

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice, and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services; the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program; and the United States Department of Veterans Affairs, Veterans Health Administration (“VA”) (collectively, the “United States”), Celgene Corporation (“Celgene”), and Relator Beverly Brown (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

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 filed a *qui tam* action in the United States District Court for the Central District of California captioned *United States, et al. ex rel. Beverly Brown v. Celgene Corporation*, Case 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) (the “FCA”). Relator filed an Amended Complaint on May 3, 2013, a Second Amended Complaint on November 6, 2013, and a Third Amended Complaint on February 5, 2014. The United States did not intervene in the Civil Action.

E. In addition to the Civil Action, two other *qui tam* actions were filed against Celgene under the FCA. On February 25, 2011, Celgene former employee David Schmidt filed a *qui tam* action in the Eastern District of Texas captioned *United States, et al. ex rel. David Schmidt v. Celgene Corporation*, Case No. 4:11-cv-94 (the “Schmidt Action”). Mr. Schmidt amended his complaint five times; the Fifth Amended Complaint was filed on February 8, 2013. On April 14, 2014, the Schmidt Action was dismissed without prejudice. On August 17, 2011, Celgene former employee J. Patrick Eddins filed a *qui tam* action in the Northern District of Alabama captioned *United States, et al. ex rel. James Patrick Eddins v. Celgene Corporation*,

Case No. 5:11-cv-02880 (the “Eddins Action”). On February 5, 2014, the Eddins Action was dismissed without prejudice. The United States did not intervene in the Schmidt and Eddins Actions. Nothing in this Agreement shall be construed to entitle David Schmidt or J. Patrick Eddins to a Relator share or to statutory fees and costs.

F. The Agreement is based on civil claims against Celgene, as specified in Paragraph 2 below, 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 Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”); TRICARE, 10 U.S.C. §§ 1071-1110b; and VA, 38 U.S.C. Chapter 17, 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 Medicare, Medicaid, and TRICARE or cause purchases by VA.

(3) Celgene, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b: (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 of the foregoing conduct, Celgene allegedly caused false or fraudulent claims for payment for Thalomid® and Revlimid® to be submitted to, or allegedly caused purchases by, Medicare, Medicaid, TRICARE and the VA.

G. Celgene will be entering into separate settlement agreements described in Paragraph 1.b. below (referred to as the "Medicaid State Settlement Agreements") with certain states, commonwealths, and the District of Columbia in settlement of the Covered Conduct. States with which Celgene executes a Medicaid State Settlement Agreement shall be defined as "Medicaid Participating States."

H. 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 United States that the claims are not well founded. Celgene denies the allegations in Paragraph F, and in the Civil Action, the Schmidt Action and the Eddins Action.

I. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement. Relator further claims entitlement to recover from Celgene reasonable expenses, attorneys' fees and costs, pursuant to 31 U.S.C. § 3730(d). Celgene, Relator and Relator's counsel will be entering into a separate agreement, pursuant to 31 U.S.C. §

3730(d), providing for Celgene's payment of attorney fees and costs in connection with the Civil Action (the "Fees and Costs Agreement").

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. Celgene shall pay to the United States and the Medicaid Participating States, collectively, Two-Hundred Eighty Million Dollars (\$280 million) (the "Settlement Amount").
  - a. Celgene shall pay to the United States the sum of \$259,269,640 ("Federal Settlement Amount") no later than ten business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Department of Justice.
  - b. Celgene shall pay to the Medicaid Participating States the sum of \$20,730,360 ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Celgene will enter into with the Medicaid Participating States.
2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Celgene's full payment of the Settlement Amount, the United States releases Celgene, together with its current and former parent corporations; direct and indirect subsidiaries; brother and sister corporations; divisions; affiliates; corporate owners; and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States has 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 creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Pt. 0, Subpart I, 0.45(d); or common law theories of payment by mistake, unjust enrichment, and fraud.

3. Subject to the exceptions in Paragraph 4 below and conditioned upon Celgene's full payment of (a) the Settlement Amount in accordance with the terms of Paragraph 1, above, and (b) the Fee Amount as that term is defined in the Fees and Costs Agreement, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, and any other person or entity acting on her behalf or asserting her rights (collectively, the "Relator Releasers"), releases Celgene together with its current and former parent corporations; direct and indirect subsidiaries; related entities; divisions; affiliates; corporate owners; operating companies; and the corporate successors and assigns of any of them; as well as Celgene's current and former officers; directors; agents; and employees (collectively, the "Celgene Released Parties"), from any civil monetary or administrative claim the Relator Releasers have on behalf of the United States and the Medicaid Participating States for all claims related to or asserted in the Civil Action, the Schmidt Action and the Eddins Action, including claims based on or related to the Covered Conduct, under the False Claims Act, 31 U.S.C. §§ 3729-3733 and any State or local equivalents and the other acts, provisions, and theories set out in Paragraph 2.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Any administrative liability, including mandatory or permissive 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 obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. Relator Releasers shall not object to this Agreement but 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). The United States and Relator Releasers agree that they each retain all of their rights pursuant to the False Claims Act and 31 U.S.C. § 3730(d) on the issue of the share percentage that Relator should receive of any proceeds of the settlement of her claims.

6. Conditioned upon Celgene's full payment of (a) the Settlement Amount in accordance with the terms of Paragraph 1, above, and (b) the Fee Amount as that term is defined in the Fees and Costs Agreement, the Relator Releasers hereby release and forever discharge the Celgene Released Parties from any and all causes of action, lawsuits, proceedings, complaints, charges, debts, contracts, judgments, damages, claims, and attorney's fees against the Celgene Released Parties, whether known or unknown, which any Relator Releaser ever had, now has, or may have prior to the date this Agreement is signed by Relator, due to any matter whatsoever



(collectively, the "Relator Released Claims"). The Relator Released Claims include, but are not limited to, any claim that any of the Celgene Released Parties violated the Federal False Claims Act, and/or the False Claims Act of any State or Municipality; any claim arising from the filing of the Civil Action; and any claim that any of the Released Parties violated any other federal, state or local statute, law, regulation, wage order, or ordinance; any and all civil or administrative monetary claims or causes of action of any kind, whether under federal or state statute or regulation or common law; any claim of unlawful discrimination, retaliation or defamation of any kind; any public policy, contract, tort, or common law claim; and any claim for damages, costs, fees, or other expenses including attorney's fees incurred in connection with the Civil Action, the Schmidt Action, and the Eddins Action. Notwithstanding the foregoing, this Release does not apply to any claim for indemnification under Labor Code Section 2802, workers' compensation, a vested pension benefit, or any claim that as a matter of law cannot be released. It is the intention of the Relator and Celgene in executing this instrument that it shall be effective as a bar to each and every claim specified in this paragraph. In furtherance of this intention, Relator Releasers hereby expressly waive any and all rights and benefits conferred upon her by the provisions of Section 1542 of the California Civil Code and expressly consent that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims as herein above specified. Section 1542 provides:

"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."

Having been so apprised, Relator Releasers nevertheless hereby voluntarily elect to and does waive the rights described in Civil Code Section 1542 and elect to assume all risks for claims herein above specified that now exist in her favor, known or unknown.

7. Celgene waives and shall not assert any defenses Celgene 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.

8. Celgene fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Celgene has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. Celgene, its officers, directors and related entities, fully and finally releases the Relator Releasers from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Celgene has asserted, could have asserted, or may assert in the future against the Relator Releasers, related to the Covered Conduct and the Relator's investigation and litigation thereof.

10. 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, TRICARE or VA contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Celgene agrees not to resubmit to any Medicare, TRICARE or VA contractor or any state payer any previously denied claims related to the Covered Conduct,

agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

11. Celgene agrees to the following:

a. Unallowable Costs Defined: 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Celgene, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) Celgene's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Celgene makes to the United States pursuant to this Agreement and the payment that Celgene makes to Relator pursuant to the Fees and Costs Agreement.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE, VA, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Celgene, and Celgene 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 Celgene or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, VA, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for

Payment: Celgene 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, VA 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 Celgene 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. Celgene agrees that the United States, at a minimum, shall be entitled to recoup from Celgene 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 Celgene or any of

its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Celgene 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 Celgene's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 13 (waiver for beneficiaries paragraph) below.

13. Celgene 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.

14. Upon receipt of the payment described in Paragraph 1, 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 United States as to the Covered Conduct, and without prejudice to the United States as to any other claims in the Civil Action. The Stipulation shall provide that the Court shall retain jurisdiction to adjudicate, if necessary, Relator's claim for a share of the proceeds of the Civil Action pursuant to 31 U.S.C. § 3730(d).

15. Except as set forth in the Fees and Costs 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.

16. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Central District of California. For purposes of construing this Agreement, 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.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

21. This Agreement is binding on Celgene's successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

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

24. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**SIGNATURES ON NEXT PAGE**

**THE UNITED STATES OF AMERICA**

DATED: 7/12/17

BY: William E Olson  
William E. Olson  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Brent Whittlesey  
Assistant United States Attorney  
Central District of California

**CELGENE CORPORATION**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Gerald Masoudi  
Executive Vice President, General Counsel and Corporate  
Secretary

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Toni-Ann Citera  
Karen P. Hewitt  
Brian Hershman  
Jones Day  
Counsel for Celgene Corporation

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Kimberly A. Dunne  
Sidley Austin LLP  
Counsel for Celgene Corporation

**BEVERLY BROWN**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Beverly Brown

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Reuben Guttman  
Counsel for Beverly Brown

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
William E. Olson  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: July 27, 2017 BY: Brent Whittlesey  
Brent Whittlesey  
Assistant United States Attorney  
Central District of California

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Counsel for Beverly Brown



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Central District of California

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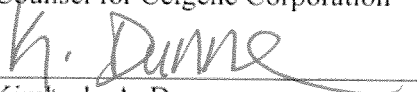
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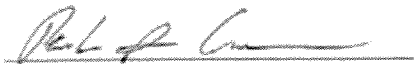
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