

### JOSH STEIN ATTORNEY GENERAL

# STATE OF NORTH CAROLINA DEPARTMENT OF JUSTICE

SETH DEARMIN CHIEF OF STAFF

October 10, 2017

North Carolina Senate President Pro Tempore Phil Berger North Carolina House of Representatives Speaker Tim Moore Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Warren Daniel
Senator Shirley Randleman
Senator Norman W. Sanderson
Representative James Boles, Jr.
Representative Ted Davis, Jr.
Representative Allen McNeill
Representative Rena W. Turner
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly Raleigh, North Carolina 27601-1096

Re: G.S. §114-2.5; Report on Settlement Agreements for Charlotte-Mecklenburg Hospital Authority, James Taggart and Celgene Corporation

#### Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matters. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

### Charlotte Mecklenburg Hospital Authority (CMHA)

A Settlement has been executed between CMHA and the State of North Carolina.

The settlement resolves allegations that from January 1, 2011 through December 31, 2015, CMHA upcoded certain urine drug tests to obtain higher payment than they should have received for those tests.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$6,500,000.00. Of that amount the federal government will receive \$5,413,983.05 for North Carolina's federal portion of Medicaid and Medicare recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$230,017.96 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$608,006.25 as restitution. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$168,898.43 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive \$61,899.27 for investigative costs and \$17,195.04 for costs of collection.

### James Taggart

A settlement has been executed between James Taggart and the State of North Carolina.

The settlement resolves allegations that from January 1, 2008 through April 30, 2013, James Taggart and Physicians Pharmacy Alliance ("PPA") provided gift cards to patients, physician office employees, and community health center employees in order to induce them to enroll or refer patients to PPA. It was also alleged that James Taggart and PPA waived copays for Medicare and Medicaid beneficiaries who had their prescriptions filled at PPA.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$995,000.00. Of that amount the federal government will receive \$822,268.00 for North Carolina's federal portion of Medicaid and Medicare recoveries. The North Carolina Medicaid Program will receive \$156,771.56 as restitution. Pursuant to G.S. § 1-608(c), the North Carolina Department of Justice will receive \$15,960.44 for investigative costs.

### **Celgene Corporation**

A settlement has been executed between Celgene and the State of North Carolina.

The settlement resolves allegations that from April 27, 2000 through June 30, 2015, Celgene engaged in a variety of marketing schemes to promote the use of its drugs Thalomid and Revlimid for off-label use, and paid kickbacks to induce prescribing of these drugs.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$1,918,498.03. Of that amount the federal government will receive \$1,262,614.50 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$186,926.81 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$212,812.56 as restitution. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$212,812.55 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive \$21,665.81 for investigative costs and \$21,665.80 for costs of collection.

We will be happy to respond to any questions you may have regarding this report.

In Du

Very truly yours,

Seth Dearmin Chief of Staff

SD:ng

cc: Kristine Leggett, NCGA Fiscal Research Division

### 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 and the North Carolina Office of the Attorney General (collectively, the "Government"), The Charlotte-Mecklenburg Hospital Authority and Mark McGuire (hereafter collectively referred to as "the Parties"), through their authorized representatives.

### **RECITALS**

- A. The Charlotte-Mecklenburg Hospital Authority (hereinafter Defendant) is a non-profit hospital authority organized under the laws of North Carolina with a principal place of business in Charlotte, North Carolina. Defendant does business under the name of Carolinas HealthCare System. In addition to its owned facilities, Defendant manages or has managed a number of other healthcare providers (the "Contracted Hospitals") (listed in Exhibit A).
- B. On April 6, 2015, Mark McGuire (hereinafter "Relator") filed a *qui tam* action in the United States District Court for the District for the Western District of North Carolina captioned *United States of America and the State of North Carolina ex rel. Mark McGuire v. The Charlotte-Mecklenburg Hospital Authority, et al.* (Case No. 3:15-cv-147) pursuant to the *qui tam* provisions of the United States False Claims Act, 31 U.S.C. § 3730(b) and the North Carolina False Claims Act, N.C.G.S. § 1-608(b) (the "Civil Action"). On June 27, 2017, Relator filed his Amended Complaint in the Civil Action. Relator alleged that Defendant submitted false claims to government healthcare programs for urine drug testing. Specifically Relator alleged that Defendant used an incorrect billing code that resulted in higher reimbursement from Medicare and Medicaid than Defendant was entitled to for the tests that it conducted.

- C. The Government contends that Defendant submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III ("Medicare") and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid").
- D. The Government contends that it has certain civil claims against Defendant for submitting false claims and causing the submission of false claims by hospitals under management contracts with Defendant as listed in Exhibit A.
  - E. The Government contends the following:
    - (1) During the relevant time period, urine drug tests were classified by the Food and Drug Administration ("FDA") as either waived, moderate, or high complexity pursuant to certain criteria under the Clinical Laboratory Improvement Amendments ("CLIA").
    - (2) From January 1, 2011, to December 31, 2015, claims for tests classified as CLIA moderate complexity should have been submitted with Healthcare Common Procedure Coding System ("HCPCS") code G0434, and claims for tests classified as CLIA high complexity should have been submitted with HCPCS code G0431.
    - (3) From January 1, 2011, to December 31, 2015, Defendant and the Contracted Hospitals conducted CLIA moderate complexity tests, but submitted CLIA high complexity testing claims (G0431) for these tests, causing Defendant and certain Contracted Hospitals to obtain higher payment than they should have received for those tests.

This conduct recited above in Paragraph E is referred to below as the "Covered Conduct."

- F. This Settlement Agreement is neither an admission of liability by Defendant nor a concession by the Government that its claims are not well founded. Defendant denies the allegations of the United States and Relator and denies that it engaged wrongful conduct related to the Covered Conduct or that it retaliated against the Relator.
- G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

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. Defendant shall pay to the United States six million five hundred thousand dollars (\$6,500,000.00) (the "Settlement Amount") no later than 15 business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Western District of North Carolina.
- Conditioned upon the United States receiving the Settlement Amount from
   Defendant and as soon as feasible after receipt, the United States shall pay the State of North
   Carolina an amount determined in accordance with the State share of Medicaid program
   damages.
- 3. Conditioned upon the United States receiving the Settlement Amount from Defendant and as soon as feasible after receipt, the United States shall pay one million three hundred sixty five thousand dollars (\$1,365,000.00) to Relator by electronic funds transfer.
- 4(a). In full satisfaction of any expenses, legal fees, or costs that may be due Relator or his attorneys pursuant to 31 U.S.C. § 3730(d)(1) or N.C.G.S. § 1-610(d), Defendant shall, within 15 business days, pay to Relator's attorneys \$84,930.33.

- 4(b). In full satisfaction of any claims Relator may have related to his employment with Defendant, including but not limited to any claims under 31 U.S.C. § 3730(h) or N.C.G.S. § 1-613, and in exchange for his agreement not to apply for employment with any entity owned, in whole or in part, by The Charlotte-Mecklenburg Hospital Authority, Defendant shall, within 15 business days, pay to Relator (through Relator's attorneys) \$30,000. Defendant makes no representation as to the appropriate tax treatment of such amount. The parties agree that any tax liability shall be Relator's.
- 5. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Defendant's full payment of the Settlement Amount, the United States releases Defendant and the Contracted Hospitals, together with their predecessors, current and former parents, direct and indirect subsidiaries, and divisions, individually and collectively, 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; or the common law theories of payment by mistake, unjust enrichment, and fraud.
- 6. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Defendant's full payment of the Settlement Amount, the State of North Carolina releases Defendant and the Contracted Hospitals, together with their predecessors, current and former parents, direct and indirect subsidiaries, and divisions, individually and collectively, from any civil or administrative monetary claim that North Carolina has for the Covered Conduct under the North Carolina False Claims Act, N.C.G.S. § 1-605, et seq., or the common law theories of payment by mistake, unjust enrichment, and fraud.
- 7. Subject to the exceptions in Paragraph 8 below, and conditioned upon

  Defendant's full payment of the Settlement Amount and the amounts set forth in Paragraphs 4(a)

and 4(b), Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, and Relator's attorneys, release Defendant and the Contracted Hospitals, together with their predecessors, current and former parents, direct and indirect subsidiaries, and divisions, individually and collectively, as well as their current or former owners, officers, directors, shareholders, attorneys, agents, and employees, individually and collectively, from any civil monetary claim the relator has on behalf of the United States for the Covered Conduct under the United States False Claims Act, 31 U.S.C. §§ 3729-3733 and the North Carolina False Claims Act, N.C.G.S. § 1-605, et seq. In addition, Relator and his attorneys release and discharge Defendant, the Contracted Hospitals, their predecessors, current and former parents, direct and indirect subsidiaries, and divisions, individually and collectively, as well as their current or former owners, officers, directors, shareholders, attorneys, agents, and employees, individually and collectively, from any and all claims, charges, actions, causes of action, sums of money due, suits, demands or liabilities whether known or unknown, fixed or contingent, that Relator may have or claim to have against them for any reason as of the Effective Date of this Agreement, including, but not limited to, any claims under 31 U.S.C. § 3730(h) or N.C.G.S. § 1-613.

- 8. Notwithstanding the releases given in paragraphs 5, 6, and 7 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;
  - Except as explicitly stated in this Agreement, 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; and
- f. Any liability of individuals.
- 9. Relator and his heirs, successors, attorneys, agents, and assigns 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). Conditioned upon Relator's receipt of the payment described in Paragraph 3, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States and the State of North Carolina, their agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730 and N.C.G.S. § 1-605 and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.
- 10. Conditioned upon receiving the payment set forth in Paragraphs 4(a) and 4(b), Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, and Relator's attorneys release Defendant and the Contracted Hospitals, together with their predecessors, current and former parents, direct and indirect subsidiaries, and divisions, individually and collectively, as well as their current or former owners, officers, directors, shareholders, attorneys, agents, and employees, individually and collectively, from any liability to Relator or Relator's attorneys arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) or N.C.G.S. § 1-610(d) (for expenses or attorney's fees and costs), or under 31 U.S.C. § 3730(h) or N.C.G.S. § 1-613 (for any retaliation claim).
- 11. Defendant waives and shall not assert any defenses Defendant 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

Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

- 12. Defendant fully and finally releases the United States and the State of North Carolina, their agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the United States or the State of North Carolina, their agencies, officers, agents, employees, and servants, related to the Covered Conduct and the Government's investigation and prosecution thereof.
- 13. In consideration of the obligation of the Relator set forth in this Agreement,

  Defendant fully and finally releases the Relator from any claims (including attorney's fees, costs,
  and expenses of every kind and however denominated) that Defendant has asserted, could have
  asserted, or may assert in the future against the Relator, related to the Covered Conduct and the
  Relator's investigation and prosecution thereof.
- 14. Conditioned upon Defendant's full payment of the Settlement Amount and the amounts set forth in Paragraphs 4(a) and 4(b), Relator agrees not to apply for employment with any entity owned, in whole or in part, by the Charlotte-Mecklenburg Hospital Authority, and Relator agrees that the Charlotte-Mecklenburg Hospital Authority is under no obligation to consider him for further employment. Should the Charlotte-Mecklenburg Hospital Authority receive an inquiry from an employer or prospective employer regarding Relator Mark McGuire, consistent with its personnel policies and the North Carolina Public Hospital Personnel Act (N.C.G.S. § 131E-257.2), and absent a court order or other lawful legal process, the Charlotte-

Mecklenburg Hospital Authority will provide only Mark McGuire's name, age, dates of employment, and position title.

- 15. 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 contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Defendant agrees not to resubmit to any Medicare 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.
  - 16. Defendant agrees to the following:
- a. <u>Unallowable Costs Defined</u>: 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendant, 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) Defendant'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; and

(5) the payment Defendant makes to the United States pursuant to this

Agreement and any payments that Defendant may make to Relator,
including costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, 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 in nonreimbursable cost centers by Defendant, and Defendant 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 Defendant or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment:

  Defendant further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendant 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. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant 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 Defendant or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendant 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 Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 17. Defendant agrees to cooperate fully and truthfully with the Government's investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Defendant 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. Defendant further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, 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.
- 18. 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 Paragraphs 5, 6, 7, 10, and 19 (waiver for beneficiaries paragraph) below.

- 19. Defendant 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.
- 20. Upon receipt of the payment described in Paragraph 1, above, the United States and the State of North Carolina shall promptly sign and file a stipulation of dismissal of the Civil Action, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1).
- 21. Upon receipt of the payments described in Paragraphs 1, 4(a), and 4(b), Relator shall promptly sign and file a stipulation of dismissal of the Civil Action, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1).
- 22. With the exception of Relator's expenses, legal fees, and costs as agreed in Paragraph 4(a), each Party shall bear its own expenses, legal fees, and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 23. 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.
- 24. 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 Western District of North Carolina. 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.
- 25. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 26. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

- 27. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 28. This Agreement is binding on Defendant's successors, transferees, heirs, and assigns.
  - 29. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.
- 30. All parties consent to the United States' and the State of North Carolina's disclosure of this Agreement, and information about this Agreement, to the public.
- 31. 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.

### THE UNITED STATES OF AMERICA

DATED: <u>6-30-17</u>	BY: Jonathan H. Ferry Assistant United States Attorney Western District of North Carolina	
DATED:	BY: Lisa M. Re	
	Assistant Inspector General for Legal Affairs	
	Office of Counsel to the Inspector General	
	Office of Inspector General	
	United States Department of Health and Human Serv	ices

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d: US DHHS OIG OCIG Jun 27 2017 08:12am

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### THE UNITED STATES OF AMERICA

DATED:	
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BY:

Jonathan H. Ferry

Assistant United States Attorney Western District of North Carolina

DATED: 6/27/17

BY:

isa M. Rc

Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General

Office of Inspector General

United States Department of Health and Human Services

STATE OF NORTH CAROLINA

DATED: 6/27/17

BY:

Charles H. Hobgood
Special Deputy Attorney General
Director, North Carolina Medicaid Investigations

Division

### **DEFENDANT**

DATED:6/28/2017

BY:

Keith A. Smith

Executive Vice President and General Counsel

Carolinas HealthCare System

DATED: 6/28/2017

BY: Mark Calloway

Alston & Bird LLP Counsel for Defendant

DATED: 6/26/17	BY:	Mark McGuire Relator
DATED: 4/24/17	BY:	Thomas Greene Counsel for Relator
DATED:	BY:	W. Thompson Comerford, Jr. Counsel for Relator

### RELATOR

DATED:	BY:		
<del></del>		Mark McGuire	
		Relator	
DATED:	BY:		
<del></del>		Thomas Greene	
		Counsel for Relator	
DATED: <u>6-29-17</u>	BY:	Withompson Comentard	5, JKM
		W. Thompson Comerford, Jr.	,
		Counsel for Relator	

### **EXHIBIT A**

### **Contracted Facilities**

- 1. AnMed Health, Inc., including
  - a. AnMed Health Medical Center
  - b. AnMed Health Rehabilitation Hospital
  - c. AnMed Health Women's and Children's Hospital
  - d. AnMed Health Cannon
- 2. Blue Ridge Healthcare System, Inc., including
  - a. Carolinas HealthCare System Blue Ridge Morganton
  - b. Carolinas HealthCare System Blue Ridge Valdese
- 3. CareAlliance Health Services, including Roper Hospital
- 4. Columbus Regional Healthcare System
- 5. Moses H. Cone Memorial Hospital
- 6. MedWest Health System, Inc. (no longer contracted with CHS)
- 7. Murphy Medical Center, Inc.
- 8. Scotland Healthcare System, including Scotland Memorial Hospital
- 9. St. Luke's Healthcare Inc., including St. Luke's Hospital
- 10. Wilkes Regional Medical Center Hospital Operating Corporation, including Wilkes Regional Medical Center
- 11. Stanly Health Services, Inc. (owned by CHS as of March 1, 2014)

### **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 (HHS), the State of North Carolina, by and through the North Carolina Attorney General, and the North Carolina Division of Medical Assistance (collectively, the "Governments" includes both federal and state entities above), and James Taggart (hereafter collectively referred to as "the Parties"), through their authorized representatives.

#### RECITALS

- A. James Taggart was the president and an owner of Physicians Pharmacy Alliance, Inc. (hereinafter "PPA"), a corporation that provides pharmacy services, primarily to Medicaid and Medicare patients in North Carolina.
- B. James Taggart filed a Chapter 11 Bankruptcy Case, Case No. 16-3321-5-JNC, (hereinafter "Bankruptcy Case") in the Eastern District of North Carolina, on June 24, 2016, and remains under the protection of the Bankruptcy Court.
- C. The Governments contend that James Taggart submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare") and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid").
  - D. The Governments contend that:
  - 1. Between January 1, 2008, and January 4, 2011, James Taggart and others caused gift cards to be provided to patients, physician office employees, and community health center employees in order to induce them to enroll or refer patients to PPA in violation of the Anti-kickback statute, 42 U.S.C. § 1320a-7b; and

2. Between January 1, 2008, and April 30, 2013, James Taggart and others caused copayments to be waived for Medicare and Medicaid beneficiaries who had their prescriptions filled at PPA.

The Governments contend that through the above conduct, James Taggart caused PPA to submit false and fraudulent claims to Medicare and Medicaid in violation of the False Claims Act. This conduct is referred to below as the Covered Conduct.

E. This Settlement Agreement is neither an admission of liability by James Taggart nor a concession by the Governments that their claims are not well founded. James Taggart denies the Governments' allegations in Paragraph D.

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. The Settlement Amount (defined below) shall constitute a debt to and an allowed claim of the Governments within the meaning of 11 U.S.C. § 502. All debts and claims relating to or resulting from the Covered Conduct shall be discharged to the Governments under the following terms and conditions:
  - a. James Taggart shall pay to the Governments the total sum of \$995,000 ("Settlement Amount"), within 15 days of the Effective Date of the Plan in the Bankruptcy Case, based upon anticipated approval by the Bankruptcy Court, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the Eastern District of North Carolina.
  - b. James Taggart agrees that the Settlement Amount and the debt arising from default for nonpayment on the Governments' claims would be non-dischargeable

pursuant to 11 U.S.C. § 523 and 11 U.S.C. § 1141, but the liability for the Covered Conduct will be dischargeable based upon full payment of the Settlement Amount. The Governments' Adversary Proceeding in the Bankruptcy Case regarding non-dischargeability, AP No. 16-147-5-JNC, shall be dismissed with prejudice upon the later of full payment of the Governments' Settlement Amount or the Effective Date of the Plan.

- c. The terms of the Chapter 11 Plan shall be consistent with this Agreement. The Governments' \$995,000 claim shall be classified separately as an Unsecured General Claim, deemed impaired under the Plan, and paid in full under the Plan within 15 days of the Effective Date. The Governments agree to vote to accept a Plan consistent with this Agreement. In addition, in the event of dismissal or conversion of the Bankruptcy Case, voluntary or otherwise, James Taggart and the Governments intend that a Fed. R. Bankr. P. 9019 motion and order relating to this Agreement shall survive said dismissal or conversion. To the extent that any provision of any plan of reorganization conflicts with any provision of the Agreement, the provisions of this Agreement control.
- 2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon James Taggart's full payment of the Settlement Amount, the United States releases James Taggart 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; or the common law theories of payment by mistake, unjust enrichment, and fraud, and shall not file a civil action against James Taggart for the Covered Conduct.
- 3. In consideration of the obligations of James Taggart set forth in this Agreement, conditioned upon James Taggart's full payment of the Settlement Amount, and subject to the

exceptions in Paragraph 4 below, the State of North Carolina releases James Taggart from any civil or administrative monetary claim the State of North Carolina has for the Covered Conduct under the North Carolina False Claims Act, N.C.G.S. § 1-605 et. seq., the North Carolina Medical Assistance Provider False Claims Act, N.C.G.S. § 108A-70.10 et. seq., or the common law theories of payment by mistake, unjust enrichment, and fraud for the Covered Conduct, and shall not file a civil action against James Taggart for the Covered Conduct.

- 4. Notwithstanding the release given in paragraph 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the Governments are specifically reserved and are not released:
  - a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
  - b. Any criminal liability;
  - Except as explicitly stated in this Agreement, any administrative liability,
     including mandatory or permissive exclusion from Federal or State health
     care programs;
  - d. Any liability to the United States, North Carolina, or their agencies for any conduct other than the Covered Conduct;
  - e. Any liability based upon obligations created by this Agreement;
  - f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
  - g. Any liability for failure to deliver goods or services due; and
  - h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct,

- 5. James Taggart has filed bankruptcy petitions and accompanying schedules (as amended, the "Schedules") in his Bankruptcy Case, and the Governments have relied on the accuracy and completeness of those Schedules in reaching this Agreement. James Taggart warrants that the Schedules are complete, accurate, and current. If the Governments learn of asset(s) in which James Taggart had an interest at the time of this Agreement that were not disclosed in the Schedules, or if the Governments learn of any misrepresentation by him on, or in connection with, the Schedules, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Schedules by \$50,000 or more, the Governments may at their option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount. James Taggart agrees not to contest any collection action undertaken by the Governments pursuant to this provision, and immediately to pay the Governments all reasonable costs incurred in such an action, including attorney's fees and expenses.
- 6. In the event that the Governments, pursuant to Paragraph 5 (concerning disclosure of assets), above, opt to rescind this Agreement, James Taggart agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the Governments within 30 calendar days of written notification to James Taggart that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on April 5, 2017.
- 7. James Taggart waives and shall not assert any defenses he 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 Governments concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

- 8. James Taggart fully and finally releases the Governments, their agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that he has asserted, could have asserted, or may assert in the future against the Governments, and their agencies, officers, agents, employees, and servants related to the Covered Conduct and the Government investigation and prosecution thereof.
- 9. 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 contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and James Taggart agrees not to resubmit to any Medicare 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.
  - 10. James Taggart agrees to the following:
- a. <u>Unallowable Costs Defined</u>: 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 PPA, its present or former officers, directors, employees, shareholders, and agents in connection with:
  - (1) the matters covered by this Agreement;

- (2) the Governments' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) James Taggart's investigation, defense, and corrective actions undertaken in response to the Governments' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment James Taggart makes to the Governments pursuant to this Agreement,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, 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 James Taggart, and he 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 James Taggart or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment:

  James Taggart further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information

reports, or payment requests already submitted by James Taggart, 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. James Taggart agrees that the Governments, at a minimum, shall be entitled to recoup from him 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 Governments pursuant to the direction of the Department of Justice, North Carolina Department of Justice, and/or the affected agencies. The Governments reserve their rights to disagree with any calculations submitted by James Taggart on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on his cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the Governments to audit, examine, or re-examine James Taggart's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 11. James Taggart agrees to cooperate fully and truthfully with the Governments' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, James Taggart shall use his best efforts to make available, and encourage, the cooperation of his former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. James Taggart further agrees to furnish to the Governments, upon request, complete and unredacted copies of all non-privileged documents, 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 their behalf.

- 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. James Taggart 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. James Taggart agrees to the following in exchange for valuable consideration provided in this agreement:
- a. James Taggart's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and James Taggart shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) James Taggart's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) James Taggart became insolvent as a result of the payment made to the Government; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to James Taggart. James Taggart further agrees that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which James Taggart was or became indebted to on or after the date of this transfer, with the meaning of 11 U.S.C. § 548(a)(1).
- b. If, in the event that (1) James Taggart defaults on any of his obligations under this Agreement prior to the satisfaction of the Settlement Amount, or (2) any portion of the

Settlement Agreement is avoided for any reason, including, but not limited to, through the exercise of powers granted under 11 U.S.C. §§ 544, 547, 548, 549 or 550, or any other Bankruptcy Code provision or state law provision, by entry of judgment or settlement (defined herein as an "Avoidance Event"), the United States and/or North Carolina, at their sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against James Taggart for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 4 above; however, James Taggart shall be entitled to an offset for any monies already paid to the Governments towards the satisfaction of said amount.

c. If an Avoidance Event occurs or James Taggart's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, and/or North Carolina, at their sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against James Taggart for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 4, above. James Taggart agrees that (i) any such claims, actions, or proceedings brought by the Governments are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) and (b)(4) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and James Taggart shall not argue or otherwise contend that the Governments' claims, actions, or proceedings are subject to an automatic stay; (ii) James Taggart shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the Governments within 30 calendar days of written notification to James Taggart that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on April

5, 2017; and (iii) the Governments may pursue their claims in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

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- d. The Parties agree that the Bankruptcy Court for the Eastern District of North Carolina and the United States District Court for the Eastern District of North Carolina shall retain concurrent jurisdiction to enforce this Agreement and that any action or proceeding to enforce this Agreement is not subject to the automatic stay of 11 U.S.C. § 362(a).
- 15. 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 Eastern District of North Carolina. 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 James Taggart's successors, transferees, heirs, and assigns.

- 22. All parties consent to the Governments' disclosure of this Agreement, and information about this Agreement, to the public.
- 23. 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.

### THE UNITED STATES OF AMERICA

DATED:		JOHN STUART BRUCE United States Attorney
	BY:	NEAL I. FOWLER Assistant United States Attorney 310 New Bern Avenue Federal Building, Suite 800 Raleigh, NC 27601-1461 Telephone: (919) 856-4049
DATED:	BY:	LISA M. RE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services

## THE STATE OF NORTH CAROLINA

DATED: <u>5/30/201</u> 7	BY:	CHARLIE HOBGOOD  Special Deputy Attorney General Director, North Carolina Medicaid Investigations Division
		JAMES TAGGART
DATED:	BY:	JAMES TAGGART
DATED: <u>5/22/17</u>	BY:	PETER C. ANDERSON Beveridge & Diamond Counsel for James Taggart
DATED: <u>\$ /2 2/1 7</u>	BY:	JOHN NORTHEN Northen Blue, LLP Counsel for James Taggart

### THE STATE OF NORTH CAROLINA

DATED:	BY:	CHARLIE HOBGOOD Special Deputy Attorney General Director, North Carolina Medicaid Investigations Division
		JAMES TAGGART
DATED: May 23, 2017	BY:	JAMES TAGGART
DATED:	BY:	PETE ANDERSON Beveridge & Diamond Counsel for James Taggart
DATED:	BY:	JOHN NORTHEN Northen Blue, LLP Counsel for James Taggart

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State

of North Carolina ("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.

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- 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 Lymphorna 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<sup>TM</sup> 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:

1. 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.
- \$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 \$1,918,498.03, 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 \$655,883.53 (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 Case # Celgene-122

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 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 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 NORTH CAROLINA

By: Colorles H. Holyood

Dated: 7/06/2017

CHARLES H. HOBGOOD
Director, Medicaid Investigations Division
Office of the Attorney General

DAVE RICHARD

Deputy Secretary for Medical Assistance

Division of Medical Assistance

## **CELGENE CORPORATION**

By:	
	Gerald Masoudi Executive Vice President, General Counsel and Corporate Secretary
	Celgene Corporation
Ву:	TOWAM CITCH Dated: 7/12/17
	Toni-Ann Citera
	Karen P. Hewitt
	Brian P. Hershman
	Jones Day
	Counsel to Celgene Corporation