

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of Florida ("the State") and Celgene Corporation ("Celgene"), hereinafter collectively referred to as "the Parties," through their authorized representatives.

### II. PREAMBLE

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

A. Celgene is a Delaware corporation, with its headquarters and principal place of business in New Jersey. At all relevant times, Celgene distributed, sold, and marketed pharmaceutical product(s) throughout the United States, including the drugs thalidomide under the brand name Thalomid® ("Thalomid®") and lenalidomide under the brand name Revlimid® ("Revlimid®").

B. The Food and Drug Administration ("FDA") approved Thalomid® on July 16, 1998, for use in the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum ("ENL") and as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence, which are complications of leprosy. On May 25, 2006, the FDA approved Thalomid®, in combination with dexamethasone, for use in the treatment of patients with newly diagnosed multiple myeloma.

C. The FDA approved Revlimid® on December 27, 2005, for use in the treatment of patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes (“MDS”) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, which are a group of cancers of the bone marrow. On June 29, 2006, the FDA approved the use of Revlimid® in combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy. Subsequently, on June 5, 2013, the FDA approved the use of Revlimid® for the treatment of patients with Mantle Cell Lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib; on February 17, 2015, the FDA approved the use of Revlimid® in combination with dexamethasone for the treatment of patients with multiple myeloma regardless of whether the patient received a previous treatment; and on February 22, 2017, the FDA approved the use of Revlimid® as maintenance treatment after autologous hematopoietic stem cell transplantation.

D. On April 27, 2010, Celgene former employee Beverly Brown (“Relator”), filed a *qui tam* action in the United States District Court for the Central District of California captioned *United States of America et al., ex. rel Beverly Brown v. Celgene Corporation*, Civil Action No. 10-cv-03165 (C.D. Cal.) (the “Civil Action”) pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and twenty-nine state FCA-related statutes. On May 3, 2013, the Relator filed her First Amended Complaint and on September 30, 2013 the United States, all plaintiff states, and the City of Chicago filed their joint Notice of Election to Decline Intervention. On November 6,

2013, the Relator filed her Second Amended Complaint and on January 31, 2014, the Court lifted the seal as to the operative complaint and all future filings. On February 5, 2014, the Relator filed her Third Amended Complaint and on March 21, 2014, the Court granted Celgene's motion to unseal the docket, all prior versions of the complaint, Relator's motions to amend, and the Court's orders granting leave to amend.

E. Celgene will enter into a separate civil settlement agreement (the "Federal Settlement Agreement") with the "United States of America" as that term is defined in the Federal Settlement Agreement (the "United States"), which will be receiving settlement funds pursuant to Paragraph III. 1. below.

F. The State contends that it has certain civil and administrative causes of action against Celgene for allegedly engaging in the following conduct concerning Celgene's marketing, promotion, and sale of Thalomid® and Revlimid® from April 27, 2000 to June 30, 2015 (hereafter referred to as the "Covered Conduct"):

(1) Celgene promoted Thalomid® for the treatment of multiple myeloma prior to the FDA's May 26, 2006 approval of Thalomid®; in combination with dexamethasone, for the treatment of newly diagnosed multiple myeloma; for the treatment of multiple myeloma not in combination with dexamethasone; for maintenance therapy for multiple myeloma and for treatment of multiple myeloma in patients who received a prior therapy for the disease; for the treatment of MDS; brain cancer; bladder cancer; cervical cancer; esophageal cancer; Kaposi's sarcoma;

leukemia, (including but not limited to chronic lymphocytic leukemia (“CLL”)); lymphoma; melanoma; ovarian cancer; prostate cancer; pancreatic cancer; renal cancer; thyroid cancer; lung cancer; colon and colorectal cancer; uterine cancer; and breast cancer. Celgene promoted Revlimid® for the treatment of multiple myeloma; newly diagnosed multiple myeloma; maintenance therapy for multiple myeloma; for the treatment of multiple myeloma without dexamethasone; for the treatment of MDS which is not associated with a deletion 5q cytogenetic abnormality; leukemia, (including but not limited to CLL); lymphoma; myelofibrosis; brain cancer; and prostate cancer. These indications for Thalomid® and Revlimid® were not approved by the FDA for some or all of the time-periods during which Celgene promoted the drugs for such uses. Certain of these indications were not covered by the State’s Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX) for some or all of the time-periods during which Celgene promoted the drugs for such uses.

(2) Celgene made or caused to be made false and misleading statements about Thalomid® and Revlimid® including: (a) improperly influencing the content of published drug compendia entries, medical literature, clinical studies and NCCN guidelines for Thalomid® and Revlimid® to support uses of these drugs not supported by medical science, including by making payments to physicians who had influence

over the content of published drug compendia entries, medical literature, clinical studies, and NCCN guideline entries for Thalomid® and Revlimid®; (b) concealing or downplaying adverse events associated with use of Thalomid® and Revlimid®; and (c) improperly changing or causing doctors to change ICD-9 diagnosis codes submitted as part of the RevAssist™ Risk Minimization Action Plan, a restricted distribution program for Revlimid® which was required as a condition of the FDA approval of Revlimid®, to cause the prescriptions to be reimbursed by the State's Medicaid Program.

(3) Celgene, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b and relevant state laws: (a) paid physicians who prescribed Thalomid® or Revlimid® to conduct speaker programs; (b) provided monetary support to physicians who prescribed Thalomid® or Revlimid® to conduct clinical trials and to write, or be listed as authors on, publications or medical literature; (c) paid physicians who prescribed Thalomid® or Revlimid® to work as consultants and/or serve on advisory boards; and (d) induced purchases of Thalomid® and Revlimid® by defraying patients' co-payment obligations for those drugs through its contributions to Patient Access Network Foundation (PANF) and the Leukemia and Lymphoma Society, which acted as conduits for Celgene and eliminated any price sensitivity to physicians prescribing and patients taking Thalomid® and Revlimid®.

As a result, the State contends that Celgene caused false or fraudulent claims for payment for Thalomid® and Revlimid® to be submitted to the State's Medicaid Program.

G. This Settlement Agreement is made in compromise of disputed claims. This Settlement Agreement is neither an admission of liability by Celgene nor a concession by the State that its claims are not well founded. Celgene denies the allegations in Paragraph F and in the Civil Action.

H. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation, 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:

I. Celgene agrees to pay to the United States and the Medicaid Participating States (as defined in Sub-paragraph (c) below), collectively, the sum of Two-Hundred Eighty Million Dollars (\$280 million) (the "Settlement Amount").

(a) Celgene shall pay to the United States the sum of \$259,269,640 (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Celgene shall pay to the Medicaid Participating States the sum of \$20,730,360 (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below (the "Medicaid Participating State Settlement Amount"). The Medicaid Participating State Settlement Amount shall be paid by Celgene no later than seven (7) business days after the expiration of the 21-day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid 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 Celgene.

(c) Celgene shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Celgene and the State Team have agreed, or in a form otherwise agreed to by Celgene and an individual State. The State shall constitute a Medicaid Participating State provided the State Settlement Agreement is fully executed by the State and delivered to Celgene's attorneys within 21 days of receiving this Agreement. If this condition is not satisfied within 21 days, Celgene's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Celgene and the State Team to extend the 21-day period.

(d) The total portion of the amount paid by Celgene in settlement for the Covered Conduct for the State is \$3,507,072.44, 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 net amount allocated to the State under this Agreement is the sum of \$1,415,123.56 (the "State Amount"). If the State does not execute this Agreement within 21 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Celgene absent written agreement between counsel for Celgene and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims currently pending against Celgene in State or Federal Courts for the Covered Conduct including but not limited to any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served in the Civil Action and otherwise liable to pay a Relator's share of the State Amount, agrees to pay the Relator, as soon as feasible after such receipt, such amounts as have been or will be negotiated with the Relator in the Civil Action, which shall be set forth in a side letter issued to and executed by the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, in consideration of the obligations of Celgene set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release Celgene, together with its current and former parent corporations; direct and indirect subsidiaries; brother and sister corporations; divisions; affiliates; corporate owners; and

*Celgene Corporation*  
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the corporate successors and assigns of any of them (collectively, the “Celgene Released Entities”), from any civil or administrative monetary cause of action that the State has for the Covered Conduct, including but not limited to common law theories of payment by mistake, unjust enrichment, and fraud.

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 not specifically released by this Agreement;
- (c) any civil or administrative liability that any person or entity, including the Celgene 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) 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 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.

5. Celgene 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 United States Constitution or the Excessive Fines Clause of the Eighth Amendment of the United States 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 Celgene 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 Celgene 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.

7. The amount that Celgene 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 Celgene 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. Celgene 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. Celgene expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

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

11. Upon receipt of the payment described in Paragraph I, above, the Relator and Celgene shall promptly sign and file in the Civil Action a Joint Stipulation of

Dismissal. The dismissal shall be with prejudice to Relator as to all claims against Celgene in the Civil Action, with prejudice to the State as to the Covered Conduct, and without prejudice to the State as to any other claims in the Civil Action.

12. 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.

13. 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.

14. 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.

15. In addition to all other payments and responsibilities under this Agreement, Celgene agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees not to exceed the amount of \$35,000. Celgene 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.

16. This Agreement is governed by the laws of the State. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Central District of California.

17. The undersigned Celgene 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.

18. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

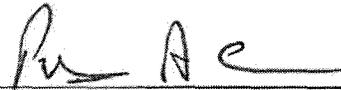
19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

20. 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.

21. 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.

STATE OF FLORIDA

The State of Florida  
Office of the Attorney  
Medicaid Fraud Control Unit

By:   
\_\_\_\_\_  
Patricia A. Conners  
Chief Deputy Attorney General

Dated: 2/14/17

*Celgene Corporation*  
*Case # Celgene-122*

