

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of North Carolina (“the State”) and Bristol-Myers Squibb Company (“Bristol-Myers”), collectively, “the Parties.”

II. PREAMBLE

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

A. At all relevant times, Bristol-Myers, a Delaware corporation with its principal place of business in New York City, New York, distributed and/or sold pharmaceutical products in the United States.

B. On December 23, 2013, Ronald J. Streck (the “Relator”) filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States of America, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Washington, the State of Wisconsin, and the District of Columbia, ex rel. Ronald J. Streck v. Biovail Pharmaceuticals, Inc. n/k/a Valeant Pharmaceuticals International, Inc., et al.*, 13-CV-7547, pursuant to the *qui tam* Bristol Myers Squibb Company Case # 13-7547 (EDPA)

provisions of the False Claims Act, 31 U.S.C. § 3730(b), and the false claims statutes of the plaintiff states (the “Civil Action”). Relator filed an amended complaint in the Civil Action on June 8, 2018. Bristol-Myers was named as a defendant in Relator’s original complaint and in the amended complaint.

F. The United States of America (the “United States”) and the States declined to intervene in the Civil Action on October 6, 2017.

C. At all relevant times, Bristol-Myers participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5.

D. In his *qui tam* complaint in the Civil Action, Relator alleges that Bristol-Myers made or caused to be made statements material to the payment of rebates pursuant to the Medicaid Drug Rebate Program and statements material to payments made by the United States to the states for the Medicaid Program.

E. The State contends that Bristol-Myers caused claims for payment to be submitted to the State’s Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including “managed care entities” as defined by 42 U.S.C. § 1396u-2.

F. The State contends that it has certain civil claims against Bristol-Myers for engaging (directly and/or through its subsidiaries or divisions) in the following alleged conduct during the period from October 1, 2007 through March 31, 2016 (hereafter referred to as the “Covered Conduct”):

1. The State contends that Bristol-Myers falsely reported improperly reduced Average Manufacturer Prices (“AMPs”) to the Centers for Medicare and Medicaid Services (“CMS”), in the manner described below, and therefore underpaid quarterly rebates owed to the

states under the Medicaid Drug Rebate Program, and caused the United States to be overcharged for its payments to the states for the Medicaid Program.

2. Pursuant to the Medicaid Drug Rebate Program, Bristol-Myers was required to report the AMP for each of its covered outpatient drugs to CMS on a monthly and quarterly basis, and to pay quarterly rebates to state Medicaid programs that were based, in part, on the quarterly AMPs reported by Bristol-Myers. Prior to enactment of the Affordable Care Act (“ACA”), the AMP for a drug generally was based on the average unit price paid to the manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade, including cash discounts and other price concessions that reduced the actual price paid for the drug. The ACA revised the definition of AMP, in part, by replacing the term “retail pharmacy class of trade” with “retail community pharmacies” and including manufacturer direct sales to retail community pharmacies. Both before and after enactment of the ACA, bona fide service fees are excluded from manufacturers’ AMP calculations.

3. Bristol-Myers entered into agreements with wholesalers and distributors (“Wholesalers”) to facilitate the distribution and sale of the pharmaceuticals listed on Attachment A hereto (“the Covered Drugs”). Pursuant to those agreements (“Services Agreements”), the Wholesalers performed various specified services, including but not limited to providing data, and Bristol-Myers compensated the Wholesalers for performing those services (“Service Fees”).

4. The State contends that, for rebate periods from October 1, 2007 through December 31, 2013, Bristol-Myers improperly treated compensation provided to the Wholesalers pursuant to the Services Agreements as price reductions, rather than as bona fide service fees, when calculating and reporting AMPs to CMS for the Covered Drugs. As a result of Bristol-Myers’s reporting such improperly reduced AMPs, Relator contends that Bristol-Myers underpaid

quarterly rebates owed to the states for the Covered Drugs under the Medicaid Drug Rebate Program, and caused the United States to be overcharged for its payments to the states for the Medicaid Program.

5. The State contends that the Services Agreements also included provisions (“Price Appreciation Provisions”) pursuant to which, when Bristol-Myers announced a price increase for one or more of its drugs, Bristol-Myers received additional value – in the form of credits against, or reductions to, the Service Fees that Bristol-Myers would otherwise have owed to the Wholesalers – for units of the drug that Bristol-Myers had previously sold to the Wholesalers and that were still in the Wholesalers’ inventory at the time Bristol-Myers announced the price increase.

6. The State contends that, for rebate periods from January 1, 2014 through March 31, 2016, Bristol-Myers improperly excluded the additional value it received from Wholesalers pursuant to the Price Appreciation Provisions when calculating and reporting AMPs to CMS for the Covered Drugs. As a result of Bristol-Myers’s reporting such improperly reduced AMPs, Relator contends that Bristol-Myers underpaid quarterly rebates owed to the states for the Covered Drugs under the Medicaid Drug Rebate Program, and caused the United States to be overcharged for its payments to the states for the Medicaid Program.

7. The State further contends that Bristol-Myers changed its treatment of Service Fees and Price Appreciation Provisions for rebate periods subsequent to the rebate periods noted in paragraphs F.4 and F.6 above, but failed to report restated AMPs to correct the improper treatment of Service Fees and Price Appreciation Provisions for the rebate periods noted in those paragraphs, and failed to pay additional quarterly rebates that Relator contends would have been due if Bristol-Myers had properly reported restated AMPs for those rebate periods.

G. Bristol-Myers denies the allegations in Paragraph F and in the Civil Action.

H. Bristol-Myers has entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the United States as that term is defined in the Federal Settlement Agreement.

I. This Agreement is neither an admission of facts or liability by Bristol-Myers nor a concession by the State that it’s claims are not well founded.

J. The Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Bristol-Myers agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of \$75,000,000.00 (“Settlement Amount”) and interest on the Settlement Amount at a rate of 0.75% per annum from May 12, 2020. The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the “Effective Date” of the Federal Settlement Agreement, as defined therein and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) Bristol-Myers shall pay to the United States the sum of \$41,360,522.93 plus interest thereon at a rate of 0.75% per annum from May 12, 2020 to and including the Effective

Date of the Federal Settlement Agreement (the “Federal Settlement Amount”), of which \$20,680,261.46 is restitution.

(b) The total recovery for the Covered Conduct is \$75,000,000.00 consisting of \$33,639,477.07 for the Medicaid Participating States pursuant to this Agreement and \$41,360,522.93 for the United States pursuant to the Federal Settlement Agreement. Bristol-Myers shall pay to the Medicaid Participating States the sum of \$33,639,477.07 plus interest thereon at a rate of 0.75% per annum from May 12, 2020 to and including the Effective Date of the Federal Settlement Agreement (the “State Settlement Amount”), subject to the Medicaid Participating State provisions and the non-participating state deduction provisions of sub-paragraphs (c) and (d) below. Bristol-Myers shall make the electronic funds transfer of the State Settlement Amount no later than fourteen calendar days after the Effective Date of the Federal Settlement Agreement to the New York State Attorney General’s National Global Settlement Account pursuant to written instructions from the state negotiating team (the “State Team”), which written instructions shall be delivered to counsel for Bristol-Myers. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (d) below. If a state elects not to become a Medicaid Participating State and participate in this settlement, the State Amount portion of the State Settlement Amount allocated to that state shall be remitted to BMS as set forth in Paragraph III. 1. (d) below.

(c) Bristol-Myers shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Bristol-Myers and the State Team have agreed, or in a form otherwise agreed to by Bristol-Myers and an individual State. The State that executes a State Settlement Agreement shall constitute a Medicaid Participating State provided that such Agreement is fully executed by the State and delivered to Bristol-Myers’ attorneys within 60 days

of receiving this Agreement. Bristol-Myers' offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Bristol-Myers and the State Team to extend the 60 day period.

(d) The total portion of the amount paid by Bristol-Myers in settlement for the Covered Conduct for the State is \$2,490,905.91, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$1,044,924.68 plus applicable interest (the "State Amount"), of which \$522,462.34 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the State Settlement Amount absent written agreement between counsel for Bristol-Myers and the State Team to extend the time period for executing this Agreement, and the State Amount shall be repaid to Bristol-Myers within 21 calendar days after the expiration of the 60 day period (or after the expiration of the extended period if agreed to by Bristol-Myers and the State Team) via check issued pursuant to instructions to be provided by Bristol-Myers' counsel to the State Team.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against the Bristol-Myers Released Entities as defined in Paragraph 3 below in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. The Parties shall promptly sign and file a Stipulation of Dismissal. The Stipulation will provide for the dismissal with prejudice as to the State for the Covered Conduct and dismissal without prejudice as to the State for other than the Covered Conduct. Contingent upon receipt of the State

Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share,

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agrees to pay the Relator the amount of \$303,028.16 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Bristol-Myers set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State, on behalf of itself, and to the extent authorized by law its agencies, departments, political subdivisions, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities, agrees to release Bristol-Myers, together with its current and former parents, subsidiaries, divisions, other affiliates (defined as an entity that controls, or is controlled by, Bristol-Myers through common ownership), successors, transferees, heirs and assigns (the “Bristol-Myers Released Entities”), from any civil or administrative monetary cause of action that the State, its agencies, departments, political subdivisions, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities, have or may have for any claims submitted or caused to be submitted to the State’s Medicaid Program for the Covered Conduct. The payment of the State Settlement Amount fully discharges the Bristol-Myers Released Entities from any obligation to pay Medicaid restitution, Medicaid damages, and/or Medicaid civil fines or Medicaid civil penalties to the State for the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

- (a) any criminal, civil, or administrative liability arising under state revenue codes;
- (b) any criminal liability;

(c) any civil or administrative liability that any person or entity, including the Bristol-Myers Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 3 above, including, but not limited to, any and all of the following claims: (i) claims involving unlawful or illegal conduct based on State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusions from the State's Medicaid Program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. Bristol-Myers waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. In consideration of the obligations of the State set forth in this Agreement, the Bristol-Myers Released Entities waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Bristol- Myers Released Entities have asserted, could have asserted, or may assert in the future against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that Bristol-Myers must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and Bristol-Myers agrees not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

8. Bristol-Myers shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors.

9. Bristol-Myers expressly warrants that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

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

11. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity.

13. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

14. In addition to all other payments and responsibilities under this Agreement, Bristol-Myers agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Bristol-Myers will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

15. This Agreement is governed by the laws of the State, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

16. The undersigned Bristol-Myers signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

17. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. The facsimile, email or other electronically delivered signatures of the parties shall be deemed to constitute acceptable binding signatures for purposes of this Agreement, and facsimile or electronic copies shall be deemed to constitute duplicate originals.

18. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

19. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

21. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

By:  Dated: 5/19/2021

Dave Richard

Name

Deputy Secretary, NC Medicaid

Title

NC Department of Health and Human Services, Division of Health Benefits

Organization

By:  Dated: 5/19/2021

F. Edward Kirby, Jr.

Name

Director

Title

NCDOJ Medicaid Investigations Division

Organization

BRISTOL-MYERS SQUIBB COMPANY

By:  Dated: 7/29/2021

Donald C. Le Gower
Name

Assistant General Counsel
Title

Bristol-Myers Squibb Company
Organization

By:  Dated: 7/30/2021

Mark A. Jensen
King & Spalding LLP
Counsel to Bristol-Myers Squibb Company

**Attachment A
COVERED DRUGS**

Product Family	NDC9	Product Family	NDC9
ABILIFY	591480006	KENALOG	000030508
ABILIFY	591480007	KLOTRIX	000870770
ABILIFY	591480008	KOMBIGLYZE	000034221
ABILIFY	591480009	KOMBIGLYZE	000034222
ABILIFY	591480010	KOMBIGLYZE	000034223
ABILIFY	591480011	LODOSYN	000560511
ABILIFY	591480012	LYSODREN	000153080
ABILIFY	591480013	MEGACE	000150508
ABILIFY	591480016	MESNEX	000153563
ABILIFY	591480640	METAGLIP	000876077
ABILIFY	591480641	METAGLIP	000876078
AVALIDE	000872775	METAGLIP	000876081
AVALIDE	000872776	MONOPRIL	000870158
AVALIDE	000872788	MONOPRIL	000870609
AVALIDE	000872875	MONOPRIL	000871202
AVALIDE	000872876	MONOPRIL	000871492
AVAPRO	000872771	MONOPRIL	000871493
AVAPRO	000872772	MUTAMYCIN	000153001
AVAPRO	000872773	MUTAMYCIN	000153002
AZACTAM	000032230	MUTAMYCIN	000153059
AZACTAM	000032240	MYALEPT	667800310
AZACTAM	000032560	MYCOLOG	000030466
AZACTAM	000032570	MYCOLOG	000030566
BARACLUDE	000031611	MYCOSTATIN	000030593
BARACLUDE	000031612	NIACIN	000030537
BARACLUDE	000031614	NULOJIX	000030371
BICNU	000153012	ONGLYZA	000034214
BLENOXANE	000153010	ONGLYZA	000034215
BLENOXANE	000153063	OPDIVO	000033772
BUSPAR	000870818	OPDIVO	000033774
BUSPAR	000870819	ORENCIA	000032187
BUSPAR	000870822	ORENCIA	000032188
BUSPAR	000870824	OXACILLIN	000157103
BYDUREON	667800219	PARAPLATIN	000153210
BYDUREON	667800226	PARAPLATIN	000153211
BYETTA	667800210	PARAPLATIN	000153212
BYETTA	667800212	PARAPLATIN	000153213
CEENU	000153030	PARAPLATIN	000153214
CEENU	000153031	PARAPLATIN	000153215
CEENU	000153032	PARAPLATIN	000153216
CEENU	000153034	PLATINOL	000153072
CEFZIL	000877718	PLAVIX	636531171

Product Family	NDC9	Product Family	NDC9
CEFZIL	000877719	PLAVIX	636531332
CEFZIL	000877720	PRAVACHOL	000035154
CEFZIL	000877721	PRAVACHOL	000035178
COUMADIN	000560168	PRAVACHOL	000035194
COUMADIN	000560169	PRAVACHOL	000035195
COUMADIN	000560170	PRAVIGARD	000035183
COUMADIN	000560172	REVIA	000560011
COUMADIN	000560173	REYATAZ	000033622
COUMADIN	000560174	REYATAZ	000033623
COUMADIN	000560176	REYATAZ	000033624
COUMADIN	000560188	REYATAZ	000033631
COUMADIN	000560189	REYATAZ	000033638
COUMADIN	005900324	SEBUTONE	000725000
CYTOXAN	000150502	SERZONE	000870033
CYTOXAN	000150503	SINEMET	000560521
CYTOXAN	000150504	SINEMET	000560601
CYTOXAN	000150505	SINEMET	000560647
CYTOXAN	000150506	SINEMET	000560650
DAKLINZA	000030213	SINEMET	000560654
DAKLINZA	000030215	SPRYCEL	000030524
DESYREL	000870778	SPRYCEL	000030527
DESYREL	000870796	SPRYCEL	000030528
DROXIA	000036335	SPRYCEL	000030852
DROXIA	000036336	SPRYCEL	000030855
DROXIA	000036337	SPRYCEL	000030857
ELIQUIS	000030893	SUMYCIN	597720815
ELIQUIS	000030894	SUSTIVA	000560470
EMPLICITI	000032291	SUSTIVA	000560473
EMPLICITI	000034522	SUSTIVA	000560474
EMSAM	395060033	SUSTIVA	000560510
EMSAM	395060044	SYMLIN	667800110
EMSAM	395060055	SYMLIN	667800115
ERBITUX	667330948	SYMLIN	667800121
ERBITUX	667330958	TAXOL	000153475
ETOPOPHOS	000153404	TAXOL	000153476
EVOTAZ	000033641	TAXOL	000153479
FARXIGA	000031427	TEQUIN	000151117
FARXIGA	000031428	TEQUIN	000151177
GLUCOPHAGE	000876060	TEQUIN	000151179
GLUCOPHAGE	000876063	TEQUIN	000151180
GLUCOPHAGE	000876070	TEQUIN	000151181
GLUCOPHAGE	000876071	TESLAC	000030690
GLUCOVANCE	000876072	VEPESID	000153091

Product Family	NDC9	Product Family	NDC9
GLUCOVANCE	000876073	VIDEX	000876632
GLUCOVANCE	000876074	VIDEX	000876633
GLUCOXR	000876064	VIDEX	000876650
HALOG	000031494	VIDEX	000876651
HYDREA	000030830	VIDEX	000876652
IFEX	000150556	VIDEX	000876653
IFEX	000150557	VIDEX	000876665
IFEX	000153554	VIDEX	000876671
IFEX	000153556	VIDEX	000876672
IFEX	000153564	VIDEX	000876673
IXEMPRA	000151910	VIDEX	000876674
IXEMPRA	000151911	VUMON	000153075
K-LYTE	000870761	YERVOY	000032327
K-LYTE	000870766	YERVOY	000032328
K-LYTE	000870767	ZERIT	000031964
K-LYTE	000870771	ZERIT	000031965
KENALOG	000030293	ZERIT	000031966
KENALOG	000030494	ZERIT	000031967
KENALOG	000030502	ZERIT	000031968
KENALOG	000030506		