State of North Carolina

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March 9, 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 Agreement for Biocompatibles, Inc

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 matter. 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.

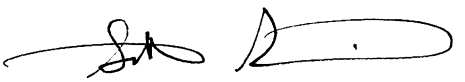
A Settlement has been executed between Biocompatibles and the State of North Carolina. The settlement resolves allegations that from May 1, 2006 through December 31, 2011, Biocompatibles off-label marketed its LC Bead medical device.

Under the terms of North Carolina's settlement, the State of North Carolina will recover $94,397.29. Of that amount the federal government will receive $64,612.91 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 $6,331.09 of North Carolina's recovery. The North Carolina Medicaid Program will receive $10,827.43 as restitution and interest. 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 $10,489.97 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. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive $1,067.95 for investigative costs and $1,067.94 for costs of collection.

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

Very truly yours,



Seth Dearmin
Chief of Staff

SD:ng

cc: Kristine Leggett, NCGA Fiscal Research Division
Robert Paschal, DOJ Legislative Liaison

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Biocompatibles, Inc. ("Biocompatibles"), hereinafter collectively referred to as "the Parties."

II. PREAMBLE

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

A. Biocompatibles is a Delaware corporation with its principal place of business in Conshohocken, Pennsylvania. Biocompatibles is wholly-owned subsidiary of Biocompatibles International Ltd, a company organized under the laws of the United Kingdom ("UK") that was acquired in 2011 by another UK company, BTG plc. At all relevant times, Biocompatibles developed and manufactured a medical device sold in the United States under the trade names GelSpheres Embolic Agent, GelSpheres Compressible Microspheres, and LC Bead (collectively referred to as "LC Bead"). At all relevant times, LC Bead was distributed, marketed, and/or sold in the United States through third-party distributors. At all relevant times, LC Bead was cleared by the U.S. Food and Drug Administration ("FDA") only for use in embolization of hypervascular tumors and arteriovenous malformations ("bland embolization"). At no time did Biocompatibles receive clearance or approval from the FDA to market a LC Bead with an intended use as a drug eluting device.

B. On July 23, 2013, Ryan Bliss filed a *qui tam* action in the United States District Court for the Western District of Texas captioned *United States of America et al.,*

ex rel. Bliss v. Biocompatibles, Inc., et al., Civil Action No. SA-13-CA-0667-H. This *qui tam* action will be referred to collectively as the "Civil Action."

C. Biocompatibles has entered into a plea agreement with the United States Attorney for the District of Columbia and the Consumer Protection Branch, U.S. Department of Justice, and, if the plea agreement is approved by the Court, will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to one misdemeanor count of causing the introduction and delivery for introduction into interstate commerce of a misbranded medical device, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), as described in an Information filed in *United States v. Biocompatibles, Inc.*, Criminal Action No. [to be assigned] (D.D.C) (the "Federal Criminal Action").

D. Biocompatibles has entered 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) hereinafter referred to as the "United States."

E. The State contends that Biocompatibles caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)).

F. The State contends that it has certain civil and administrative causes of action against Biocompatibles for engaging in the following conduct (the "Covered Conduct"):

> (1) The State alleges that as Biocompatibles planned to enter the U.S. market in 2005, it intended for the LC Bead to be used as a drug-delivery device in combination with chemotherapeutic agents, specifically in a medical procedure known as drug-eluting bead transarterial chemo-embolization or "DEB-TACE." More specifically, Biocompatibles intended for LC Bead to be used as a drug delivery-device in DEB-TACE

procedures for patients diagnosed with hepatocellular carcinoma ("HCC") and metastatic colorectal cancer ("mCRC").

LC Bead was cleared by the United States Food and Drug Administration (FDA) only for bland embolization. LC Bead used as a drug-eluting bead in combination with prescription drugs constituted a new combination drug-device product that was not approved or cleared by the FDA. Absent certain exceptions that are not applicable in this case, the Medicaid program does not cover devices that are not approved or cleared by the FDA.

In October 2006, Biocompatibles sought to obtain a 510(k) marketing clearance that identified transarterial chemoembolization as the intended use for LC Bead. The FDA responded that such an intended use would require a Premarket Approval (PMA) before it could be legally marketed. In December 2009, Biocompatibles filed a PMA application for a drug-eluting bead combination product, intended for use in transarterial chemoembolization of unresectable HCC. In February 2010, the FDA informed Biocompatibles that the FDA was not accepting the PMA application because the predetermined endpoint, overall tumor response rate, of the clinical studies included in the application did not provide adequate evidence of a therapeutic benefit. To date, Biocompatibles has not obtained approval or clearance from the FDA for a drug-eluting bead combination product.

Notwithstanding the company's unsuccessful attempts to obtain FDA approval or clearance for a drug-eluting bead combination product, Biocompatibles, through its third-party distributors, marketed and distributed LC Bead for use as a combination drug-device product.

For example, training provided by Biocompatibles' U.S. distributor to its LC Bead sales force described the product as "a drug-delivery device" and stated that it was "specifically designed for chemoembolization." Instructions for selling the LC Bead included directions to tell physicians the product was "unique" because "LC Bead is designed to 'upload' doxorubicin and then slowly elute it over 14 days." Certain sales representatives went so far as to state that LC Bead was FDA "approved" for chemoembolization. Sales representatives routinely claimed DEB-TACE procedures using LC Bead was a "better" or "superior" therapy for treating HCC and mCRC without disclosing the company's unsuccessful attempts to obtain FDA approval or clearance for a drug-eluting bead combination product. Sales representatives also routinely told physicians that DEB-TACE with LC Bead was "safer" and "less toxic" than alternative treatments when, in fact, there was insufficient clinical evidence that LC Bead had a superior safety profile.

Finally, during the relevant period, Biocompatibles was aware that many insurers declined to provide coverage for DEB-TACE due, in part, to the lack of FDA approval of the LC Bead as a drug delivery combination product. Nonetheless, Biocompatibles allowed its U.S. distributor to develop materials that instructed providers to submit claims for DEB-TACE procedures by using billing codes intended for bland embolization procedures because there was no established procedure code that precisely described DEB-TACE.

(2) As a result of the conduct described in Subparagraph F.(1), the State alleges that between May 1, 2006 and December 31, 2011, Biocompatibles knowingly caused false or fraudulent claims for LC Bead to be submitted to the State's Medicaid program.

G. This Agreement is neither an admission of facts or liability by Biocompatibles nor a concession by the State that its allegations are not well founded. Except for the specific conduct for which Biocompatibles is pleading guilty as described in the plea agreement filed in the Federal Criminal Action, Biocompatibles expressly denies the allegations of the State as set forth herein and in the Civil Action.

H. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, 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. Biocompatibles agrees to pay to the United States and the Medicaid Participating States (as defined in Sub-paragraph (c) below), collectively, the sum of

$25,000,000.00, plus accrued interest on that amount of 2.125% per annum commencing on February 9, 2016, and continuing and including the day payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Biocompatibles shall pay to the United States the sum of $23,636,957.00, plus accrued interest on that amount at the rate of 2.125% per annum commencing on February 9, 2016, ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Biocompatibles shall pay to the Medicaid Participating States the sum of $1,363,043.00, plus accrued interest ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after: (i) the expiration of the 60 day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below or, (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea in the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later. 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

("State Team"), which written instructions shall be delivered to counsel for Biocompatibles.

(c) Biocompatibles shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Biocompatibles and the State Team have agreed, or in a form otherwise agreed to by Biocompatibles and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Biocompatibles' attorneys within 60 days of receiving this Agreement. If this condition is not satisfied within 60 days, Biocompatibles' offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Biocompatibles and the State Team to extend the 60 day period.

(d) The total portion of the amount paid by Biocompatibles in settlement for the Covered Conduct for the State is $94,059.83, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $29,446.92, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Biocompatibles absent written agreement between counsel for Biocompatibles and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Biocompatibles in State or Federal Courts for the Covered Conduct, including any supplemental state law claims

asserted in the Civil Action. Contingent upon the receipt of its respective State Amount, the State, if served with the Civil Action and liable to pay a Relator's share, agrees to pay the Relator the amount of $6,331.09, plus applicable interest. This amount is to be paid through the State Team and has been addressed via a side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Biocompatibles set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release Biocompatibles, together with its current and former direct and indirect parent corporations and each of their current and former direct and indirect subsidiaries, brother or sister corporations, divisions, and affiliates; and the predecessors, successors, assigns, and transferees of any of them (the Biocompatibles' Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:

(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 any 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/or (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 to the State arising from the Covered Conduct for claims submitted to any and all payors and insurers under the State's Medicaid Managed Care program;

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

(g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services provided by Biocompatibles;

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

(j) any liability based on a failure to deliver goods or services due; or

(k) any liability of individuals.

5. This Agreement is expressly conditioned upon resolution of the Federal Criminal Action. In consideration of the acceptance of Biocompatibles' plea of guilty in the Federal Criminal Action, the State's Medicaid Fraud Control Unit agrees that it shall not further criminally investigate, prosecute, or refer for prosecution or criminal investigation to any agency, Biocompatibles, its present and former parents, divisions, and subsidiaries and their predecessors, successors and assigns, for the Covered Conduct.

6. Biocompatibles 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 Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, Biocompatibles waives and discharges the State, its agencies, employees, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Biocompatibles has against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Biocompatibles 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 payor, for the Covered Conduct; and Biocompatibles agrees not to resubmit to the State's Medicaid program or any other state 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.

9. Biocompatibles 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.

10. Biocompatibles 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.

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

12. Biocompatibles agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice, Biocompatibles shall facilitate, and agrees not to impair, the cooperation of its directors, officers, employees or agents, for interviews and testimony, consistent with the rights and privileges of such individuals and of Biocompatibles. Upon request, Biocompatibles agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in their possession, custody or control, concerning the Covered Conduct. Biocompatibles shall be responsible for all costs it may incur in complying with this paragraph.

13. 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.

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

15. 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.

16. In addition to all other payments and responsibilities under this Agreement, Biocompatibles agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Biocompatibles 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.

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

18. The undersigned Biocompatibles 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.

19. 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.

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

21. 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.

22. 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: Charles H. Hobgood Dated: 11/15/2016

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

By: Dave Richard Dated: 11-9-2016

DAVE RICHARD
Deputy Secretary for Medical Assistance
Division of Medical Assistance

Biocompatibles, Inc.

By: _____ Dated: 1/10/17

Ken Pugh
President
Biocompatibles, Inc.

By: _____ Dated: 1/8/17

Richard L. Scheff
Partner and Executive Chairman
Montgomery McCracken Walker & Rhoads LLP
Counsel to Biocompatibles, Inc.