

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of California (“the State”) and Novartis Pharmaceuticals Corporation (“Novartis”), collectively, “the Parties.”

### II. PREAMBLE

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

A. At all relevant times, Novartis, (a subsidiary of Novartis International AG, which is headquartered in Basel, Switzerland) was a corporation with its principal place of business in East Hanover, New Jersey, distributed, marketed and/or sold pharmaceutical products in the United States, including drugs sold under the trade names of Lotrel, Valturna, Starlix, Tekamlo, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, and Exforge HCT (the “Covered Drugs”).

B. On January 5, 2011, Oswald Bilotta, (the “Relator”) filed a sealed *qui tam* action, which was subsequently amended on October 19, 2012, as of right on April 3, 2013 (pursuant to an unopposed motion dated March 21, 2013), and on July 10, 2013 (pursuant to a stipulation dated July 8, 2013) (the “Civil Action”) in the United States District Court for the Southern District of New York captioned *United States of America et al., ex rel. Oswald Bilotta et al. v. Novartis Pharmaceuticals Corporation* Civil Action No. 11-cv-00071, alleging, *inter alia*, that Novartis violated the False Claims Act (“FCA”) and the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) (the “AKS”), by paying doctors remuneration to prescribe the drugs Lotrel, Valturna, Starlix, Tekturna, Tekturna HCT, Diovan, Diovan HCT, Exforge, and Exforge HCT through the mechanism of speaker program honoraria and related misconduct.

On April 26, 2013, the United States intervened in the Civil Action against Novartis by filing a Notice of Election to Intervene and Complaint-in-Intervention, in which it is asserted that claims against Novartis under the FCA and common law. On July 17, 2013, most plaintiff states except New York, filed a Notice to the Court of the States' Election to Decline Intervention in the matter. On August 26, 2013, the United States filed an Amended Complaint-in-Intervention in the Civil Action (the "Government Complaint"). On August 26, 2013, the State of New York also intervened in the Civil Action.

C. Novartis entered into a separate civil Stipulation and Order of Settlement and Dismissal (the "Federal Settlement Agreement") with the United States of America through the United States Attorney's Office for the Southern District of New York (the "United States").

D. The State alleges that Novartis 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.

E. The State alleges that it has certain civil and administrative causes of action against Novartis for engaging in the following conduct:

(i) from January 1, 2002 through November 21, 2011, Novartis offered and paid remuneration in the form of cash, meals, alcohol, hotels, travel, entertainment, and honoraria payments to health care practitioners ("HCPs") who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or lunch-n-learns to induce them to prescribe Lotrel, Valturna, Starlix, Tekamlo, Diovan HCT, Tekturna HCT, and Exforge HCT, in violation of the AKS, and thereby caused false claims for prescriptions for those drugs to be submitted to and paid by Medicaid in violation of the FCA and other analogous state statutes; and (ii) from January 1, 2010 through November 21, 2011, Novartis paid remuneration in the form of cash, meals, alcohol, hotels, travel, entertainment, and

honoraria payments to HCPs who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or lunch-n-learns to induce them to prescribe Diovan, Tekturna, and Exforge, in violation of the AKS, and thereby caused false claims for prescriptions for Diovan, Tekturna, and Exforge to be submitted to and paid by Medicaid, in violation of the FCA and analogous state statutes. The conduct described in this Paragraph is the “Covered Conduct” for purposes of this Agreement.

F. 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. Novartis admits, acknowledges, and accepts responsibility for the following facts and conduct:

#### **The Anti-Kickback Statute**

- a. The AKS prohibits pharmaceutical companies, such as Novartis, from knowingly and willfully providing remuneration to doctors in order to induce them to write prescriptions for the company’s pharmaceutical products that are ultimately paid for by federal health care programs.
- b. Between January 2002 and November 2011 (the “Relevant Period”), Novartis understood that it had to comply with the AKS. Throughout the Relevant Period, Novartis had an ethics and compliance policy that applied to all of its employees and associates, which stated that the AKS “makes it a criminal offense to, among other things, knowingly and willfully offer . . . any ‘remuneration’ in exchange for, or to induce the . . . recommendation of, any item or service for which payment may be made under Medicare [or] Medicaid.”
- c. During the Relevant Period, Novartis knew that Medicare providers, Part D plan sponsors and pharmacies that contracted with Part D plan sponsors were required to agree that they would comply with applicable laws and regulations, including, but not limited to, the AKS and the FCA.

- d. During the Relevant Period, Novartis knew that state Medicaid programs required providers, including doctors and pharmacies, to certify compliance with federal requirements and such certification encompassed compliance with the AKS.
- e. Moreover, during the Relevant Period, Novartis knew that the TRICARE program required providers to agree to abide by federal laws and regulations. Similarly, pharmacies filling prescriptions for TRICARE beneficiaries were also required to abide by federal laws.

#### **Marketing of the Covered Drugs through Meetings and Events**

- f. During the Relevant Period, Novartis marketed and sold a number of drugs to treat hypertension, including Lotrel, Diovan and Diovan HCT, Exforge and Exforge HCT, Tekturna and Tekturna HCT, Valturna, and Tekamlo. Novartis also marketed and sold Starlix, a drug to treat Type 2 diabetes (collectively, the "Covered Drugs").
- g. Lotrel was approved by the U.S. Food and Drug Administration ("FDA") in 1995, Diovan in 1996, and Diovan HCT in 1998. Starlix was approved in 2000. Exforge and Exforge HCT were approved by the FDA in 2007 and 2009, respectively. Exforge is a combination of Diovan and amlodipine besylate, which was approved by the FDA for treatment of hypertension in 1992. Exforge HCT combines Exforge with a diuretic, hydrochlorothiazide. Tekturna and Tekturna HCT were approved by the FDA in 2007 and 2008, respectively. The FDA approved Valturna in 2009 and Tekamlo in 2010.
- h. Novartis conducted meetings and events as part of its marketing efforts for each of the Covered Drugs, including events referred to as speaker programs and roundtables.
- i. Pursuant to the Novartis compliance policies in place during the Relevant Period, speaker programs were supposed to be promotional programs led by a speaker who was approved and trained by the company and who received an honorarium for presenting an on-label and medically relevant slide presentation and Q&A session related to a Novartis product. Novartis paid for the attendees' meals and alcohol for programs held in restaurants.
- j. Pursuant to the Novartis compliance policies in place during part of the Relevant Period, roundtables were supposed to be events, typically held at restaurants, where a Novartis sales representative used company-approved promotional materials to facilitate a medical discussion between the doctors in attendance concerning one or more Novartis drugs. Novartis paid for the attendees' meals and alcohol. Novartis's policies allowed roundtables to include dinners attended by a single doctor hosted by a sales representative.

- k. In 2002, Novartis signed the PhRMA Code, an industry-wide code of conduct, and adopted internal compliance policies in response to the Code. The Code stated that meals should only be provided to doctors in connection with “[i]nformational presentations and discussions” that “provide scientific or educational value,” and that were “modest,” “occur[red] in a venue and manner conducive to informational communication,” and were provided “on [no] more than an occasional basis.”
- l. The majority of Novartis’s speaker programs and roundtables were organized by sales representatives, who selected the venue, chose the speakers, and determined which doctors to invite.

### **Budgets for Promotional Programs**

- m. Novartis sales representatives were provided with budgets specifically for promotional programs, which included speaker programs and roundtables.
- n. Many Novartis sales managers directed their sales representatives to spend all of their budgets for promotional programs.
- o. Many Novartis sales representatives were specifically evaluated in their annual reviews as to how much of their budget for promotional programs they had used, as part of an evaluation of their overall sales efforts. If a sales representative failed to spend all of his/her budget, that could be a negative factor in his/her annual review.
- p. Novartis incentivized its sales representatives and managers through bonus compensation to grow the local market share of the Novartis drugs for which they were responsible.
- q. “Share of voice” is a marketing concept that measures a pharmaceutical company’s marketing presence relative to competitors. A company’s “share of voice” for a drug is equal to doctors’ exposure to marketing for that drug, divided by their exposure to marketing for all drugs in that class. This exposure can include attendance at events like speaker programs and roundtables.
- r. A presentation Novartis marketing executives sent to Novartis’s Chief Operating Officer in 2005 stated that Novartis aimed to “[e]stablish Novartis CV [cardiovascular] franchise as the 800-pound gorilla” in that space by increasing its annual spending on “meetings and events” like speaker programs and roundtables from \$57 million to \$105 million.
- s. As a result of the Covered Conduct, and the conduct to which Novartis admitted and accepted responsibility for in this Paragraph 2, Novartis obtained at least \$40 million in net proceeds from prescriptions of the Covered Drugs that were ultimately reimbursed by Federal health care programs.

### **Selection of Speakers**

- t. Throughout the Relevant Period, Novartis representatives and their managers had broad discretion to decide which local doctors to nominate to become company-approved speakers.
- u. Novartis gave its sales representatives prescribing data that showed the number of prescriptions for Novartis and competitor drugs written by the doctors in their territories. The Novartis sales force used this prescribing data to identify high-volume prescribers and track their prescriptions over time.
- v. Using this prescribing data, some Novartis sales representatives selected high-prescribing doctors to become speakers and intended the honoraria paid to induce these doctors to continue to write or write more Novartis products.
- w. During the Relevant Period, Novartis paid many high-prescribing doctors tens or hundreds of thousands of dollars in honoraria. For instance, over the course of the Relevant Period, Novartis paid over \$320,000 in honorarium to a doctor who wrote more than 8,000 prescriptions for the Covered Drugs; over \$220,000 in honorarium for a doctor who wrote more than 9,000 prescriptions for the Covered Drugs; and over \$200,000 to a doctor who wrote more than 3,600 prescriptions for the Covered Drugs.

### **Excessive Meal and Alcohol Spend**

- x. Some Novartis sales representatives hosted speaker programs or roundtables at expensive restaurants, intending to induce the doctors in attendance to continue to write or write more Novartis prescriptions.
- y. During the Relevant Period, Novartis sales representatives conducted speaker programs and roundtables at some of the most expensive restaurants in the United States, including Masa, Daniel, Gramercy Tavern, Il Mulino, Babbo, Peter Luger, Le Bernardin, and Eleven Madison Park in New York City; Charlie Palmer's in Washington, D.C.; Morton's Steakhouse and the Four Seasons in Chicago, Illinois; Joe's Stone Crab in Miami; Abacus, Nobu and the Four Seasons in Dallas; Gary Danko in San Francisco; Patina and Matsuhisa in Los Angeles; Grill 225 in South Carolina; and Commander's Palace in New Orleans.
- z. Throughout the Relevant Period, according to Novartis database information about its programs, more than 12,000 speaker programs and roundtables had meal spends that were considerably in excess of the \$125 per person limit set by Novartis's compliance policies. For example, in 2008, at a speaker program held at Ruth's Chris Steakhouse in Pikesville, Maryland, Novartis held an event with only one doctor in the audience for the speaker's presentation, at which it spent \$448 per person on food and alcohol, in addition to the \$1,000 honorarium payment provided to the speaker. In other



examples, in 2008, Novartis spent \$521 per person for food and alcohol at a dinner held at Skye Restaurant in Peoria, Arizona, and \$680 per person for a dinner event held at Danton's Gulf Coast Seafood Restaurant in Houston, Texas.

- aa. In 2006, an internal Novartis presentation noted that between August 2005 and April 2006 "[o]ver 24% of the [speaker] events appear to have exceeded the guideline for average [food and beverage] cost per attendee in major cities." It noted that one of the "[r]easons for excessive costs per person" was that "[e]vents are planned with high costs (e.g. very exclusive places, expensive menu choices, no control over alcohol spending)."
- bb. In certain instances, Novartis's internal records understated how much was spent per doctor at each event, as some Novartis employees falsified records to make it appear that the amount spent on alcohol and food for doctors at speaker programs and roundtables was less than what was actually spent.
- cc. During the Relevant Period, Novartis typically paid for alcohol provided at Novartis's speaker programs and roundtables. Some doctors demanded expensive bottles of wine. Doctors sometimes consumed alcohol in large quantities at these events, to the point of intoxication.
- dd. During the Relevant Period, some Novartis sales representatives conducted speaker programs and roundtables on the Covered Drugs at venues where the focus was on entertainment, including fishing trips, sporting events, wine tastings, and hibachi tables. Novartis conducted hundreds of events at wineries and golf clubs. Sales representatives also conducted roundtables at Hooters.

### **Minimal Medical Discussion**

- ee. Although Novartis's ethics and compliance policies required that speaker programs and roundtables provide medical information regarding the company's products to health care practitioners, at many Novartis events, there was little to no medical discussion.
- ff. At many of the speaker programs, the sales representative hosting the event did not require the speaker, who was being paid an honorarium, to deliver a presentation at all, or allowed the speaker to click through the power point presentation in a matter of minutes. In those instances, the majority of the time was spent socializing and enjoying dinner.
- gg. Novartis in a number of instances paid doctors honoraria for purportedly speaking at events that never took place.
- hh. On Long Island, at least one sales representative organized fraudulent speaker programs by arranging for a restaurant to create fake receipts to make it

appear that a dinner had taken place, and then used the budgeted funds to purchase gift cards that were distributed to high-prescribing doctors. Doctors were then also paid honoraria for “speaking” at these sham events.

### **Repeat Attendance**

- ii. Novartis had staff in its marketing science group to measure its return on investment (“ROI”) from speaker programs and roundtables, based on the number of new prescriptions for its drugs written by doctors in attendance.
- jj. In July 2004, Novartis’s marketing science group sought to determine whether its meetings and events, including a doctor’s repeated attendance at events, had any “impact on share growth.”
- kk. The following month, Novartis’s marketing science group presented an analysis showing that, for Lotrel roundtables, the ROI for doctors who attended more than one roundtable was 1,200%.
- ll. In 2005, in response to the direction to double Novartis’s “share of voice” in cardiovascular meetings and events, Novartis executives developed “goals” for the number of speaker programs and roundtables Novartis sales representatives should hold each month.
- mm. In November 2005, a Novartis sales executive wrote an email in which she stated that certain proposed “goals” for the number of speaker programs and roundtables to be expected of Novartis sales representatives for the months of January and February 2006 were “very difficult to defend [as] . . . achievable,” and further that “attendance by these [doctors] would need to be excessive.” Novartis ultimately set expectations “on the higher end” of what she thought was “possible.”
- nn. In 2007, the marketing science group recommended that high-prescribers of hypertensive drugs attend approximately a dozen meetings and events on Diovan, Diovan HCT, and Lotrel each year. The group reaffirmed these recommendations in 2008. These recommendations informed the national budgets Novartis set for its meetings and events.
- oo. To achieve these goals, many Novartis representatives would repeatedly invite the same doctors to attend promotional programs for the same drugs and presentations with the same title. Novartis’s records show that more than 19,235 doctors attended programs with the exact same title three or more times in a six-month period.
- pp. In thousands of instances, Novartis paid for the same group of doctors, often colleagues or friends, to have dinners together repeatedly (along with other doctors or health care providers on occasion). Doctors in these groups would sometimes rotate being the speaker and receiving the honorarium payment.



- qq. For example, five doctors in Harrisburg, Pennsylvania went to more than 100 speaker program events at which some or all of the five doctors were in attendance over the course of five years, sometimes as often as five times a month. At these events, the five doctors would take turns being the designated speaker and receiving the honorarium payment.
- rr. In Rockford Illinois, Novartis held 124 speaker programs over the course of eight years at which the same ten doctors or a subset of that group of doctors were the only persons in attendance. The same doctor was paid by Novartis to speak at 102 of those events. Some of the doctors who attended received a portion of that speaker's honoraria payment as a cash payment.

### **Novartis's Compliance Program**

- ss. Despite the known AKS risk posed by conducting meetings and events, during the Relevant Period, Novartis failed to develop and implement a compliance program that adequately ensured that its sales personnel was not using Novartis speaker and roundtable events as a means to induce doctors to prescribe Novartis drugs in violation of the AKS.
- tt. Novartis created a compliance department in 1999 but did not allocate the personnel and resources to adequately monitor that the tens of thousands of speaker and roundtable events that Novartis organized throughout the country each year complied with the AKS.
- uu. For the first two years of its existence, from 1999-2001, Novartis's compliance department consisted of one employee.
- vv. While Novartis hired additional compliance personnel in later years, it did not employ sufficient staff to investigate potential AKS violations. As a result, there was a large backlog of potential AKS violations that needed to be investigated. Because of this backlog and the resulting passage of time, in many cases Novartis did not investigate potential misconduct at all.
- ww. Novartis did not conduct a comprehensive field audit of speaker events until 2008, after approximately 90 percent of the events at issue in this case had already occurred. Novartis supervisors and compliance staff attended only a small number of the hundreds of thousands of speaker and roundtable events that Novartis arranged during the Relevant Period. Prior to the 2008 audit, sales representatives would typically receive advance notice if their programs were going to be audited.
- xx. Even though Novartis adopted a policy in 2002 prohibiting a doctor from bringing a spouse or guest who was not a prescribing health care professional to promotional programs, in practice spouses or other guests were often invited to or allowed to attend such dinners.

- yy. During part of the Relevant Period, Novartis compliance policies allowed sales representatives to spend as much as \$125 on each doctor's meal and alcohol, regardless of where in the United States the dinner event was located. Novartis policies also set no limits on how many dinner events doctors could attend concerning the same drug.
- zz. Novartis's compliance training materials suggested that emails advocating illegal kickbacks were improper in part because they "reflect[] ignorance of the import of written communications, and put[] the Company at risk." Novartis's Chief Compliance Officer also stated in training presentations: "If you don't have to write it, don't. Consider using the phone."

### **The 2010 Settlement and Corporate Integrity Agreement**

- aaa. In 2010, Novartis settled the United States and the States claims relating to Diovan, Exforge, Tekturna, Trileptal, Zelnorm, and Sandostatin. In that suit, the United States and the States alleged that, between 2002 and 2009, Novartis provided illegal remuneration to doctors, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel, and meals), to induce them to prescribe these drugs, in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b).
- bbb. As part of that settlement, in September 2010 Novartis entered into a five-year Corporate Integrity Agreement ("2010 CIA") with the United States Department of Health and Human Services Office of Inspector General. The 2010 CIA required Novartis to make various changes to its auditing, monitoring, investigations, discipline, and other compliance policies.
- ccc. The 2010 CIA also required an outside expert to audit Novartis's compliance program.
- ddd. The 2010 CIA required the expert to conduct a "Year One Compliance Program Effectiveness Review" a year after the 2010 CIA went into effect. As part of the review, the expert concluded that Novartis had only "partially" met its compliance goals in certain areas. For example, the expert concluded that compliance monitoring had still largely remained "the responsibility of the business [team]," rather than those working in the compliance department, and that Novartis had not "defined" how that monitoring was to occur or how the business team's findings would be reported to compliance officials. The expert found that there were no written policies or procedures addressing how to conduct investigations of allegations of speaker program abuses and that the reporting of investigative results had not been standardized. The expert also found that Novartis did not consistently undertake "appropriate disciplinary action" for compliance violations in non-termination cases.

2. Novartis 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 \$ 678,000,000.00 plus accrued interest (the “Settlement Amount”). 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) Novartis shall pay to the United States the sum of \$629,848,726.34, plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$103,183,766.85 consisting of \$48,151,273.66 for the states pursuant to this Agreement and \$55,032,493.19 for the United States pursuant to the Federal Settlement Agreement. Novartis shall pay to the Medicaid Participating States the sum of \$48,151,273.66 plus accrued interest on that amount of 2.5% per annum commencing on May 17, 2019 and continuing to and include the day payment is made under this Agreement (the “Medicaid State Settlement Amount”), subject to the non-participating state deduction provision of sub-paragraph (d) below (the “Medicaid Participating State Settlement Amount”), no later than ten (10) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid and immediately deposited by electronic funds transfer 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 Novartis. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 2. (d) below.

(c) Novartis shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Novartis and the State Team have agreed, or in a form otherwise agreed to by Novartis and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Novartis's attorneys within 60 days of receiving this Agreement. Novartis offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Novartis and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Novartis in settlement for the Covered Conduct for the State is \$19,858,488.54, 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 \$11,810,312.30 plus applicable interest (the "State Amount"), of which \$5,905,156.15, and the interest associated with that amount, 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 Medicaid State Settlement Amount and shall not be paid by Novartis absent written agreement between counsel for Novartis and the State Team to extend the time period for executing this Agreement.

3. 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 Novartis in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator the amount of

\$3,247,835.88 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.

4. Subject to the exceptions in Paragraph 5 below, in consideration of the obligations of Novartis set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Novartis, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively, the “Novartis Released Entities”), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State’s Medicaid Program for the Covered Conduct.

5. Notwithstanding the releases given in Paragraph 4 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 Novartis 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 4 above, including, but not limited to, any and all of the following claims: (i) 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 exclusion 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.

6. In consideration of the obligations of Novartis set forth in this Agreement, and the Corporate Integrity Agreement (the "CIA") that Novartis has entered into with the Office of the Inspector General of the United States Department of Health and Human Services in connection with this matter, and conditioned on receipt by the State of the State Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid Program against Novartis for the Covered Conduct, except as reserved in Paragraph 5 above. Nothing in this Agreement precludes the State from taking action against Novartis in the event that Novartis is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

7. Novartis 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.



8. In consideration of the obligations of the State set forth in this Agreement, the Novartis 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 Novartis Released Entities have 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.

9. The amount that Novartis must pay to the State pursuant to Paragraph III.2. 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 Novartis 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.

10. Novartis 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.

11. Novartis 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.

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

13. Novartis agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice of such an

investigation, Novartis shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals and of Novartis. Upon request, Novartis agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in its possession, custody or control, concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf, as well as complete and unredacted copies of any other non-privileged documents in its possession, custody, or control relating to the Covered Conduct.

14. 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.

15. 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.

16. 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.

17. In addition to all other payments and responsibilities under this Agreement, Novartis agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Novartis 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.

18. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, 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.

19. The undersigned Novartis 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.

20. 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.


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

22. 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.

23. 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.

24. 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.

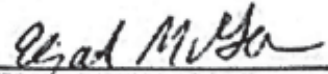
State of California

By:  Dated: 9-2-2020  
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By:  Dated: 8.28.2020  
Erika Sperbeck  
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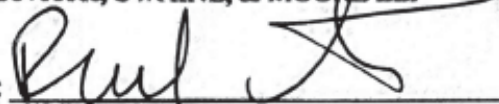
**NOVARTIS PHARMACEUTICALS CORPORATION**

NOVARTIS PHARMACEUTICALS CORPORATION

By:   
ELIZABETH MCGEE  
General Counsel, US Pharma  
US Country Head Legal  
Novartis Pharmaceuticals Corporation

Dated: 9/9/2020

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