-20.

publicly disclosed.[109] Some courts have used variations of the following formula to explain the Public Disclosure Bar:

> If X+Y=Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed. Under the framework, X stands for the allegedly false set of facts set forth in the claim at issue, and Y is a proxy for the allegedly true set of facts. Thus when X (the false set of facts) and Y (the true set of facts) surface publicly, or when Z is broadcast there is little need for *qui tam* actions and the claim will be barred.[110]

In contrast, where the Government might "benefit from obtaining information about separate allegations of wrongdoing" against defendants that have not been previously disclosed, the Public Disclosure Bar would not prohibit the claim.[111] Accordingly, prior general allegations of fraud that do not "fairly characterize[]" the kind of fraud alleged by the relator and which would not be "sufficient to enable [the Government] adequately to investigate the case and make a decision on whether to prosecute" do not trigger the Public Disclosure Bar.[112]

Thus, like the rest of the FCA, the "based upon" requirement must be interpreted in light of the goals of the statute.[113] The essence of the inquiry turns on the question of whether the previously undisclosed allegations "are valuable to the government in remedying the fraud that is being

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[109] *United States ex rel. Foundation Aiding the Elderly v. Horizon W. Inc.*, 265 F.3d 1011, 1014-15 (9th Cir. 2001) (citation omitted). Thus, a "relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000) (citation omitted).

[110] *United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC*, 659 F. Supp. 2d 262, 267-68 (D. Mass. 2009) (citations omitted); *see also Foundation Aiding the Elderly*, 265 F.3d at 1015.

[111] *See United States ex rel. Alfatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 523 (9th Cir. 1999).

[112] *Foundation Aiding the Elderly*, 265 F.3d at 1016 (citation omitted).

[113] *See United States ex rel. Biddle v. Board of Trustees of the Leland Stanford, Jr., Univ.*, 161 F.3d 533, 538-39 (9th Cir. 1997).

committed against it" or whether they "confer no additional benefit upon the government" because they simply repeat previously disclosed allegations of fraud.[114]

Here, the Defendants do not appear to contend that the specific transactions identified by the Relators were previously disclosed. Rather, they claim that the allegations of Medicaid fraud based on off-label prescriptions of psychotropic drugs to minors were publicly disclosed numerous times before the instant actions were filed.[115]

The Relators argue that the allegations in the prior disclosures are not "substantially similar" to their allegations in the instant actions. The Relators rely on *United States ex rel. Alfatooni v. Kitsap Physicians Servs.*[116] and *United States ex rel. Foundation Aiding the Elderly v. Horizon West Inc.*,[117] for the proposition that "the public disclosure bar only applies to defendants identified in the public disclosure" and "that allegations of general or widespread fraud do not trigger the public disclosure bar."[118] As these decisions make clear, however, the relevant question when examining the level of detail in prior disclosures is whether those disclosures "would give the government sufficient information to initiate an investigation" against the defendants.[119]

The Relators similarly urge this Court to reject or distinguish cases suggesting that industry-wide allegations of fraud are sufficient to invoke the Public Disclosure Bar.[120] Indeed, there is no

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[114] *Id.* at 539.

[115] *See* Dkt. 119 at 14.

[116] 163 F.3d 516, 523 (9th Cir. 1999).

[117] 265 F.3d 1011, 1016 n.5 (9th Cir. 2001).

[118] Dkt. 111 at 9-10.

[119] *Foundation Aiding the Elderly*, 265 F.3d at 1016 n.5 (citing *United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999)); *see also Alfatooni*, 163 F.3d at 523 (determining that the relators' allegations against certain defendants were not barred because "the government may still benefit from obtaining information about separate allegations of wrongdoing against" those defendants despite some prior disclosures).

[120] *See* Dkt. 111 at 10; *Grynberg v. Pacific Gas & Elec. Co.*, 562 F.3d 1032, 1042-43 (10th Cir. 2009) (finding that allegations that "allow[] the government to target its investigation toward specific actors and a specific type of fraudulent activity" constitute public disclosures even where

consensus on that broad proposition.[121] A fair reading of all of these cases, however, supports the proposition that where the information in the prior disclosure is sufficient for the Government to initiate an investigation against the defendants, the Public Disclosure Bar applies.[122]

Examining the disclosures here, plainly, some of them - standing alone - would not provide the Government with enough information to initiate an investigation against the Defendants. General allegations that health care providers are prescribing psychotropic drugs to children would not be sufficient for the Government to initiate an investigation.[123] However, many of the prior disclosures reveal considerably more than that. Indeed, these disclosures reveal: (a) that health care

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they are directed "industrywide" instead of toward specific defendants); *United States ex rel. Gear v. Emergency Med. Assoc. of Ill., Inc.*, 436 F.3d 726, 729 (7th Cir. 2006) ("Industry-wide public disclosures bar *qui tam* actions against any defendant who is directly identifiable from the public disclosures." (citation omitted)); *United States ex rel. West v. Ortho-McNeil Pharma., Inc.*, 538 F. Supp. 2d 367, 383 n.10 (D. Mass. 2008) (finding that "even assuming Defendant was not named, the jurisdiction bar can still apply" where the disclosures "set the government squarely on the trail of fraud" (citation omitted)); *see also United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 685-88 (D.C. Cir. 1997) (finding that the publicly available information which did not include the defendant's identity was sufficient to allow the government to bring a suit against the defendant and accordingly, the relator's claim was publicly disclosed); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 571-72 (10th Cir. 1995) (finding that prior disclosures barred FCA action where they "set the government squarely on the trail of the alleged fraud" despite not naming the potential defendants, where there were a limited number of potential defendants and they were "easily identifiable").

[121] *See Cooper v. Blue Cross & Blue Shield of Fl.*, 19 F.3d 562, 566-67 (11th Cir. 1994) (finding that prior allegations must be "specific to a particular defendant" in order to trigger the Public Disclosure Bar because identifying the "individual actors engaged in the fraudulent activity" will aid the Government's efforts to reveal fraud); *United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC*, 659 F. Supp. 2d 262, 268 (D. Mass. 2009) (rejecting the defendants' argument that industry wide disclosures invoked the Public Disclosure Bar where the defendants and drugs at issue were not readily identifiable from the disclosures).

[122] *See United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999).

[123] *See* Dkt. 91 at 7-8 (citing Dkt. 91-7 at 11-17 (discussing PsychRights' efforts to lobby the Alaska state legislature and PsychRights' favored reform program)).

providers are prescribing psychotropic drugs to minors;[124] (b) that some of these minors are covered by Medicaid;[125] (c) that in many instances, these drugs are being prescribed for "off-label" or potentially unsupported uses;[126] and (d) that these unsupported uses may not be reimbursable through Medicaid under the law.[127] Some tie all this information together, even alleging that this activity constitutes Medicaid fraud. This is true of the CMS/Utah Correspondence,[128] PsychRights' filings in the State Case,[129] and several of the other media reports and documents.[130] In other words, these disclosures reveal the X, the Y, and the Z.

Certainly, not all of the disclosures cited by the Defendants identify all of the drugs discussed by the Relators or all of the Defendants. However, the disclosures do identify at least some of the drugs - indeed, PsychRights' Complaint in the State Case appears to identify most, if not all, of them[131] - and the State Case even identifies some of the Defendants. The fact that the prior disclosures do not identify all of the Defendants or all of the transactions is irrelevant - they provide more than enough information for the Government to investigate the conduct at issue. And, as the Defendants note, here, the Government is in a better position that the Relators to identify the parties engaging in that conduct.[132]

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[124] *See* Dkt. 91-9; Dkt. 91-10; Dkt. 91-11; Dkt. 91-13; Dkt. 91-14

[125] *See* Dkt. 91-10; Dkt. 91-13; Dkt. 91-14.

[126] *See* Dkt. 91-9; Dkt. 91-11; Dkt. 91-13; Dkt. 91-14.

[127] *See, e.g., United States ex rel. Franklin v. Parke-Davis*, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS, at *5-10 (D. Mass. Aug. 22, 2003).

[128] Dkt. 91-4.

[129] Dkt. 91-7 at 53-56; 91-8 at 1-2.

[130] Dkt. 91-12 at 11-12; Dkt. 91-15, Dkt. 91-16, Dkt. 91-17, Dkt. 91-18.

[131] *See* Dkt. 91-7 at 28-41; *see also* Dkt. 91-4 at 4 (Zyprexa); Dkt. 91-9 (Ritalin); Dkt. 91-10 (Ritalin and Prozac); Dkt. 91-11 (Ritalin); Dkt. 91-12 (discussing various categories of drugs and mentioning Ritalin, Paxil, Effexor, Wellbutrin, and Doxepin by name).

[132] Dkt. 119 at 11.

Moreover, the Relators' position is betrayed by their own prior admissions. The Relators note in their opposition brief that the Government already "has pursued False Claims Act cases and achieved extremely large recoveries against drug companies for causing the presentment of claims to Medicaid for prescriptions of psychotropic drugs that are not for medically accepted indications, including Geodon and Seroquel for use in children and youth."[133] Thus, the Relators have conceded that the Government already knows about the conduct that the Relators are complaining about here, and has already investigated it.[134]

PsychRights also alleges in the Amended Complaint that its State Case filings "informed" Defendants Sandoval and McComb "that presenting or causing the presentment of Medicaid claims that are not for medically accepted indications [namely, psychotropic drugs prescribed to children] are false claims."[135] The Defendants note that PsychRights also referred to the State Case in its statutorily required disclosure statement describing its claim for the Government.[136] PsychRights specifically quoted paragraph 22 of its amended complaint in the State Case (quoted in full above) and indicated that it became aware of the basis for the Matsutani Action while litigating that case.[137] Essentially, PsychRights has affirmatively alleged that it already publicly disclosed the allegations at issue here in the State Case.

Additionally, in seeking to have this Court unseal its Complaint, PsychRights submitted the Utah/CMS Correspondence to the Court in support of its argument that the Government was "unlikely" to intervene in the Matsutani Action. PsychRights argued that "the false or fraudulent nature of claims for prescriptions that are not for a medically accepted indication[] had been brought

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[133] Dkt. 111 at 14.

[134] Notably, Geodon and Seroquel are also both included in the PsychRights' Amended Complaint. Am. Compl. ¶¶ 166(h), 167(v).

[135] Am. Compl. ¶ 185.

[136] Dkt. 161. When a private person or entity initiates an FCA action it must provide the Government with a copy of the complaint and a "written disclosure of substantially all material evidence and information the person possesses" in order to allow the Government to make an informed decision on whether to intervene in the action. 31 U.S.C. § 3130(b)(2).

[137] Dkt. 161-1 at 3; Dkt. 151-1 at 3.

to the Government's attention in October of 2007[] and the Government declined to stop the fraud."[138] In other words, PsychRights was arguing that Utah had already brought the same issue that it is seeking to litigate here to the Government's attention eighteen months before it commenced the Matsutani Action. Indeed, the Utah/CMS Correspondence specifically raises that issue: whether prescriptions of psychotropic drugs for off-label uses to minors violate the Medicaid reimbursement law.[139]

The Relators also attempt to avoid the Public Disclosure Bar by arguing that "a public disclosure cannot trigger the public disclosure bar as to false claims that post date such public disclosure," relying on the Ninth Circuit's decision in *United States ex rel. Bly-Magee v. Premo.*[140] In *Bly-Magee*, the relator had brought a series of FCA actions against the defendants alleging that they had "violated federal procurement standards in awarding contracts, forced the Government to 'purchase unnecessary and duplicative services,' gave contracts to irresponsible parties, and falsely certified that they had conducted audits."[141] The Ninth Circuit held that the allegations that were disclosed in one of the earlier cases and a state audit report were publicly disclosed.[142] However, the court permitted the relator to move forward based on allegations related to a more recent time period which had not been encompassed by the prior disclosures.[143]

Here, unlike *Bly-Magee*, the public disclosures allege a continuing course of conduct which are not limited to specific time periods. The Relators' allegations would not provide the Government with any new basis to investigate these well-disclosed allegations.[144]

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[138] Dkt. 3 at 9.

[139] *See* Dkt. 91-4 at 4.

[140] Dkt. 111 at 17 (citing 470 F.3d 914, 920 (9th Cir. 2006)).

[141] 470 F.3d at 916-17.

[142] *Id.* at 916-19.

[143] *Id.* at 920.

[144] Moreover, the most recent prior disclosure dates from three weeks before the Matsutani Action was filed. *See* Dkt. 91-7 at 2-3. The specific claims described by the Relators all predate that

In summary, the prior public disclosures provided the Government with more than sufficient information to investigate the allegations that the Relators are making in this case. Accordingly, under the controlling statute here, the Relators' allegations have been publicly disclosed.

C. Original Source

Even where there has been a prior public disclosure, a relator may still pursue a *qui tam* action under the FCA where the relator is an "original source" of the information. Prior to the recent amendment, the FCA defined "original source" as follows:

> For the purposes of this paragraph, 'original source' means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.[145]

The Ninth Circuit has explained that in order to qualify as an "original source," a relator must demonstrate that he or she: (1) has "direct and independent knowledge" of the information that the allegations are based on; (2) "voluntarily provided the information to the government" before filing

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filing with the exception of one claim for $283.94 on September 11, 2009. Am. Compl. ¶ 188. This transaction cannot change the fact that the substance of the Relator's allegations have been widely disclosed in a number of public sources. Nor can the Relators' request for injunctive relief, which may not even be available under the FCA. *See United States v. Sriram*, 147 F. Supp. 2d 914, 946 n.21 (N.D. Ill. 2001) (discussing the legislative history of the FCA 1986 amendments and noting that a provision providing the Government with explicit authorization to obtain preliminary injunctive relief was dropped from the bill); *Robbins v. Desnick*, No. 90 C 2371, 1991 WL 5829, at *3 (N.D. Ill. 1991) (determining that injunctive relief was inappropriate and noting that the plaintiff failed "to cite any cases where injunctive relief was granted for FCA violations"); *see also United States ex rel. Dep't of Defense v. CACI Int'l Inc.*, 953 F. Supp. 74, 79 (S.D.N.Y. 1995) (finding that the plaintiff had not shown that the public would suffer if the court did not issue an injunction since "the civil and treble damages that the government may recover under the [FCA] will serve to punish the defendants for their fraudulent conduct and to deter others from doing the same."); *cf. United States ex rel. Green v. Northrop Corp.*, 59 F.3d 953, 968 (9th Cir. 1995) (indicating that the goal of the FCA is to compensate the Government by returning funds to the federal treasury and thereby deter future fraud).

[145] 31 U.S.C. § 3730(e)(4)(A) (2006).

the *qui tam* action; and (3) "had a hand in the public disclosure of allegations that are a part of the suit."[146]

A relator "must show that he [or she] had firsthand knowledge of the alleged fraud, and that he [or she] obtained this knowledge through his [or her] own labor unmediated by anything else" in order to satisfy the "direct knowledge" requirement.[147] Where a relator adds detail to information he or she obtained from another source that does not "add[] anything of significance" to the original information, the relator does not have "direct" knowledge.[148] In order to satisfy the "independent knowledge" requirement, the relator must show that he or she "kn[ew] about the allegations before that information [wa]s publicly disclosed."[149] Additionally, a relator is not an "original source" merely because the relator was the first to publicize allegations.[150] Rather, the relator's disclosure must have "'triggered' the investigation that led to the publicly disclosed information."[151]

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[146] *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1201 (9th Cir. 2009) (citation omitted); *United States ex rel. Zaretsky v. Johnson Controls, Inc.*, 457 F.3d 1009, 1013 (9th Cir. 2006) (citation omitted).

[147] *United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1020 (9th Cir. 1999); *United States ex rel. Devlin v. California*, 84 F.3d 358, 361 (9th Cir. 1996) (finding that the relators did not satisfy the "original source" requirement where "[t]hey did not see the fraud with their own eyes or obtain their knowledge of it through their own labor unmediated by anything else.").

[148] *See Devlin*, 84 F.3d at 361-62 (finding that the relator's efforts to verify the alleged fraud "did not make a genuinely valuable contribution to the exposure of the alleged fraud" since the "federal investigators would have done precisely the same thing" with the information).

[149] *Meyer*, 565 F.3d at 1202 (citation omitted).

[150] *Cf. Devlin*, 84 F.3d at 360-61 (9th Cir. 1996) (finding that the relator did not qualify as the "original source" of the information despite the fact that the relators had first revealed allegations to the media); *see also United States ex rel. Alfatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 522 (9th Cir. 1999) (rejecting relator's argument that "his allegations were not 'based upon' publicly disclosed information because he was the source of the information provided to the news media").

[151] *Seal 1 v. Seal A*, 225 F.3d 1154, 1162 (9th Cir. 2001).

Here, the Relators have explicitly conceded that they are "not asserting original source status."[152] Indeed, they cannot credibly claim to have direct, firsthand knowledge of fraud that adds anything of significance to the disclosures generated by others. The Relators here are simply not the types of "whistleblowers" that the FCA was created to encourage and reward. The Relators obviously feel very strongly about the issues raised in their pleadings. However, they are essentially echoing issues that have been previously raised by others and considered by the Government. The FCA is not the proper vehicle for the Relators to challenge these practices.

IV. CONCLUSION

For the foregoing reasons, the Court hereby ORDERS that:

1. The Defendants' motions to dismiss (Dkts. 89 and 141) and related request to present supplemental materials (Dkt. 161) are GRANTED;
2. The Parties' remaining motions (Dkts. 83, 90, 92, 113, 122, 133, 143, 156, 160, and 162) are DENIED as moot; and
3. Both of the instant actions are hereby DISMISSED with prejudice.

Dated at Anchorage, Alaska, this 24th day of September, 2010.

/s/ Timothy Burgess
TIMOTHY M. BURGESS
UNITED STATES DISTRICT JUDGE

[152] Dkt. 111 at 19.

EXHIBIT C

STATE OF UTAH

OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

October 22, 2007

Steve E. Phurrough, M.D., MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for clarification regarding Medicaid "covered outpatient drugs"

Dear Dr. Phurrough:

In working on state actions recently against various pharmaceutical manufacturers for off-label promotion causing the filing of false Medicaid claims, it has come to our attention that many state Medicaid programs are liberally reimbursing -- and presumably receiving Federal Financial Participation ("FFP") -- for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia. Clarification on the permissible scope of FFP-eligible reimbursement by state Medicaid programs for covered outpatient drugs is critically important.

More specifically, §1927 of the Social Security Act (42 U.S. Code §1396r-8, often referred to as OBRA '90) provides:

- in subsection (k)(3) that the term "covered outpatient drug" excludes "a drug or biological used for a medical indication which is not a medically accepted indication."
- in subsection (k)(6) that the term "medically accepted indication" means any use approved by the FDA or "supported" in one or more specified compendia
- in subsection (g)(1)(B)(i) that the specified compendia are American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications) and the DRUGDEX Information System

ISSUE #1: ***Does CMS interpret federal law to restrict FFP for state Medicaid programs to uses of otherwise "covered outpatient drugs" that are either FDA-approved or supported in the specified compendia?***

ISSUE #2: ***If the answer to question #1 is yes, has the federal government delegated to the states any authority to approve exceptions, i.e., to expand FFP-eligible Medicaid prescription drug coverage?*** *(e.g., May a state grant its Drug Utilization Review Board the authority to approve FFP-eligible Medicaid reimbursement for off-label indications not supported in the specified compendia?)*

ATTORNEY GENERAL'S OFFICE • MEDICAID FRAUD CONTROL UNIT • 5272 SO. COLLEGE DRIVE, #200 • MURRAY, UTAH 84123 • TEL: (801) 281-1259 • FAX: (801) 281-1250

Steve E. Phurrough, M.D., MPA
October 22, 2007
Page Two of Two

Your clarification regarding these Medicaid drug coverage issues is respectfully requested.

Very truly yours,

David R. Stallard

David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov

/DRS

cc: David Frank, Director, Medicaid Integrity Group

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

DEC 6 2007

David R. Stallard, CPA
Assistant Attorney General
Office of the Attorney General
5272 S. College Drive, #200
Murray, Utah 84123

Dear Mr. Stallard:

Thank you for your recent letter to Dr. Steve E. Phurrough regarding clarification of reimbursement by Medicaid for covered outpatient drugs. Your letter has been forwarded to me for response.

Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations. Section 1927(d) of the Act authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act), however, it does not explicitly require them to do so. States are responsible for defining this coverage in their approved Medicaid State plan and implementing policies. To determine the indications for the coverage of a drug, you would need to review the State's approved plan and policies on the specific coverage of that drug.

I appreciate your concern regarding the necessity for proper reimbursement under the Medicaid drug program.

Sincerely,

Bill Fawcett

Dennis G. Smith
Director

EXHIBIT E

STATE OF UTAH

OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

December 17, 2007

Dennis G. Smith, Director
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Re: Improper Off-Label Indications - definition of "covered outpatient drugs"

Dear Mr. Smith:

Thank you for your reply dated December 6, 2007, in which you stated that "the Social Security Act does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter," namely for uses other than "medically accepted indications" (i.e., for uses not FDA-approved or "supported" in the specified compendia).

With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) **does not include "a drug or biological used for a medical indication which is not a medically accepted indication."**

This federal statute defining the term "covered outpatient drug" clearly delineates that Medicaid drugs are covered only so long as they are used for "medically accepted indications." Congress apparently intended that Medicaid not be so restrictive as to prohibit all off-label use, but that it not be so expansive as to cover experimental uses not yet medically accepted. The criterion Congress chose for permissible off-label use was that the particular use be "supported" in at least one of the specified compendia [(k)(6)].

Frankly, I do not see how CMS can ignore this unambiguous statutory definition of "covered outpatient drug." I conclude from your letter that CMS, while ignoring the clear statutory definition, is focusing on the Limitations subsection (d) that lists permissible restrictions, including prescribed uses not for a medically accepted indication at subsection (d)(1)(B)(i).

ATTORNEY GENERAL'S OFFICE • MEDICAID FRAUD CONTROL UNIT • 5272 SO. COLLEGE DRIVE, #200 • MURRAY, UTAH 84123 • TEL: (801) 281-1259 • FAX: (801) 281-1250

Apparently an inference is being drawn from this subsection that, since a State may exclude coverage for a prescribed use that is not a medically accepted indication, it is not required to do so. But for the clear, unambiguous definition of "covered outpatient drug," it would appear to be reasonable to draw such an inference; however, as a principle of statutory construction, a mere negative inference from a Limitations section (the purpose of which is to identify restrictions to coverage, not to expand coverage) does not trump a clear delineation of coverage in the definitional section.

I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.

A "poster child" example of exactly why this issue is important not only for cost considerations, but also for patient safety, is the atypical antipsychotic drug Zyprexa manufactured by Eli Lilly. For about 10 years it has been at or near the highest dollar volume drug reimbursed by Medicaid nationwide. It is only approved for schizophrenia and bipolar disorder in adults, a very narrow segment of the population. It has been widely reported that approximately 50% of utilization is off-label, including for infants and toddlers. Based on recent lawsuit settlements totaling over a billion dollars and involving thousands of Zyprexa users, the drug causes substantial weight gain and diabetes in a significant percentage of cases. In other words, Medicaid is not only paying for a very expensive drug for uses that are not "medically accepted indications," but its reimbursement of this drug is resulting in many Medicaid recipients developing diabetes, a life-threatening condition with many adverse health complications for the individuals and a significant cost burden on taxpayers for treating these complications.

I implore you to look into this drug coverage issue resulting in substantial overpayments and jeopardizing the health and safety of hundreds of thousands of Medicaid recipients.

Very truly yours,

David R. Stallard

David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov
/DRS
cc: Steven E. Phurrough, M.D., MPA, Director, Coverage and Analysis Group
David Frank, Director, Medicaid Integrity Group

EXHIBIT F

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations
Disabled and Elderly Health Programs Group (DEHPG)

JAN 3 0 2008

RECEIVED
FEB 4 2008
UTAH ATTORNEY GENERAL
MEDICAID FRAUD CONTROL UNIT

David R. Stallard, CPA
Office of the Attorney General
Medicaid Fraud Control Unit
5272 S. College Drive, #200
Murray, UT 84123

Dear Mr. Stallard:

Thank you for your letter expressing further concerns regarding the Utah Medicaid Program's coverage of outpatient drugs. I've been asked to respond to you directly since this program area is the responsibility of my group.

I wish to confirm that our previous response to you is correct. As we noted in that response, the State may limit coverage for drugs to medically accepted indications. To verify what Utah has chosen to do for coverage of a particular drug, we again suggest you contact State personnel and review the State's approved State plan and policies on the specific coverage of drugs, including Zyprexa.

I hope this information adequately addresses your concerns.

Sincerely,

for Gale P. Arden
Director

EXHIBIT
F
Blumberg No. 5208

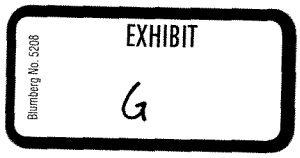
EXHIBIT G

JAMES B. GOTTSTEIN, ABA # 7811100
LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
Tel: (907) 274-7686
Fax: (907) 274-9493
jim.gottstein@psychrights.org

Attorney for Law Project for Psychiatric Rights

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA *Ex rel.* Law Project for Psychiatric Rights, an Alaskan non-profit corporation, Plaintiff, vs. OSAMU H. MATSUTANI, MD, *et al.*, Defendants.	)	Case No. 3:09-CV-00080-TMB



OPPOSITION TO MOTION TO DISMISS UNDER RULE 12(b)(6)

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) opposes the Defendants' Motion to Dismiss under Rule 12(b)(6), Dkt. No. 92, (12(b)(6) Motion). The 12(b)(6) Motion directly raises the question of whether PsychRights is correct that Congress restricted reimbursement for outpatient drugs by the federal government under Medicaid to those that are "medically accepted indications," defined as indications approved by the Food and Drug Administration (FDA), or the use of which is supported by one or more citations included or approved for inclusion in (i) American Hospital Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System (Covered

Outpatient Drugs). 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6); 42 USC § 1396r-8(g)(1)(B)(i).

I. CONGRESS RESTRICTED FEDERAL MEDICAID REIMBURSEMENT FOR OUTPATIENT DRUGS TO MEDICALLY ACCEPTED INDICATIONS.

A. Congress Limited Medicaid Federal Financial Participation to Covered Outpatient Drugs

42 USC 1396R-8(k)(3) provides in pertinent part, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) provides:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 USC § 1396R-8(g)(1)(B)(i), in turn, designates the compendia as

> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System.

(Compendia).

In sum, Medicaid is only permitted by Congress to reimburse the states for expenditures on outpatient drugs for "medically accepted indications," defined as indications approved by the FDA or "supported" by a citation in any of the three Compendia.

In their 12(b)(6) Motion, the Defendants assert Congress did not limit Medicaid coverage of outpatient drugs to "covered outpatient drugs" as set forth above, citing 42 U.S.C. §1396d(a)(12), which includes "prescribed drugs" in the definition of "medical assistance," for the proposition that Medicaid pays for all drugs prescribed by someone

licensed to do so, and §1396r-8(d)(1)(B)(i) for the proposition that because it allows states to limit coverage to covered outpatient drugs, prescription drug coverage under Medicaid must not otherwise be limited to covered outpatient drugs. They assert Congress established "covered outpatient drugs" as a floor or minimum, not a ceiling or maximum, also stating that the sections cited by PsychRights nowhere say or even imply that Medicaid payments are limited to "covered outpatient drugs." This is simply not true. States are not required to offer drug coverage, although they all have elected to do so, and federal reimbursement for such prescription drug coverage is limited under §1396b(i)(10) to "covered outpatient drugs," except as otherwise specifically allowed.[1]

The structure of the Medicaid Statutes, which are found at 42 U.S.C. §1396 to 42 U.S.C. §1396w-2,[2] is that §1396a sets forth the requirements of "State Plans," §1396b sets forth how reimbursement to the states is determined, §1396d defines certain terms, and other provisions of the statutes set forth specific requirements for what medical assistance is authorized to be reimbursed by the Medicaid program. §1396r-8, which is at issue here, defines the scope and requirements for prescription drug coverage, and other sections address other types of medical assistance. That a service or product is included in the definition of "medical assistance" in §1396d(a) does not mean that Medicaid pays for all of such service or product.

For example, while §1396(d)(15) includes "services in an intermediate care facility for the mentally retarded" in the definition of "medical assistance," §1396a(a) requires that "a State plan for medical assistance must," at §1396a(a)(30)(B)(i)

---

[1] At §1396r-8(a)(3)(A) Congress allowed Medicaid to pay for drugs that are not covered outpatient drugs

> if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d) of this section.

[2] Hereafter, citations to sections within this statutory range omit the Title Number.

> (30) provide, under the program described in subparagraph (A), that-- (i) each admission to a[n] . . . intermediate care facility for the mentally retarded . . . is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved,

and at §1396a(a)(31) that

> (31) with respect to services in an intermediate care facility for the mentally retarded (where the State plan includes medical assistance for such services) provide, with respect to each patient receiving such services, for a written plan of care, prior to admission to or authorization of benefits in such facility, in accordance with regulations of the Secretary, and for a regular program of independent professional review (including medical evaluation) which shall periodically review his need for such services.[3]

In §1396i, Congress mandated an entire certification and approval process for intermediate care facilities for mentally retarded Medicaid beneficiaries. This is analogous to the restrictions on prescription drug coverage, including to medically accepted indications, contained in §1396r-8, and is an illustration of the principle that, contrary to the Defendants' assertion, the Medicaid statutes do not allow payment for everything defined as "medical assistance" in 1396d(a).

Similarly, the inclusion of "prescription drugs" in the definition of "medical assistance," at §1396d(a)(12) does not allow Medicaid to pay for all prescriptions by a licensed prescriber as asserted by the Defendants. Instead, §1396a(a)(54) requires that if a state elects to provide prescription drug coverage, it must comply with the requirements concerning "covered outpatient drugs" contained in §1396r-8, and at §1396b(i)(10)(A) prohibits payment "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8 of this title with respect to such drugs or unless section §1396r-8(a)(3) of this title applies." The exception in §1396r-8(a)(3)[4] makes no sense whatsoever under the Defendants' interpretation.

---

[3] *See*, also §1396a(B)(i)(44).
[4] *See*, note 1, *infra*.

The Defendants are simply wrong when they assert at page 7 of their 12(b)(6) Motion that "covered outpatient drugs" establishes a floor or minimum, not a ceiling or maximum. There are a number of provisions that allow or mandate the states to restrict payment for "covered outpatient drugs." §1396r-8(d)(1)(A) allows states to establish prior authorization programs for covered outpatient drugs so long as they comply with §1396r-8(d)(5). §1396r-8(d)(1)(B) allows states to exclude or otherwise restrict coverage of covered outpatient drugs used for anorexia, weight loss, weight gain, cosmetic purposes or hair growth, smoking cessation, and sexual or erectile dysfunction, or to promote fertility. §1396r-8(d)(4) allows states to establish formularies under specified rules.

B. The United States District Courts for the Districts of Massachusetts and Illinois, and the United States Department of Justice Agree With PsychRights' Interpretation

In contesting this straightforward interpretation, the Defendants, rely on 42 USC §1396r-8(d)(1)(B)(i), which provides:

> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
>
> > (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

The Defendants' argument is this language implies Medicaid must cover more than for "medically accepted indications," because otherwise there is no reason for this provision allowing the States to exclude or restrict coverage to medically accepted indications. In other words, the Defendants' argument is that PsychRights' interpretation renders §1396r-8(d)(1)(B)(i) superfluous and an interpretation that a statutory provision is superfluous is disfavored.

In support of this contention, Defendants cite to the following in the unpublished decision in *U.S. ex rel. Franklin v. Parke Davis*, 2003 U.S. Dist. LEXIS 15754, 2003 WL 22048255, p 3 (D.Mass. 2003):

> Thus, in Relator's view, § 1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation.

(citation omitted). However, the *ex rel Franklin* district court specifically declined to rule on the issue:

> It is not clear which side gets the better of the statutory-tail-chases-cat debate. The Court would appreciate an amicus brief from federal officials, providing the federal government's understanding of the extent to which the Medicaid statute empowers states to provide coverage of off-label, non-compendium prescriptions.

Id.

Most importantly the district court there did not overrule its previous published opinion where it concluded PsychRights' interpretation is correct:

> Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* §1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. Id. § 1396r-8(k)(6). See also *id.* § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

U.S. ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44,45 (D.Mass 2001) (footnote omitted).

In a later published decision, *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008) the District Court for the District of Massachusetts again agreed with PsychRights' interpretation, holding:

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported

by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).

Similarly, the US District for the District of Illinois *U.S. v. Ortho-McNeil Pharmaceutical, Inc.*, 2007 WL 2091185, p. 2 (N.D.Ill. 2007), has held that Medicaid coverage is limited to "covered outpatient drugs," which excludes indications that are not for a medically accepted indication.

While not filing the *amicus* brief desired by the Massachusetts District Court in the 2003 unpublished *Franklin* opinion,[5] the Department of Justice has since taken a consistent position, repeatedly asserted, that agrees with PsychRights' interpretation. For example, in September of 2009 the Department of Justice issued a news release announcing a $2.3 Billion settlement with Pfizer, stating, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs." Exhibit 1, p.1.

Similarly, the Government's February 13, 2009, Complaint in Intervention in *U.S. ex rel Gobble v. Forest Laboratories*, Case No. 03-cv-10395-NMG, District of Massachusetts, Exhibit 2, p. 9, at ¶s 26-30, sets forth the Government's position that prescriptions caused to be presented to Medicaid that are not for medically accepted indications are false claims. Paragraph 37, Exhibit 2, p.10, also recites that Celexa (citalopram) and Lexapro (escitalopram) have no medically accepted indications for children and youth[6] and at p.31, ¶97, specifically alleges that claims presented to

[5] 2003 U.S. Dist. LEXIS 15754, 2003 WL 22048255, p 3.
[6] The FDA subsequently approved Lexapro for Major Depressive Disorder. In the First Amended Complaint herein, Dkt. No. 107, that Celexa has no medically accepted indication for children and youth is set forth at p. 34, ¶166(c), and that the only medically accepted indication for Lexapro is Major Depressive Disorder at ¶167(m).

Medicaid as a result of prescriptions of Celexa and Lexapro by physicians for use in children and youth are false or fraudulent for that reason. *See*, also ¶100, Ex. 2, p. 32. The settlement agreement in *U.S. ex rel Wetta v. AstraZeneca Pharmaceuticals*, Case No. 04-cv-3479-BMS, Eastern District of Pennsylvania, Exhibit 3, p. 6, also sets forth the Government's position that claims presented to Medicaid for outpatient drugs not for a medically accepted indication are false or fraudulent.

Thus, the Massachusetts and Illinois US District Courts and the Department of Justice all agree with the interpretation that Congress has limited federal reimbursement for outpatient drugs to "medically accepted indications."

C. Statutory Construction Principles Confirm PsychRights,' The Massachusetts and Illinois District Courts,' and the Department of Justice's Interpretation

The Defendants rely on the maxim or canon of statutory construction that an interpretation that anything in a statute is superfluous is disfavored, but of course, there are competing maxims of statutory construction.

> [A]s every judge knows, the canons of construction are many and their interaction complex. The canons "are not mandatory rules." *Chickasaw Nation v. United States,* 534 U.S. 84, 94, 122 S.Ct. 528, 151 L.Ed.2d 474 (2001). They are guides "designed to help judges determine the Legislature's intent."

Xilinx, Inc. v. C.I.R. ,598 F.3d 1191, 1196 (9th Cir. 2010).

In *Chickasaw Nation*, 453 U.S. at 94, the Supreme Court specifically rejected the canon of construction that an interpretation rendering part of a statute superfluous was controlling there:

> The canon requiring a court to give effect to each word "if possible " is sometimes offset by the canon that permits a court to reject words "as surplusage" if "inadvertently inserted or if repugnant to the rest of the statute ...."

Of course, the first thing to examine is the language of the statute itself:

> In interpreting the statute we look to general principles of statutory construction and begin with the language of the statute itself. *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241, 109 S.Ct. 1026, 103 L.Ed.2d 290 (1989)

Siripongs v. Davis, 282 F.3d 755 (9th Cir. 2002).

Defendants' interpretation of the statute immediate falls apart when looking at the provision upon which they rely, §1396r-8(d)(1)(B)(i), which states:

> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
>
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

This is circular because, "covered outpatient drug" is defined in 42 USC 1396R-8(k)(3) to "not include any . . . drug . . . used for a medical indication which is not a medically accepted indication."

Thus, substituting the definition of "medically accepted indication" the statutory provision relied upon by the Defendants states,

> A State may exclude or otherwise restrict coverage of a covered outpatient drug to a covered outpatient drug.

or, substituting the definition of "covered outpatient drug:"

> A State may exclude or otherwise restrict coverage of drugs prescribed for a medically accepted indication to drugs prescribed for a medically accepted indication.

There is thus simply no avoiding the conclusion that 42 U.S.C. §1396r-8(d)(1)(B)(i) is superfluous. Most importantly, it can not be used to override Congress' explicit limitation of Medicaid coverage for outpatient drugs to medically accepted indications.

Defendants cite to *Boise Cascade Corp. v. U.S. E.P.A.*, 942 F.2d 1427, 1432 (9th Cir. 1991), for the proposition that courts " must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous."

PsychRights respectfully suggests this maxim supports PsychRights' position rather than Defendants' because Defendants' position writes out of the statute that part of the definition of "covered outpatient drugs" that limits it to medically accepted indications, doing violence to the whole Medicaid statutory scheme in the process. The Defendants' interpretation that all prescribed drugs are covered under Medicaid because prescribed drugs are one of the elements of medical assistance is contrary to the whole structure and intent of the Medicaid statutes and the intent of Congress to limit prescription drug coverage in OBRA 1990.

For example, §1396b(i)(10)(A), provides, "Payment under the preceding provisions of this section shall not be made . . . with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8 of this title with respect to such drugs or unless §1396r-8(a)(3) of this title applies.[7] This evinces Congress' intent to restrict payments for outpatient drugs, among quite a few other things,[8] to "medically accepted indications."

PsychRights respectfully suggests its, the Massachusetts and Illinois District Courts,' and the Department of Justice's interpretation that Congress restricted coverage for outpatient drugs to covered outpatient drugs is correct.

II. THAT ALASKA'S PLAN HAS BEEN SEEKING REIMBURSEMENT FOR DRUGS THAT ARE NOT FOR A MEDICALLY ACCEPTED INDICATION IS IRRELEVANT

In Part II.C., of their 12(b)(6) Motion, the defendants demonstrate that Alaska has been obtaining reimbursement under its approved plan for prescription drugs that are not for medically accepted indications, arguing this means the reimbursements are

[7] It seems worth noting here that the title to §1996(b)(i), includes "other restrictions," and "Titles are also an appropriate source from which to discern legislative intent." *United States v. Nader*, 542 F.3d 713, 717 (9th Cir. 2008). Moreover, §1396r-8 is contained in §4401 of OBRA 1990, which is the first section in, "Part 1-Reductions in Spending," and itself is titled, "Reimbursement for prescribed drugs," denoting that the whole section pertains to the requirements for reimbursement for prescribed drugs.

[8] *See* §1396r-8(k)(3) which has quite a few restrictions in addition to the one that restricts coverage to "medically accepted indications."

authorized. This is a reason for granting a preliminary injunction against the practice rather than shedding any light on whether the practice is permitted under Medicaid.

> Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law

Heckler v. Community Health Services, 467 U.S. 51, 63, 104 S.Ct. 2218, 2225 (1984).

Citing to *Heckler*, in *U.S. ex rel Hagood v. Sonoma County Water Agency*, 929 F. 2d 1416, 1422 (9th Cir 1991), in a False Claims Act case such as this, the Ninth Circuit held that United States government officials' approval of a contract based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's dismissal under Rule 12(b)(6). That the State of Alaska has promulgated regulations and acts thereunder contrary to the law, and the officials who approved the State of Alaska's Medicaid Plan have acquiesced, is no defense--it is an admission.

III. CONCLUSION

For the foregoing reasons, the Defendants' Motion to Dismiss under Rule 12(b)(6), Dkt. No. 92, should be denied.

RESPECTFULLY SUBMITTED this 7th day of May, 2010.

Law Project for Psychiatric Rights, an Alaskan non-profit corporation

By: /s/ James B. Gottstein
James B. Gottstein
Alaska Bar No. 7811100
406 G Street, Suite 206
Anchorage, Alaska 99501
Tel: (907) 274-7686
Fax: (907) 274-9493
E-mail: jim.gottstein@psychrights.org

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 7, 2010, a true and correct copy of this document was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN

EXHIBIT H

STATE OF ILLINOIS
COUNTY OF COOK } ss:

(Rev. 2/4/98) CCJP 0604 A

4700 Disp. Ord.

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
DEPARTMENT OF JUVENILE JUSTICE AND CHILD PROTECTION
CHILD PROTECTION DIVISION

IN THE INTEREST OF
Jacqueline Nicholson
Minor(s)

No. 02JA1025

DISPOSITION ORDER
(Placement) 705 ILCS 405/2-27

☒ original ☐ modified order

This cause coming on to be heard for disposition hearing or on the _____ of _____. The Court having considered the evidence and having jurisdiction of the subject matter and the parties and the minor having been found to be (neglected/abused/dependent), and all statutory prerequisites having been fully complied with:

THE COURT FINDS:

☒ 1. The minor:

7116 ☒ A. is adjudged a ward of the court, it being in the best interest and welfare of the minor and the public; or

☐ B. was previously adjudged a ward of the court on _____

☒ 2. The mother, Lynda Nicholson, is:

7127 ☐ A. fit, able, and willing to care for, protect, train, and discipline the minor. OR

7128 ☒ B. unable for some reason other than financial circumstances alone to care for, protect, train, or discipline the minor; and/or

7129 ☐ C. unwilling to care for, protect, train, or discipline the minor; and/or

7227 ☐ D. unfit.

7130 ☐ E. deceased.

ENTERED
JUN 05 2003
DOROTHY BROWN
CLERK OF CIRCUIT COURT

☒ 3. The father, Donald Procunier, is:

7131 ☐ A. fit, able, and willing to care for, protect, train, and discipline the minor. OR

7132 ☒ B. unable for some reason other than financial circumstances alone to care for, protect, train, or discipline the minor; and/or

7133 ☒ C. unwilling to care for, protect, train, or discipline the minor; and/or

7231 ☐ D. unfit.

7134 ☐ E. deceased.

☐ 4. The (guardian/legal custodian/both) _____ is:

7135 ☐ A. fit, able, and willing to care for, protect, train, and discipline the minor. OR

7136 ☐ B. unable for some reason other than financial circumstances alone to care for, protect, train, or discipline the minor; and/or

7137 ☐ C. unwilling to care for, protect, train, or discipline the minor; and/or

7235 ☐ D. unfit.

7138 ☐ E. deceased.

DOROTHY BROWN, CLERK OF THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS

13

EXHIBIT
H
Blumberg No. 5208

☒ 5. Reasonable efforts have:

7108 ☒ A. been made to prevent or eliminate the need for removal of the minor from the home.

7108 ☐ B. been provided to make it possible for the minor to return to the parent, guardian or legal custodian.

7208 ☐ C. not been made.

☒ 6. Appropriate services aimed at family preservation and family reunification have been

☐ A. successful.

☒ B. unsuccessful.

☒ 7. It is in the best interest of the minor to remove the minor from the custody of the parents, guardian or custodian.

☐ 8. It is not in the best interest of the minor to become a ward of the state.

IT IS ORDERED:

☐ 8001 A. The case is dismissed.

☐ 4122 B. The minor shall (be returned to/remain in) the care and custody of _____, the (mother/father/parents/guardian/custodian/responsible relative).

☐ C. The order of protection entered against _____ (mother/father/parents guardian/custodian/reponsible relative) on _____, _____ is vacated.

☐ 4711 D. Temporary custody is terminated and appointment is vacated.

☐ E. The 405/2-24 Order of Protective Supervision entered this date is incorporated herein.

☒ F. 1. The minor shall be placed in the (custody/guardianship) of DOP

4702 ☐ a. a private custodian/guardian whose relationship to the minor is _____;

4703 ☒ b. a DCFS Guardianship Administrator with right to place the minor;

4704 ☐ c. a probation officer.

2. The 405/2-25 Order of Protection entered against _____ on _____, is hereby incorporated in this order.

3. The clerk of the court shall deliver a certified copy of this order to the custodian or guardian as proof of his/her authority. No other process is necessary as authority for the keeping of the minor.

4. This custody shall continue until the minor reaches age (19/21) unless otherwise ordered by the court.

5. The custodian is authorized to consent to any required major medical and dental treatment by a licensed physician.

4284 ☒ Appeals Rights Given.

☐ This cause is set on 7-8-03, 9:30, for TVG

4390 ☒ Status 4290 ☐ Progress Report ~~4291 ☐ Permanency Planning Hearing~~

Before the: 4391 ☐ Judge 4393 ☐ Hearing Officer

DATED: JUNE 5, 2003 ENTERED: _____ 1838

Judge Judge's No.

DOROTHY BROWN, CLERK OF THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS

EXHIBIT I

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHRISTOPHER R. GOBBLE, *et al.*,	**Civil Action No. 03-10395-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	**FILED UNDER SEAL**
Defendants.	
UNITED STATES OF AMERICA *ex rel.* JOSEPH PIACENTILE, *et al.*,	**Civil Action No. 05-10201-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC.,	
Defendant.	

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of the defendants, Forest Laboratories, Inc. ("Forest Labs"), and Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") (collectively, "Forest"). Over the course of more than half a decade, Forest illegally marketed two related antidepressant drugs, Celexa and Lexapro, for off-label use in pediatric patients when both drugs had been approved only for adult use. During much of that

time, Forest misled physicians by promoting the results of a positive study on pediatric use of Celexa while failing to disclose the results of a contemporaneous negative study for the same pediatric use. Forest also illegally paid kickbacks to physicians to induce them to prescribe the drugs. By knowingly and actively promoting these antidepressants for off-label pediatric use without disclosing the results of the negative pediatric study and by paying kickbacks, Forest caused false claims to be submitted to federal health care programs in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

2. The United States bases its claims on Forest causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1).

3. Within the time frames detailed below, Forest engaged in a fraudulent scheme to market and promote Celexa (citalopram) and Lexapro (escitalopram) off-label to treat depression and other psychiatric conditions in pediatric patients. Forest did so even though the Food and Drug Administration ("FDA") had not approved the drugs as safe and effective for any use in the pediatric population. In the case of Celexa, the FDA had specifically denied approval for any pediatric use.

4. In furtherance of its off-label marketing scheme, Forest disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety

and efficacy of Celexa and Lexapro in treating pediatric patients. At the same time that Forest was actively touting pediatric use of the drugs, the company failed to disclose the negative results of a large, placebo-controlled study that found Celexa no more effective than placebo for pediatric use and in which more patients taking Celexa attempted suicide or reported suicidal ideation than those taking only placebo. The negative data that Forest failed to disclose was among the data later considered by the FDA when mandating that Forest add a "black box" warning to both the Celexa and Lexapro labels for pediatric use.

5. In addition to its illegal off-label marketing scheme, Forest sought to induce physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment, and other valuable goods and services, all in violation of the federal anti-kickback statute, 42 U.S.C. § 3120a-7b(b) ("AKS").

6. As the direct, proximate, and foreseeable result of Forest's fraudulent course of conduct, as set forth above and herein, Forest caused thousands of false or fraudulent claims to be submitted to the federal health care programs for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use and/or were ineligible for payment as a result of illegal kickbacks.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345.

8. This Court may exercise personal jurisdiction over Forest pursuant to 31 U.S.C.

§ 3732(a) and because Forest transacts business in the District of Massachusetts.

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Forest has transacted business in this District.

III. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"); the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administers the Medicaid program; and the Department of Defense, which administers the TRICARE/CHAMPUS program ("TRICARE") (collectively, "federal health care programs").

11. Relator Christopher R. Gobble is a resident of Virginia and a former employee of Forest. In March 2003, Mr. Gobble filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

12. Relator Joseph Piacentile is a resident of New Jersey. On August 20, 2001, Mr. Piacentile filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

13. Defendant Forest Labs is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York. Forest Labs has a license from H. Lundbeck A/S ("Lundbeck"), a Danish company, to promote and sell Celexa and Lexapro in the United States.

14. Defendant Forest Pharmaceuticals is a wholly owned subsidiary of Forest Labs

with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals manufactures, distributes, and sells Forest prescription products in the United States.

IV. THE LAW

A. The False Claims Act

15. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government. 31 U.S.C. § 3729(a)(1).

16. The FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

17. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for

violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

18. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The statute was enacted in 1972; Congress strengthened it in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

19. The AKS prohibits any person or entity from offering, making, or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> * * *
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

20. Under the AKS, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to prescribe drugs for which payment may be made by federal health care programs.

21. The AKS not only prohibits outright bribes, but also prohibits any remuneration by a drug company to a physician that has as one of its purposes inducement of the physician to write prescriptions for the company's pharmaceutical products.

V. THE FEDERAL HEALTH CARE PROGRAMS

A. The Medicaid Program

22. The Medicaid program is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program and receives funding from the federal government, known as federal financial participation, based upon a formula set forth in the federal Medicaid statute.

23. Before the beginning of each calendar quarter, each state submits to CMS an

estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as actual provider claims are presented for payment). After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding (to reconcile the estimated expenditures to actual expenditures).

24. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

25. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

26. While federal drug coverage is an optional benefit available to the states, most states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

27. The Medicaid Rebate Statute generally prohibits federal financial participation for a covered outpatient drug unless there is a rebate agreement in effect with the manufacturer for that drug. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a state is generally required to cover that drug under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

28. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for

inclusion in any of the compendia" set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

29. A drug does not generally meet the definition of a "covered outpatient drug" if it is being prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. §§ 1396r-8(k)(2)(A), (k)(3).

30. Thus, even if a drug is FDA-approved for a certain indication, Medicaid ordinarily does not cover off-label uses that do not qualify as medically accepted indications. Many state Medicaid programs prohibit covering such uses. *See, e.g.*, 40-850-026 DEL. CODE REGS. § 3.5.4.1 (2008); IND. CODE § 12-15-35-4.5 (2008); N.J. ADMIN. CODE § 83C-1.14(1) (2008); N.M. CODE R. § 8.325.4 (2008).

B. The TRICARE Program

31. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

32. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

33. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. §199.4(g)(15)(i)(A)(Note). TRICARE will not knowingly provide reimbursement for off-label use if the prescriptions result from illegal off-label marketing.

VI. FOREST'S SCHEME

A. The Celexa And Lexapro Labels

34. Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRIs") drugs. Lundbeck developed both Celexa and Lexapro, which contains the active agent in Celexa, and subsequently licensed both drugs to Forest for marketing in the United States. Forest began selling Celexa in 1998. In 2002, with Celexa soon due to face generic competition, Forest began selling Lexapro.

1. The FDA Has Not Approved Celexa Or Lexapro For Pediatric Use.

35. In 1998, the FDA approved Celexa for the treatment of adult depression. The FDA never approved Celexa for treatment of any conditions other than adult depression, or for any pediatric use.

36. In 2002, the FDA approved Lexapro for the treatment of adult depression. In 2003, Lexapro received approval for treatment of Generalized Anxiety Disorder ("GAD") in adults. Lexapro has not been approved for any other conditions and was not approved for pediatric use.

37. The use of Celexa and Lexapro in pediatric patients is not supported by a citation included or approved for inclusion in any of the compendia. The use of Celexa and Lexapro in pediatric patients is not a "medically accepted" indication for those drugs.

38. If a manufacturer conducts pediatric clinical studies on a drug, a manufacturer may obtain an additional six months of patent exclusivity for the previously-approved, on-label

indications for that particular drug subject to certain FDA requirements. 21 U.S.C. § 355a. In such circumstances, the FDA issues a "Written Request" that details the studies that should be performed. 21 U.S.C. § 355a(c)(2)(A).

39. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa." On April 28, 1999, the FDA issued a Written Request to Forest to conduct "two independent, adequate and well-controlled clinical trials in pediatric depression" for Celexa.

40. On September 24, 1999, Forest submitted to the FDA protocols for two pediatric studies: 1) a double-blind, placebo-controlled pediatric study being conducted in Europe by Lundbeck (the "Lundbeck study"); and 2) a double-blind, placebo-controlled pediatric study to be conducted in the United States by Forest through University of Texas child psychiatrist Karen Wagner (the "Wagner study").

41. In mid-2001, the Wagner and Lundbeck studies were unblinded and their results were disseminated to senior Forest executives. The Wagner study was positive, *i.e.*, it indicated that Celexa was more effective than placebo in treating pediatric patients suffering from depression, but the Lundbeck study was negative, *i.e.*, it did not show Celexa to be any more effective than placebo in treating pediatric depression. Furthermore, in the Lundbeck study, 14 of the patients taking Celexa attempted suicide or reported suicidal ideation (*i.e.*, contemplation of suicide) compared to only 5 patients taking placebo. Under one statistical test, this result was "significant," and, under another statistical test, it was "borderline significant."

42. On April 18, 2002, Forest submitted the results of both the Lundbeck and Wagner studies to the FDA in support of requests for both a six-month extension of patent exclusivity

and a pediatric indication for Celexa. Forest's submission to the FDA was not public.

43. On July 15, 2002, the FDA granted Celexa six additional months of patent exclusivity for the on-label use of treating depression in adults.

44. On September 23, 2002, the FDA denied Forest's request for a pediatric indication for Celexa. The FDA concluded that the Lundbeck study "is a clearly negative study that provides no support for the efficacy of citalopram in pediatric patients with [major depressive disorder]."

2. The FDA-Mandated Black Box Warnings On The Celexa And Lexapro Labels

45. On March 22, 2004, the FDA issued a public health advisory requesting that certain SSRI manufacturers, including Forest, change the labels on their SSRI drugs to include "a [w]arning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality."

46. Later that year, the FDA directed the SSRI manufacturers, including Forest, to include on their labels a black box warning and expanded statements to alert physicians about the potential for increased risk of suicidality in children and adolescents taking SSRIs. The black box warning specifically stated that "[a]ntidepressants *increased the risk* of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." (Emphasis added). In addition, the FDA required SSRI manufacturers to state, in relevant part, that:

> The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in

> children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants.

47. The Lundbeck study on pediatric use of Celexa was one of the 24 trials considered by the FDA in mandating this warning.

48. Forest revised the Celexa and Lexapro labels in early 2005 to include the required black box warning and to state under each label's "Pediatric Use" subheading that "[s]afety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS-Clinical Worsening and Suicide Risk)." The Celexa label further stated that "[t]wo placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients," while the Lexapro label stated that "[o]ne placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients."

49. In 2007, the Celexa and Lexapro labels were again modified to state that, after evaluating the pooled analyses of placebo-controlled SSRI trials in children and adolescents and of trials in adults, "[t]here was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied."

50. To date, Forest has not obtained FDA approval for a pediatric indication for Celexa or Lexapro. Both the Celexa and Lexapro labels currently include black box warnings explicitly indicating that the safety and efficacy of the drugs in the pediatric population have not

been established.

B. Forest's Dissemination Of Half Truths As A Result Of Its Failure To Disclose The Results Of The Negative Lundbeck Study

51. Although Forest submitted the Lundbeck study to the FDA in 2002 in order to seek a six-month extension of patent exclusivity for Celexa (which Forest later valued at $485 million), Forest failed otherwise to disclose the negative study beyond a small group of its senior executives. At the same time, Forest aggressively promoted the Wagner study, thereby relaying the false impression that the only available pediatric data on Celexa was positive.

52. Although the Forest senior executives learned about the negative Lundbeck results in mid-2001, Forest failed for the next three years to disclose that negative data to, among others: its thousands of sales representatives who were detailing pediatric specialists; pediatric specialists whom it hired to give promotional speeches on Celexa and Lexapro; the members of its Executive Advisory Board of leading psychiatrists upon whom it ostensibly relied for advice concerning new data and upon whom it also relied to convey information to others; its own Professional Affairs Department, which it charged with disseminating "balanced" information in response to physician requests for available data on Forest drugs; or even its own pediatric researchers such as Dr. Wagner.

53. During this same time period, Forest took aggressive steps to publicize the positive results of the Wagner study. On August 27, 2001, Forest presented the Wagner study results to its Executive Advisory Board without making any mention of the contemporaneous negative Lundbeck results. Forest thereafter arranged for Dr. Wagner to present a poster summary of the Wagner study to various professional groups, including the American Psychiatric

Association, the American College of Neuropsychopharmacology, and the Collegium Internationale Neuro-Psychopharmalogicum. In conjunction with these presentations, Forest coordinated the "placement" of news stories about the positive Wagner data in numerous national and local media outlets.

54. Over the course of 2002, Forest arranged for Dr. Wagner to give promotional presentations on the pediatric use of Celexa and to serve as the chair of a seven-city Continuing Medical Education ("CME") program on treating pediatric depression. Forest also sponsored 20 CME teleconferences that addressed the Wagner study results.

55. Forest's simultaneous failure to disclose the negative Lundbeck study results and wide publication of the positive Wagner study results caused Forest and its consultants to make false or misleading statements. For example, because not even Dr. Wagner was aware of the negative Lundbeck data, she never discussed that data in her many Forest-sponsored talks addressing the pediatric use of Celexa and Lexapro. Her slide presentations addressed negative studies on pediatric use of other SSRIs, but falsely indicated that there were no negative studies on the pediatric use of Celexa.

56. Forest's failure to disclose the negative Lundbeck results to the members of Forest's Executive Advisory Board caused those members to make false or misleading statements in promotional teleconferences on Celexa and Lexapro. During the teleconferences, which were targeted to large numbers of physicians across the country, the Forest Executive Advisory Board members represented, based on the Wagner data, that Celexa was safe and effective for pediatric use even though, unbeknownst to them, the FDA had specifically rejected

Forest's attempt to gain approval for such a claim because of the negative Lundbeck data.

57. During details to physicians, Forest's sales representatives made false or misleading representations by distributing off-label publications on the pediatric use of Celexa and Lexapro that did not include the negative Lundbeck data. Forest sales managers, also unaware of the Lundbeck data, directed the dissemination of these publications.

58. Forest had a Professional Affairs Department that responded to health care provider inquiries. Under the company's own written policy, the Professional Affairs Department was:

> *required to provide balanced information* to help the health care practitioner (HCP) make the best decision on behalf of the patient. For this reason, *there is an ethical prohibition in "cherry picking" studies that are favorable to Forest products*. The Food and Drug Administration Division of Drug Marketing, Advertising, and Communications (DDMAC) monitors drug information departments to insure information provided to HCPs is balanced, and that it is not selective.

(Emphasis added.) Forest's failure to disclose the negative Lundbeck data to its Professional Affairs Department caused it to disseminate misleading information to physicians on the pediatric use of Celexa and Lexapro. When physicians sought information from Forest's Professional Affairs Department in the years following the un-blinding of the Wagner and Lundbeck studies, the Professional Affairs Department responded with letters that cited only positive data. The letters cited just one double-blind placebo-controlled trial on the use of Celexa to treat pediatric depression, the Wagner Study. The letters never mentioned that there was another, negative, double-blind placebo-controlled trial, the Lundbeck study.

59. Several senior Forest executives – including Lawrence Olanoff (then Forest's

Chief Scientific Officer and now its President), Ivan Gergel (Vice President of Clinical Development and Medical Affairs), and Amy Rubin (Director of Regulatory Affairs) – reviewed the letters before the Professional Affairs Department disseminated them. All of these senior Forest executives knew about the negative Lundbeck data.

60. Forest paid a medical writing firm to ghost-write an academic article on the Wagner study, and Forest arranged to have the article published in the June 2004 issue of *The American Journal of Psychiatry*, with Dr. Wagner listed as the lead author. The article did not mention that the only other double-blind, placebo-controlled trial on pediatric use of Celexa had shown no efficacy and had an incidence of suicide attempts and suicidal ideation among those taking Celexa that was almost three times higher than in the group taking the placebo.

61. On June 21, 2004, *The New York Times* published a news story titled "Medicine's Data Gap – Journals in a Quandry; How to Report on Drug Trials." The story featured *The American Journal of Psychiatry* article on the Wagner study, revealing the negative results of the Lundbeck study and noting that the Wagner article failed to mention them.

62. Three days after the story ran, Forest issued a press release acknowledging the existence of the Lundbeck study and its finding that Celexa "did not show efficacy versus placebo." That same day, Forest also disclosed the results of an earlier double-blind placebo-controlled study of Lexapro in children and adolescents. That study also failed to show efficacy in comparison to placebo.

63. By failing to disclose the Lundbeck study results, which raised serious questions about the efficacy and safety of Celexa, while simultaneously promoting the Wagner study,

Forest told prescribing physicians a half-truth and thereby prevented them and the public from having all potentially available information when making decisions about how to treat a serious medical condition in pediatric patients.

64. Forest's conduct regarding the Lundbeck study results was consistent with the way it handled prior negative study data on Celexa. Just a few months before the pediatric Lundbeck study was unblinded, senior executives from Forest and Lundbeck discussed whether publicly to disclose the negative results from a study of Celexa in a primary care population. The study included three groups: patients taking Lexapro, patients taking Celexa, and patients taking placebo. Although Lexapro showed efficacy versus the placebo in the study, Celexa did not. Minutes of a December 2000 meeting of senior Forest and Lundbeck executives show that Forest wanted to publicize only the Lexapro versus placebo results, while Lundbeck wanted the results from the entire study to be publicly disclosed. As Lundbeck executives noted a month earlier, "Forest made clear their concern over disclosing any data that could put Celexa in an unfavorable light." In May 2001, Lundbeck executives observed that "Forest are at the moment unwilling to release data where citalopram does not sufficiently surpass placebo." Forest ultimately prevailed over Lundbeck and, as it did later with Lundbeck's negative pediatric data, kept the negative Celexa versus placebo results confidential.

C. Forest's Fraudulent Course Of Conduct To Promote Celexa And Lexapro For Off-Label, Pediatric Use

65. To obtain FDA approval for a drug, a drug must be demonstrated to be safe and effective for each of its proposed uses. The approved uses for a drug are limited to those uses identified in the FDA-approved product label. *See* 21 U.S.C. § 355(a), (b). "Off-label" use

refers to the promotion of an approved drug for any purpose, or in any manner, other than what is described in the drug's FDA-approved labeling.

66. From 1998 through at least 2005, Forest engaged in a widespread campaign to promote Celexa and Lexapro for pediatric use, even though neither drug was approved for pediatric use and the science was, at best, inconclusive about the safety and efficacy of these drugs for pediatric use. Forest used its sales representatives to detail or target pediatric specialists; paid pediatric specialists to give promotional speeches to other physicians on pediatric use; selectively distributed publications on pediatric uses to pediatric specialists; misrepresented the safety and effectiveness of the drugs; and made extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses.

67. Forest knew that its off-label promotion for pediatric use was unlawful. Shortly before the FDA ordered the black box warning in September 2004, a Forest executive testified before Congress: "I want to emphasize that, because the FDA has not approved pediatric labeling for our products, Forest has always been scrupulous about not promoting the pediatric use of our antidepressant drugs, Celexa and Lexapro. That is the law, and we follow it." In fact, Forest had been illegally promoting the pediatric use of Celexa and Lexapro throughout the preceding six years.

68. Forest assigned its sales representatives to specific geographic regions across the United States. Within each region, sales representatives encouraged specific doctors to increase their prescriptions of Celexa and Lexapro. A specific component of this marketing scheme included the promotion of Celexa and Lexapro for pediatric indications.

69. From 1998 through the end of 2004, the lists of physicians whom Forest directed its sales representatives to target, also known as "call panels," included thousands of child psychiatrists, pediatricians, and other physicians who specialized in treating children. Forest had more than 500,000 promotional sales calls or "details" with these pediatric specialists. The sales representatives documented these details through "call notes." Forest recorded thousands of call notes evidencing pediatric promotion. Examples of such notes include the following:

- "discussed cx [Celexa] use in children . . . and results of dr. karen wagner study regarding cx use for children and adolescents."
- "went over peds use, 0 drug interactions, less ae, less compliance issues for children, he is sold on that. closed on keeping cx first choice."
- "went over Celexa children, the invitation to the winery."
- "[doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!"
- "discuss lx [Lexapro] brief and what he [is] using dosing w children . . . reinforce safety for children."
- "Let him know some child psychs are using LX for children."
- "Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat the anxiety and depression and OCD."
- "dinner program [with child psychiatrist as speaker] at amato's with yale child study center."
- "focus on Lexapro efficacy at just 10mg..great choice for child/adolescents."
- "mainly sees children but always felt comfortable with CX & children - got his commitment to give [Lexapro] a fair clinical trial."

- "went over lxp use on children and efficacy."

Call notes such as these represent only some of the instances when sales representatives memorialized their illegal off-label promotion of Celexa and Lexapro. The call notes exemplify the tip of what was a much more pervasive and widespread off-label campaign.

70. Forest's headquarters office in New York maintained a list of "approved" promotional speakers that included numerous pediatric specialists. Forest sales representatives and managers identified speakers from these lists to organize promotional lunches and dinners on Celexa and Lexapro. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on off-label pediatric use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Updates in Depression," "Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment Options in Depressive Disorders in Adolescents," "New Age Depression Treatment," "Use of Antidepressants in Adolescents," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children," "Adolescents, and Adults," "Celexa in CHP/Ped Practice," "Treating Difficult Younger Patients," "Treatment of Depression," "Assessment and Treatments of Suicidal Adolescents," and "Treating Pediatric Depression." Forest management approved each of these programs.

71. From 1999 through 2006, one pediatric specialist, Dr. Jeffrey Bostic, Medical Director of the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital, gave more than 350 Forest-sponsored talks and presentations, many of which addressed

pediatric use of Celexa and Lexapro. Dr. Bostic's programs, which took place in at least 28 states, had topics such as "Uses of Celexa in Children" and "Celexa Use in Children and Adolescents." Forest also paid Dr. Bostic to meet other physicians in their offices in order to ease their concerns about prescribing Celexa or Lexapro off-label for pediatric use.

72. Dr. Bostic became Forest's star spokesman in the promotion of Celexa and Lexapro for pediatric use. As one sales representative wrote, "DR. BOSTIC is the man when it comes to child Psych!" Between 2000 and 2006, Forest paid Bostic over $750,000 in honoraria for his presentations on Celexa and Lexapro.

D. Forest's Illegal Inducements To Physicians To Prescribe Celexa And Lexapro

73. Forest augmented its off-label promotion efforts through extensive payments and gifts to physicians to induce them to prescribe Celexa and Lexapro. Forest's marketing department directed some of the kickbacks, such as honoraria for participation in advisory boards and in a large marketing study on Lexapro. Forest's sales representatives, often acting with the knowledge and encouragement of their managers, arranged for other kickbacks, such as restaurant gift certificates for physicians, lavish entertainment of physicians and their spouses, and grants to individual physicians.

1. Advisory Boards

74. Between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro, with over 19,000 advisory board attendees that Forest called "consultants." Forest paid each "consultant" an honorarium of $500.

75. Ostensibly, Forest paid physicians to attend these advisory boards to get their

feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal company documents, Forest intended that the advisory boards induce the attendees to prescribe more Celexa and Lexapro.

76. In a May 2000 proposal for a series of 44 Celexa advisory boards, a Forest contractor, Intramed, wrote that the advisory boards, each with 20 physicians attendees, would "give Forest an opportunity to influence more physicians." Forest's marketing department approved this proposal. Later that year, Steve Closter, the Forest marketing executive who organized the advisory boards, wrote that the Celexa advisory boards begun in June 2000 had been successful and, as a result, "will become an even larger part of the promotional mix in the future." For years thereafter, Forest's marketing department included the cost of advisory boards in its annual promotional budgets for Celexa and Lexapro.

77. With the early success of the advisory board programs, the Forest sales force enthusiastically used them to drive up sales. As one Forest District Manager told his Regional Director in a November 2000 planning document, he intended to conduct a local advisory board to "target[] the highest prescribers" in several of his territories because "[t]here is no doubt that a program of this magnitude will increase Celexa market share." In approximately January 2002, a marketing strategy slide deck given to Forest's chief executive, Howard Solomon, quoted a Regional Director stating that, "[w]ell planned Advisory Board meetings will be key to our efforts of reaching hesitant physicians."

78. In June 2002, Forest's two Vice Presidents of Sales sent a memorandum to all sales managers observing that, notwithstanding new promotional guidelines for the industry,

advisory boards remained among "the wealth of activities and programs that we can conduct that will impact physicians." Similarly, in August 2002, a Forest Regional Director sent an e-mail to his District Managers stating that, "[w]ith the new guidelines in place, Ad Boards have become even a more valuable resource, thus each one needs to be a home run! With your attention and focus, we can make [*sic*] maximize this opportunity!"

79. In the fall of 2002, to coincide with the launch of Lexapro, Forest conducted a series of 200 advisory boards reaching over 4,000 potential new Lexapro prescribers.

80. Forest monitored its return on investment, or "ROI," from the advisory boards. To conduct its ROI analyses, Forest measured the increase in prescriptions written by physicians that attended the local advisory boards, and then compared the value of those prescriptions to the cost – primarily the honoraria payments – of putting on the programs. A November 2000 ROI analysis of a single advisory board program reached the following conclusion:

> Post program the Ad Board group [24 attendees] wrote an average of 19.6% Celexa as measured by a 5-week 1st Rx average. This is an increase of 3.7% in share. At first glance, the share increase might not appear substantial. However, considering the volume of SSRIs written by these physicians, 3.7% translates into almost 2000 new prescriptions on a yearly basis.

81. In May 2001, an internal ROI analysis of all of the Celexa advisory boards in 2000 found that "participants in the program prescribed nearly 14 additional prescriptions of Celexa vs. the control group over a seven-month period."

82. Three months later, in August 2001, the author of the ROI analysis reiterated to the Celexa marketing team that, "[o]ur goal is to increase the ROI on these advisory boards." That same month, a Forest Regional Director reported to the company's Vice President of Sales

that three local advisory boards had "generated close to $30K" from just a subset of the attendees and that "the scripts will continue, and continue to generate additional $$$ and ROI."

83. After 2003, Forest stopped conducting ROI analyses of advisory boards because of concerns about memorializing illegal intent, but the company continued to use the same types of advisory board programs as a means of inducing doctors to prescribe Celexa and Lexapro. As a Forest Area Business Director noted in a September 2003 memorandum to his Regional Directors, "[w]e are not able to do as many Ad Boards as we have in the past, so it [is] critical that we get the best targets to the programs." Similarly, in March 2004, a Texas-based Forest District Manager reported to her Regional Director and fellow District Managers that she had met with her sales team about "the types of doctors" they wanted to recruit for an upcoming advisory board and that they had come "up with 40 doctors that are either high Celexa writers or can be converted/persuaded to write Lexapro." In August 2004, a Massachusetts District Manager wrote to his colleagues and sales team that, for an upcoming Lexapro advisory board, "we are looking for the best ROI."

2. The EXCEED Study

84. In 1998, Forest successfully used a so-called "seeding study" – a clinical study intended to induce participating physicians to prescribe the drug under study – as part of the promotional strategy for the launch of Celexa. With the launch of Lexapro in 2002, Forest sought to replicate the success of the Celexa seeding study. Forest called the Lexapro seeding study EXCEED (EXamining Clinical Experience with Escitalopram in Depression).

85. In the planning stages for EXCEED, a senior Forest marketing executive wrote

that the purpose of the study was to ensure a "fast uptake" for Lexapro. The overall Lexapro marketing plan, which was reviewed by the company's most senior executives, stated:

> Another component of the rapid uptake of Lexapro will be to encourage trial. The experience trial for Lexapro (EXCEED) will follow approval and will be larger in scope than the Celexa experience trial (EASE). More prescribers will have the ability to trial Lexapro on several patients to gain experience. Trial leads to adoption and continued usage of a product if a prescriber has successful results.

At the conclusion of EXCEED, Forest's marketing department planned to calculate the study's "ROI," *i.e.*, the number of prescriptions generated as compared against the cost of funding the study.

86. To the extent the EXCEED trial had a scientific purpose, it was secondary to the purpose of inducing participating physicians to prescribe Lexapro. Forest conceived the study as a promotional tool and then sought out company scientists "to discuss possible endpoints/outcomes to look at for our early usage trial." Forest hired Covance, a contract research organization, to conduct the study, but, according to Covance's own study implementation plan, Covance, too, understood that "the primary goal of this trial is to provide experience to physicians." Similarly, Forest openly referred to the EXCEED trial as a "seeding" study in their internal communications.

87. Forest aimed the EXCEED study at 2,000 physicians. Under the study protocol, each participating physician could enroll up to five patients in the study, which would last eight weeks and involve three patient visits. After the first visit, the physician would fill out a one-page form with the patient's age, race, gender, and basic medical history, and Forest would pay the physician $50. After each of the next two visits, the physician would fill out an additional

page requiring the physician to write the date of the visit and to check one of seven boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference.

88. By the time the EXCEED study was completed, Forest had made study participation payments to 1,053 physicians, who in turn put 5,703 patients on Lexapro during the course of the study.

3. Preceptorships

89. Between 1999 and 2003, Forest paid millions of dollars to physicians who participated in so-called "preceptorships." Each physician who participated in a preceptorship received a "grant" of as much as $1,000 per preceptorship.

90. Ostensibly, preceptorships were a training opportunity where Forest sales representatives would spend a half-day or full day with a physician and learn about how Celexa and Lexapro were used in practice. In reality, Forest sales representatives used the preceptorships to induce physicians to prescribe Celexa and Lexapro.

91. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out "Return on Investment (R.O.I.)" forms to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a

statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify the cost to Forest. Senior Forest sales managers and headquarters staff reviewed and approved the completed preceptorship ROI forms.

92. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments, included the following:

- "Dr. ___ is the managing partner of the '____ Psychiatric Group' and is very influential among his colleagues in the ___ Hospital network. He currently averages @ 12 per week on 1st RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. ___."
- "Dr. ___ is the largest prescriber of SSRI's in a 3 state area. . . . We are currently her first line SSRI. We must, however, continue to support her monetarily or this will not continue to be the case. . . . We have to keep the pressure on to continue to receive the growth we are getting with Dr. ___."
- "Dr. ___ is my largest prescribing Celexa physician. He is a high maintenance target and doing round tables and preceptorships will help me to keep his business and to continue to grow his business."
- "2 different preceptorhsips. Doc is 3rd ranked phys. in SSRI potential + bus had dropped. Needed his full attention."
- "Dr. ___ is my fourth largest SSRI writer. . . . A preceptorship will provide opportunity for rapport and for future detail time and sales."
- "# 1 physician in Territory. . . . Dr. ___ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship."

- "This full day preceptorship will give me the opportunity to sell Celexa as a first-line choice in doctor ___'s practice."

- "To influence doctor to Rx Celexa."

Forest approved all of these preceptorship payment justifications.

4. Lavish Entertainment And Gifts

93. During the period from 1998 through at least 2005, each Forest sales representative typically had a quarterly marketing budget of thousands of dollars to spend on physicians. As a Forest Regional Director put it in an April 2006 memo to his sales team, "we have a ton of promotional money." Forest sales managers put pressure on their sales representatives to spend their entire marketing budgets.

94. Prior to 2003, Forest sales representatives commonly spent their marketing money on fishing, golf, and spa outings for physicians, and on buying tickets to sporting events and the theater for physicians. Both prior to and after 2003, Forest sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."

- In September 2002, a sales representative gave a high-prescribing

child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.

- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.

- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.

- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.

- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."

- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.

- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would "always rxlex [*i.e.*, prescribe Lexapro] #1 aslong [*sic*] as we have fun and take care of him."

95. All of this spending was intended to induce physicians to prescribe Celexa or Lexapro.

VII. FALSE CLAIMS

96. As a result of Forest's fraudulent course of conduct, Forest caused the submission of false or fraudulent claims for Celexa and Lexapro to federal health care programs. These claims were not reimbursable because they were not covered for off-label pediatric use and/or

were ineligible for payment as a result of illegal kickbacks.

97. The chart set forth below identifies examples of false or fraudulent claims caused by Forest's off-label promotion. The chart includes: (a) the prescribing physician; (b) the number of promotional sales calls by Forest to each physician; (c) the number of pediatric Medicaid claims resulting from that physician; and (d) the amount paid for those pediatric claims by Medicaid.

CELEXA			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. A.	58	1927	$110,865
Dr. B.	70	977	$70,311
Dr. C.	133	871	$85,980
Dr. D.	58	777	$42,568
Dr. E.	33	586	$44,280
Dr. F.	50	589	$39,807
LEXAPRO			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. G.	257	1769	$197,052
Dr. H.	118	7790	$428,627
Dr. I.	76	4565	$251,378
Dr. J.	192	3219	$229,469
Dr. K.	296	2441	$252,879

98. The chart set forth below provides examples of false or fraudulent claims caused by Forest's illegal kickbacks to a physician, Dr. L. The chart identifies: (a) the year; (b) the type

of meeting or event Dr. L attended; (c) the amount paid to Dr. L; (d) the number of claims resulting from Dr. L; and (e) the amount paid for those claims by Medicaid.

Year	Type of Meeting or Event	Amount Paid	Claims	Medicaid Payment
2000	Advisory Boards	$500	197	$12,867
2001	Advisory Boards/Speaker Programs	$1,250	221	$14,646
2002	Advisory Boards/Speaker Programs/ Sponsorships	$2,500	367	$25,570
2003	Advisory Boards/Speaker Programs/Sponsorships	$10,250	302	$21,175
2004	Sponsorships	$500	272	$20,402

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

99. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

100. Forest knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use, and/or were ineligible for payment as a result of illegal kickbacks.

101. By virtue of the false or fraudulent claims that Forest caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION
(Unjust Enrichment)

102. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

103. The United States claims the recovery of all monies by which Forest has been unjustly enriched.

104. As a consequence of the acts set forth above, Forest was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Forest as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the damages sustained and/or amounts by which Forest was unjustly enriched or by which Forest retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

MICHAEL F. HERTZ
ACTING ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

Dated: February 13, 2009 By: 

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3366

JOYCE R. BRANDA
JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 305-0546

FILED UNDER SEAL

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

UNITED STATES OF AMERICA, ex rel. JAMES WETTA,	)	
Plaintiff,	)	C.A. No. 04-3479
v.	)	Filed Under Seal
ASTRAZENECA CORPORATION,	)	
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 above-captioned action pursuant to 31 U.S.C. §3730(b) for the purposes of settlement and dismissal.

The United States, relator James Wetta and defendant AstraZeneca have reached an amicable resolution of these matters. A copy of the Settlement Agreement is attached as Exhibit A. The parties agree that, upon receipt of the Settlement Amount as defined in the Settlement Agreement, the United States and relator will file a Stipulation of Dismissal in accordance with

the terms of the Settlement Agreement.

Respectfully submitted,

MICHAEL L. LEVY
United States Attorney

Virginia A. Gibson

VIRGINIA A. GIBSON
First Assistant United States Attorney

COLIN M. CHERICO
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 and the United States Attorney's Office for the Eastern District of Pennsylvania, the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity ("TMA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"); James Wetta ("Wetta"); Stephan Kruszewski, M.D. ("Kruszewski"); and Astra Zeneca LP and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"), 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. AstraZeneca LP and AstraZeneca Pharmaceuticals LP are Delaware limited partnerships with their principal places of business in Wilmington, Delaware. At all relevant times herein, AstraZeneca distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Seroquel.

B. On July 24, 2004, Wetta filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. James Wetta v. AstraZeneca Corporation, Civil Action No. 04-3479 (hereinafter "Civil Action I").

C. On September 8, 2006, Kruszewski filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. Stephan Kruszewski v. AstraZeneca Pharmaceuticals LP, Civil Action No. 06-4004

(hereinafter "Civil Action II"). Civil Action I and Civil Action II hereinafter may be referred to collectively as the "Civil Actions."

D. AstraZeneca has entered or will be entering into separate settlement agreements, described in Paragraph 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 AstraZeneca executes a Medicaid State Settlement Agreement in the form to which AstraZeneca and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by AstraZeneca and an individual State, shall be defined as "Medicaid Participating States."

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

F. The United States further alleges that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395hhh; the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 et seq; and caused purchases of Seroquel by the Department of Veterans' Affairs ("DVA"), Department of Defense, and the Bureau of Prisons ("BOP") (collectively, the "other Federal Health Care Programs").

G. The United States contends that it has certain civil claims, as specified in Paragraph 2, below, against AstraZeneca for engaging in the following conduct during the period January 1, 2001 through December 31, 2006 (hereinafter referred to as the "Covered Conduct"):

(1) AstraZeneca promoted the sale and use of Seroquel to psychiatrists, other physicians (including primary care physicians) and other health care professionals in pediatric and primary care physician offices, in long-term care facilities and hospitals and in prisons for certain uses that were not approved by the Food and Drug Administration as safe and effective for those uses (including aggression, Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness) ("unapproved uses"). AstraZeneca also promoted the unapproved uses by engaging in the following conduct: AstraZeneca improperly and unduly influenced the content of and speakers in company-sponsored Continuing Medical Education programs; engaged doctors to give promotional speaker programs it controlled on unapproved uses for Seroquel; engaged doctors to conduct studies on unapproved uses of Seroquel; recruited doctors to serve as authors of articles largely prepared by medical literature companies about studies they did not conduct on unapproved uses of Seroquel; and, used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel. These unapproved uses were not medically accepted indications for which the United States and the state Medicaid programs provided coverage for Seroquel.

(2) AstraZeneca offered and paid illegal remuneration to doctors: (a) it recruited to conduct studies for unapproved uses, (b) it recruited to serve as authors of articles written by AstraZeneca and its agents about these unapproved uses of Seroquel, (c) to travel to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses of Seroquel, and (d) it recruited to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel. The United States contends that these payments were intended to induce the doctors to promote and/or prescribe Seroquel for unapproved uses in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b).

As a result of the foregoing conduct, the United States contends that AstraZeneca knowingly caused false or fraudulent claims for Seroquel to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

H. The United States also contends that it has certain administrative claims against AstraZeneca, as set forth in Paragraphs 4 through 6, below, for engaging in the Covered Conduct.

I. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by AstraZeneca nor a concession by the United States that its claims are not well founded. AstraZeneca expressly denies the allegations of the United States, the Medicaid Participating States, Wetta and Kruszewski as set forth herein and in Civil Action I and Civil Action II and denies that it has engaged in any wrongful conduct. Neither this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, are intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by AstraZeneca.

J. 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

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. AstraZeneca agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of Five Hundred and Twenty Million Dollars ($520,000,000), plus

accrued interest at the rate of 3% per annum from December 1, 2009, and continuing until and including the date of payment (the "Settlement Amount"). Payments shall be made as follows:

(a) AstraZeneca shall pay to the United States the sum of $301,907,007, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than ten (10) business days after the Effective Date of this Agreement.

(b) AstraZeneca shall pay to the Medicaid Participating States the sum of $218,092,993, plus accrued interest as set forth above ("Medicaid State Settlement Amount") pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that AstraZeneca will enter into with the Medicaid Participating States.

(c) Contingent upon the United States receiving the Federal Settlement Amount from AstraZeneca, the United States agrees to pay, as soon as feasible after receipt, to Wetta $45,286,051, plus a pro rata share of the actual accrued interest paid to the United States by AstraZeneca, as set forth in Paragraph 1(a), above, ("Relator's Share") as relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d). No other relator payments of any sort shall be made by the United States to Wetta and/or Kruszewski with respect to the matters covered by this Agreement.

(d) Wetta and Kruszewski have entered into a separate agreement under which Kruszewski will receive a portion of the Relator's Share.

2. Subject to the exceptions in Paragraph 7, below, in consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of

the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release AstraZeneca, together with AstraZeneca's predecessors, current and former parents, affiliates, direct and indirect subsidiaries, brother or sister entities, divisions, transferees, successors and assigns, and all of their current or former directors, officers and employees (hereinafter, collectively "AstraZeneca Releasees") 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; any statutory provision 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); or the common law theories of payment by mistake, unjust enrichment, fraud, disgorgement of illegal profits, and, if applicable, breach of contract.

3. In consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, Wetta and Kruszewski, for themselves and for their heirs, successors, attorneys, agents, and assigns, fully and finally release the AstraZeneca Releasees from any claim the United States has, may have or could have asserted related to the Covered Conduct, and from all liability, claims, demands, actions or causes of action whatsoever existing as of the Effective Date of this Agreement, whether 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 or their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including any liability arising from the filing of the Civil Actions, except for any claims they may have under 31 U.S.C. § 3730(d) and/or 31 U.S.C.

§ 3730(h).

4. In consideration of the obligations of AstraZeneca in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and AstraZeneca, conditioned upon AstraZeneca's full payment of the Settlement Amount, 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 AstraZeneca 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 7 below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude AstraZeneca 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 7, below.

5. In consideration of the obligations of AstraZeneca set forth in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program, against AstraZeneca under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7, below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude AstraZeneca 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 AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action, against AstraZeneca under 5 U.S.C. § 8902a or 5 C.F.R. Part 919 or Part 970 for the Covered Conduct, except as reserved in Paragraph 7, below and except as 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, the following claims of the United States are specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including AstraZeneca, Wetta and/or Kruszewski):

(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;

(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 goods or services due.

8. Wetta and Kruszewski and 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) and, conditioned upon the United States' payment of the Relator's Share, as set forth in Paragraph 1(c), above, Wetta and Kruszewski, for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge the United States, and 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 Civil Action I and/or Civil Action II; and from any other claims for a share of the Settlement Amount or payment of any sort from the United States relating to the Settlement Agreement or the filing of Civil Action I and/or Civil Action II; and in full settlement of any claims Wetta and/or Kruszewski 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 Wetta and/or Kruszewki arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. AstraZeneca waives and shall not assert any defenses AstraZeneca 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. 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. AstraZeneca 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 AstraZeneca 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.

11. Conditioned upon Wetta and Kruszewski's compliance with their obligations under this Agreement, AstraZeneca fully and finally releases Wetta and Kruszewski from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that AstraZeneca has asserted, could have asserted, or may assert in the future against Wetta and/or Kruszewksi, related to the Covered Conduct and Wetta and/or Kruszewski's investigation and prosecution thereof, except to the extent related to claims Wetta or Kruszewski may have under 31 U.S.C. § 3730(d) and/or 31 U.S.C. § 3730(h).

12. 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 other state or Federal payer, related to the Covered Conduct; and AstraZeneca agrees not to resubmit to any Medicare carrier or intermediary or any other state or Federal payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such

denials of claims.

13. AstraZeneca agrees to the following:

(a) Unallowable Costs Defined: 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. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of AstraZeneca, 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 FEHBP:

(i) the matters covered by this Agreement;

(ii) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(iii) AstraZeneca's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(iv) the negotiation and performance of this Agreement;

(v) the payment AstraZeneca makes to the United States pursuant to this Agreement and any payments that AstraZeneca may make to Wetta and/or Kruszewski, including costs and attorneys fees; and

(vi) 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 the OIG-HHS.

However, nothing in this paragraph 13(a)(vi) 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 AstraZeneca. (All costs described or set forth in this Paragraph 13(a) are hereafter "Unallowable Costs.")

(b) Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately determined and accounted for by AstraZeneca, and AstraZeneca 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 AstraZeneca 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, AstraZeneca 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 AstraZeneca 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. AstraZeneca agrees that the United States, at a minimum, shall be entitled to recoup from AstraZeneca 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 the affected agencies. The United States reserves its rights to disagree with any calculations submitted by AstraZeneca or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on AstraZeneca 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 AstraZeneca's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. 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 above or in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. AstraZeneca agrees that it waives and shall not seek payment for any of the health care billings 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.

16. AstraZeneca 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 AstraZeneca, 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 to which AstraZeneca was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

17. Upon receipt of the payments described in Paragraph 1, above, the United States and Wetta shall promptly sign and file in Civil Action I a Notice of Intervention and Joint Stipulation of Dismissal with prejudice as to all federal counts in Civil Action I pursuant to the terms and conditions of the Agreement. Upon receipt of the payments described in Paragraph 1, above, Kruszewski shall promptly sign and file in Civil Action II a Notice of Dismissal with prejudice as to all federal counts in Civil Action II pursuant to the terms and conditions of the 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. AstraZeneca represents that this Agreement is freely and voluntarily entered into

without any degree of duress or compulsion whatsoever.

20. Wetta and Kruszewski 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 is the United States District Court for the Eastern District of Pennsylvania, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions 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. This Agreement may not be amended except by written consent of the Parties.

24. The individuals signing this Agreement on behalf of AstraZeneca represent and warrant that they are authorized by AstraZeneca to execute this Agreement. The individual(s) signing this Agreement on behalf of Wetta and Kruszewski represent and warrant that they are authorized by Wetta and Kruszewski 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 AstraZeneca's successors, transferees, heirs, and

assigns.

27. This Agreement is binding on Wetta and Kruszewski's successors, transferees, heirs, 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 (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4-27-10 BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: _____ BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

THE UNITED STATES OF AMERICA

DATED:_____ BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4/27/10 BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 4/27/10 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

DATED:_____ BY: _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED:_____ BY: _____

DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

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

DATED: April 23, 2010 BY: Rhonda L. Bershok, acting Deputy General Counsel
For: LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED:_____ BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

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

DATED:_____ BY: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 4/26/10 BY: Shirley R Patterson
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED: 4/26/2010 BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

ASTRAZENECA

DATED: 4/27/10 BY: _____

Glenn M. Engelmann
Vice President and General Counsel
AstraZeneca LP
AstraZeneca Pharmaceuticals LP

DATED: 4/27/10 BY: _____

JOHN C. DODDS, ESQ.
Morgan, Lewis and Bockius, LLP

RELATOR JAMES WETTA

DATED:_____ BY: _____
JAMES WETTA

DATED:_____ BY: _____
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

RELATOR JAMES WETTA

DATED: 4/23/10

BY: James Wetta by Michael Mustokoff
JAMES WETTA

DATED: 4/23/10

BY: Stephen A. Sheller
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

BY: Michael Mustokoff
MICHAEL MUSTOKOFF
MARK LIPOWICZ
TERESA CAVENAGH
DUANE MORRIS, LLP

BY: Gary M. Farmer by Michael Mustokoff
GARY M. FARMER JR.
FARMER JAFFE WEISSING EDWARDS FISTOS and LEHRMAN

[illegible]

RELATOR STEPHAN KRUSZEWSKI

DATED: 4/23/2010 BY: _____
STEFAN KRUSZEWSKI

DATED: _____ BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)

RELATOR STEPHAN KRUSZEWSKI

DATED:_____ BY: _____
STEFAN KRUSZEWSKI

DATED: 4/23/10 BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)

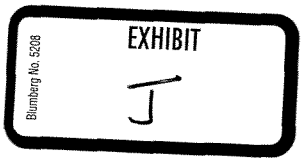
EXHIBIT J

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. DR. JESSE POLANSKY,	)	
Plaintiff,	)	No. 04-cv-0704 (ERK)(ALC)
v.	)	
PFIZER, INC.,	)	
Defendants	)	

UNITED STATES' STATEMENT OF INTEREST
IN RESPONSE TO DEFENDANT'S MOTION TO DISMISS
COUNTS I AND III THROUGH XIX OF THE FIFTH AMENDED COMPLAINT

The United States, real party in interest in this action, hereby moves to submit this Statement of Interest (Statement) pursuant to 28 U.S.C. § 517 to respond to certain arguments raised in defendant's Motion to Dismiss relator Polansky's Fifth Amended Complaint. The United States remains a real party in interest in this matter, even where it has not intervened in the action. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the United States' primary tool used to redress fraud on the government. As such, the statute should be read broadly to reach all fraudulent attempts to cause the government to pay out sums of money. *United States v. Neifert-White*, 390 U.S. 228, 233 (1968). Thus, the United States has a keen interest in the development of the law in this area and in the correct application of the law in this and similar cases.



The United States submits this Statement to clarify the legal basis for an FCA claim predicated on allegations of off-label marketing by pharmaceutical manufacturers. First, claims for payment of items or services that are not eligible for reimbursement by federal health programs are "false claims." Second, a drug manufacturer may cause a provider to submit a false claim for reimbursement if that false claim was a reasonably foreseeable consequence of the drug manufacturer's conduct. Third, the identification of specific false claims is not an absolute prerequisite to satisfying the particularity requirement of Rule 9(b) in FCA cases. So long as the complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility, a court may conclude that Rule 9(b) is satisfied. Nonetheless, the United States submits that if the Court finds that relator's complaint fails to meet that test and is subject to dismissal under Rule 9(b), then it need not reach the other issues addressed herein.[1] The United States takes no position on whether relator has adequately plead facts that would state a cognizable claim under the FCA as properly interpreted.

I. CLAIMS FOR OFF-LABEL, NON-COVERED USES ARE FALSE CLAIMS.

Physicians are free to prescribe drugs for off-label uses. Nonetheless, as defendant concedes, federal health care programs do not cover *all* uses of *all* drugs. *See* Defendant's Brief in support of its Motion to Dismiss (Def. Br.) at 12. Rather, the programs at issue here generally cover drugs for "medically accepted indications," which, by statute, are defined as indications

[1] The United States does request that should the Court decide to dismiss Relator's Fifth Amended Complaint for failure to plead fraud with particularity, the dismissal should be without prejudice as to the United States. *See United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005).

that are FDA-approved or that are "supported by a citation" in a statutorily-recognized compendium. 42 U.S.C. § 1396r-8(k)(6).

By way of background, in order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services. If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. 42 U.S.C. §§ 1396b(a)(1), 1396d(b).

Under the Medicaid Drug Rebate Statute, federal financial participation is prohibited for a drug manufacturer's covered outpatient drugs unless there is a rebate agreement between the manufacturer and the Secretary under the statute. *See* 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396r-8(d).[2]

Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act (FDCA), 21

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[2] A State may restrict from coverage or exclude altogether certain drugs or classes of drugs or certain medical uses where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i). In addition, a State also may adopt a prior authorization program, maintain a formulary, impose limits on prescription quantities to discourage waste, and address instances of fraud or abuse by individuals. 42 U.S.C. § 1396r-8(d)(4)-(6).

U.S.C. §§ 355 and 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3). The statute defines "medically accepted indication" as a use that is FDA-approved or a use that is "supported by a citation" in certain statutorily-identified compendia. *Id.* at § 1396r-8(k)(6).[3] Thus, under this statutory scheme, an off-label use that is not "supported by a citation" in the compendia falls outside the definition of a covered outpatient drug under Medicaid, and Medicaid is free to deny payment for resulting claims for such an off-label use.[4]

Courts have held that when a drug is prescribed for a use that is not covered by federal programs, the resulting claim for reimbursement of that prescription is "false" under the FCA. *See United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 13-14 (D. Mass. 2008); *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003) (*Parke-Davis II)* ; *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001) (*Parke-Davis I*) ("[T]he alleged FCA violation arises - not from unlawful off-label marketing activity itself - but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct."); *Strom ex rel. U.S. v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) ("Because the [Medicare] statute permits reimbursement only for 'reasonable and necessary' treatments, [an off-label prescription] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the

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[3] The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the Drugdex Information System. Id. at § 1396r-8(g)(1)(B)(i).

[4] Medicare Part D incorporates by reference the provisions of the Medicaid Drug Rebate Statute pertaining to "covered outpatient drugs." 42 U.S.C. § 1395w-102(e).

FCA's requirement of a 'false' statement."). Court have similarly found in other contexts that claims for services not covered by Medicare are false under the FCA. *See Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975).

This principle is consistent with a host of other situations in which courts have found FCA liability even though there may be nothing false on the face of the claims in question. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543-44 (1943) (bid rigging to obtain a contract renders the claims submitted under the fraudulently procured contract false); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (claim may be ineligible for payment where physician received a kickback for the billed service); *United States v. McLeod*, 721 F.2d 282, 284 (9th Cir. 1983) (deposit of a facially valid check to which defendant was not entitled is a false claim); *Scolnick v. United States*, 331 F.2d 598, 599 (1st Cir. 1964) (same); *United States v. Incorporated Village of Island Park,* 888 F. Supp. 419, 440 (E.D.N.Y. 1995) (facially-accurate claims resulting from conduct that violated fair housing and non-discrimination provisions in HUD program were false within the meaning of the FCA).

When a claim is false because it is for a non-reimbursable item (*e.g.*, an off-label indication that is not otherwise covered by federal health programs), an analysis under a "certification theory" is simply inapposite. *See* Def. Br. at 19 (discussing false certification theory of liability). Whether the provider "certified" on the claim for payment that the prescribed usage was on-label or otherwise reimbursable is irrelevant. Rather, the core question for "falsity" under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable. This is an objective question and is not, as defendant argues, a "subjective interpretation of defendant's legal duties" that preclude a finding

of falsity. Def. Br. at 13. For that same reason, contrary to defendant's suggestion (Def. Br. at 11, 22), whether other information on the claim form is "truthful," such as the identity of the patient or the name of the drug used, has no bearing on the fact that a prescription was for a non-covered, non-reimbursable use and thus constitutes a false claim within the meaning of the FCA.

Accordingly, defendant also is incorrect in suggesting that the claim must contain a separate "conscious and deliberate 'lie'" in order to be a false claim. Def. Br. at 10. As is clear from the language of the statute, the FCA does not require proof of double falsity – a false claim *and* a false statement. The first two sections of the FCA provide independent and distinct bases for FCA liability. *Compare* 31 U.S.C. § 3729(a)(1) (liability for false claims) *with* (a)(2) (liability for false statements).[5] By its very terms, Section 3729(a)(1) only requires that the defendant presented or caused the presentment of a false claim, not that the defendant made a false statement or lied on the claim itself. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731-33 (1st Cir. 2007) (separately analyzing false statement allegations under Section 3729(a)(2)); *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003) (same). Accordingly, a case cited by Pfizer, *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006), was wrongly decided because it demanded a showing of "extra" false statements and failed all together to consider liability under Section (a)(1), which does not require proof of any false statement at all. The *Hess* court also erred on the issue of materiality, as the question as to whether a claim is even eligible for payment is obviously material to the Government's decision to pay that claim.

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[5] The FCA was recently amended and these sections were recodified as 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B).

Furthermore, in order for a statement to be "false" under section 3729(a)(2), it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." *W. Page Keeton, Prosser & Keeton on the Law of Torts* § 106, at 738 (5th ed. 1984); *see Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA). Thus, a statement urging a physician to prescribe a drug for an unapproved use could well amount to a half-truth and satisfy the false statement requirement of section (a)(2), where, for example, the drug sales representative fails to mention evidence that does not support the drug's safety or efficacy for the unapproved use or that the FDA has specifically denied approval for that indication.

Relator here has alleged that promoting Lipitor therapy for patients outside the risk categories and cutpoints set forth in the National Cholesterol Education Program Guidelines is unlawful off-label promotion, and that resulting claims outside those Guidelines did not qualify for reimbursement under federal health care programs. This court has already observed that advocacy by Pfizer for an off-label use of Lipitor may well have violated the FDCA, but the fact that Pfizer may have done so does not automatically translate into FCA liability if the resulting claims for such prescriptions are not false under the FCA. *United States ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582, at *6-7 (E.D.N.Y. May 22, 2009). Prescriptions claims for

Lipitor would be "false" if they were prescribed for unapproved uses that were not supported by a citation in one of the statutorily-identified compendia.[6]

The United States takes no position as to whether relator has adequately alleged facts to support his claim that the Lipitor claims at issue here are false; however, Pfizer's reliance on the fact that the label for Lipitor was changed in 2009 clearly is misplaced. Def Br. at 3. If a claim was false when it was submitted in 2004, a label change five years later does not transform that false claim into a reimbursable one. To hold otherwise would be to render federal health care program restrictions on coverage meaningless. It also would undermine the gatekeeping role of the federal government in protecting public health as well as the public fisc in ensuring that, based on the information available at the time, only indications that have been FDA-approved or are sufficiently supported by scientific literature as safe and effective are reimbursed.

II. FCA Pleading Requirements

Of course, if a relator is claiming that the defendant drug company *caused* the providers to submit these false claims, the relator must adequately allege such causation. The relator need not allege an express false statement to satisfy the causation element, though such evidence would be one way the relator could do so. Assuming that a relator has supported his allegations with sufficient facts, courts analyze causation based on general tort law principles when determining whether the company may be liable for causing the submission of false claims based on off-label marketing conduct. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192

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[6] As noted, the statutory definition of "medically accepted indication" refers to off-label indications that are supported (as opposed to listed) in the compendia. *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008) (citing CMS Release No. 141); *see* 42 U.S.C. § 1396r-8(k)(6).

F.3d 402, 415 (3d Cir. 1999) (discussing principles of causation); *Parke-Davis II*, 2003 WL 22048255 at *4-6. In *Parke-Davis II*, the court found that causation is satisfied where (a) the drug manufacturer's alleged off-label marketing was a "substantial factor" in producing the false claims and (b) it was "foreseeable" that the off-label marketing would result in false claims. 2003 WL 22048255 at *4-6. That court, like others presented with FCA cases based on allegations of off-label marketing, also found that the actions of health care providers are not an intervening force that breaks the chain of legal causation, particularly because influencing those actions is the goal of off-label promotion. *Id.* at *5 ("[T]he participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud."); *see also Scios*, 676 F. Supp. 2d at 891 (denying a motion to dismiss and finding that the independent actions of physicians "only breaks the causal connection when it is unforeseeable" that a particular drug would be billed to a federal health care program). Indeed, the pharmaceutical industry would not employ the army of sales representatives who promote their products if these sales efforts had no effect on physician practices. Thus, the relevant question here is whether relator has sufficiently alleged that it was foreseeable that Pfizer's conduct would result in some false claims being submitted to federal health care programs.

Likewise, under the FCA, courts have held that a false claim is material if it "has a natural tendency to influence agency action or is capable of influencing agency action." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999).[7] Pfizer's argument that

[7] The FCA has also been recently amended to expressly define "materiality" in this fashion. *See* 31 U.S.C. § 3729(b)(4) (2009) (defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").

federal health care programs do not require certain information on claims forms that may have allowed the programs to prevent the payment of non-covered claims should be rejected because it runs counter to the courts' long-standing recognition that those who deal with the Government must "turn square corners" and cannot take advantage of government officials who may have too few resources to catch attempted fraud at its inception. *See, e.g., Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143 (1920); *Rogan*, 517 F.3d at 452 ("The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers"). The Government processes millions of claims for payment by federal health programs each year, and requiring it, as Pfizer apparently suggests, to examine every claim it pays for potential underlying misconduct is patently unreasonable.

III. Rule 9(b) Pleading Requirements

Defendant further asserts that relator has failed to identify specific claims and that regardless of whether relator has identified specific claims submitted to federal health care programs, he has failed to provide sufficient details about those claims. The United States takes no position on the sufficiency of relator's complaint; however, to the extent that defendant contends that relator's complaint must fail because it did not identify specific false claims or do so with sufficient particularity, defendant seeks to impose too rigid a pleading standard in FCA cases.

The allegation of a specific false claim is not an absolute prerequisite to pleading a viable FCA claim. Although FCA liability attaches to the claim for payment, whether specific claims must be identified for a complaint to satisfy Rule 9(b)'s particularity requirement will depend on

the circumstances of each case. *See Ebeid ex rel. U.S. v. Lungwitz*, 2010 WL 3092637, at *4-5 (9th Cir. Aug. 9, 2010); *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 31-32 (1st Cir. 2009); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849 (7th Cir. 2009); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 390-91 (D. Mass. 2008). Thus, in off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator "need not allege the details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" *See In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d at 390 (quoting *Rost*, 507 F.3d at 732). As this court has considered in examining relator's prior complaint in this action, in evaluating such matters on a case-by-case basis, the strength of the inference of fraud on the government may be measured by, for example, factual or statistical evidence tending to show fraud beyond possibility. *See Polansky*, 2009 WL 1456582, at *9; *see, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d at 390.

CONCLUSION

The United States submits this Statement regarding how to interpret and apply certain aspects of the Medicaid Act and the FCA. The United States takes no position on the sufficiency of the complaint herein.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

LORETTA LYNCH
UNITED STATES ATTORNEY

/s/ filed electronically
ERIN E. ARGO
Assistant U.S. Attorney
271 Cadman Plaza East
Brooklyn, New York 11201
(718) 254-6049

JOYCE R. BRANDA
JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
Civil Division, Commercial Litigation Branch
P. O. Box 261, Ben Franklin Station
Washington, D.C. 20004
Phone: (202) 514-6514

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