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 Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program, through its General Counsel; and the United States Department of Veterans' Affairs ("VA") (collectively the "United States"); AngioDynamics, Inc. ("AngioDynamics"); and Ryan Bliss ("Relator") through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. AngioDynamics is a medical device company based in Latham, New York, that designs, manufactures, and sells various medical, surgical, and diagnostic devices throughout the United States and internationally. From May 2006 through December 2011, medical device manufacturer Biocompatibles, Inc. engaged AngioDynamics to be the exclusive distributor for 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 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 FDA approve or clear LC Bead to be marketed 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, et al., ex rel. Bliss v. Biocompatibles, Inc., et al*., Case No. SA-13-CA-0667-XR, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action").

C. AngioDynamics has entered or will be entering into separate settlement agreements, described in Paragraph 1.b., below (hereinafter referred to as the "Medicaid State Settlement Agreements"), with certain states and the District of Columbia in settlement of the Covered Conduct. States with which AngioDynamics executes a Medicaid State Settlement Agreement in the form to which AngioDynamics and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by AngioDynamics and an individual State, shall be defined as "Medicaid Participating States."

D. The United States contends that AngioDynamics 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"); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); and the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"); and caused purchases by the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17.

E. The United States alleges that it has certain civil claims against AngioDynamics relating to the following alleged conduct (hereinafter referred to as the "Covered Conduct"):

> At all relevant times, LC Bead was cleared by 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 FDA. Absent certain exceptions that are not applicable in this case, Medicare and other federal health care programs do not cover devices that are not approved or cleared by FDA.
>
> In October 2006, FDA informed Biocompatibles, the manufacturer of the LC Bead, that a Premarket Approval (PMA) was required before LC Bead could be legally marketed for transarterial chemoembolization. In December 2009, Biocompatibles filed a PMA application for a drug-eluting bead combination product, intended for use in transarterial chemoembolization of unresectable hepatocellular carcinoma ("HCC"). In February 2010, FDA informed Biocompatibles that 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, LC Bead has not obtained approval or clearance from FDA as a drug-eluting bead combination product.

In May 2006, Biocompatibles engaged AngioDynamics to serve as its distributor of LC Bead in the U.S. market. Notwithstanding Biocompatibles' and AngioDynamics' knowledge of the limited cleared indications for LC Bead, Biocompatibles and AngioDynamics marketed and distributed 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 chemoembolization or "DEB-TACE." More specifically, Biocompatibles and AngioDynamics intended for LC Bead to be used as a drug delivery-device in DEB-TACE procedures for patients diagnosed with HCC and metastatic colorectal cancer ("mCRC").

For example, in training provided to AngioDynamics personnel, Biocompatibles and AngioDynamics personnel described LC Bead as "a drug-delivery device" that was "specifically designed for chemoembolization." Instructions for selling 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 AngioDynamics sales representatives falsely stated that LC Bead was FDA "approved" for chemoembolization. Sales representatives routinely claimed the DEB-TACE procedure using LC bead was a "better" or "superior" therapy for treating HCC and mCRC and was "safer" and "less toxic" than alternative treatments when, in fact, there was insufficient clinical evidence that LC Bead had a superior efficacy or safety profile.

Finally, during the relevant period, AngioDynamics 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, AngioDynamics developed and used materials that instructed providers to submit claims for DEB-TACE procedures by using inaccurate billing codes intended for bland embolization procedures due to the absence of procedure codes that accurately described DEB-TACE.

As a result of the foregoing conduct, the Government alleges that between May 1, 2006, and December 31, 2011, AngioDynamics knowingly caused false or fraudulent claims for LC Bead to be submitted to, or caused purchases by, Medicare, Medicaid, TRICARE, and VA.

F. 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.

G. This Settlement Agreement is neither an admission of liability by AngioDynamics nor a concession by the United States that its claims are not well founded.

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. AngioDynamics shall pay to the United States and the Medicaid Participating States collectively $11,500,000.00 plus interest at the rate of 2.375% per annum from November 3, 2017, and continuing until and including the date of payment (the "Settlement Amount") under the terms and conditions set forth in this Agreement. The Settlement Amount shall constitute a debt immediately due and owing to the United States and Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States as follows:

(a) AngioDynamics shall pay to the United States the sum of $10,878,607.00, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) business days after this Agreement is fully executed by the Parties and delivered to AngioDynamics' attorneys.

(b) AngioDynamics shall pay the Medicaid Participating States the sum of $621,393.00, plus accrued interest as set forth above, to be disbursed in accordance with written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the agreements that AngioDynamics will enter into with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Settlement Amount from AngioDynamics and as soon as feasible after receipt, the United States agrees to pay Relator the sum of $2,338,900.00, plus a pro rata share of the actual accrued interest paid to the United States by AngioDynamics, on the amount set forth above in Paragraph 1(a), as Relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d). No other payments shall be made to Relator by the United States with respect to the matters covered by this Agreement.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon AngioDynamics' full payment of the Settlement Amount, the United States releases AngioDynamics, 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 "AngioDynamics Released Parties"), from any civil or administrative monetary claim the United States has or may have 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.

4. Subject to the exceptions in Paragraph 5 below, and conditioned upon AngioDynamics' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases the AngioDynamics Released Parties from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common

law, that Relator, his heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action; provided, however, that Relator's release of the AngioDynamics Released Parties does not extend to any claim by Relator for reasonable costs and attorneys' fees under 31 U.S.C. § 3730(d).

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

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

b. Any criminal liability;

c. Any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement and 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 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its 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 from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

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

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

9. In consideration of the obligations of Relator set forth in this Agreement, AngioDynamics for itself and for its heirs, successors, transferees, attorneys, agents, and assigns, fully and finally releases Relator and his heirs, successors, attorneys, agents, and assigns from

any claims of every kind and however denominated (including attorneys' fees, costs, and expenses of every kind and however denominated) that AngioDynamics has asserted or could have asserted against Relator and his heirs, successors, attorneys, agents, and assigns, arising from or related in any way to the Civil Action; provided, however, AngioDynamics reserves any and all defenses as to, and expressly reserve the right to challenge on any and all available grounds, Relator's or Relator's counsel's claims for reasonable attorneys' fees, expenses, and costs resulting from the Civil Actions pursuant to 31 U.S.C. § 3730(d), which are reserved pursuant to Paragraph 4 above.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and AngioDynamics agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

11. AngioDynamics agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of AngioDynamics, 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 investigation(s) of the matters covered by this Agreement;

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

(4) the negotiation and performance of this Agreement; and

(5) the payment AngioDynamics makes to the United States pursuant to this Agreement;

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

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: AngioDynamics 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 AngioDynamics 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. AngioDynamics agrees that the United States, at a minimum, shall be entitled to recoup from AngioDynamics 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 AngioDynamics or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on AngioDynamics 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 AngioDynamics' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

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

13. AngioDynamics agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

14. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file a Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). The Stipulation of Dismissal shall be with prejudice as to the United States' and Relator's claims as to the Covered Conduct, and without prejudice to the United States and with prejudice as to Relator as to all other claims in the Civil Action, except claims by Relator for reasonable attorneys' fees, expenses, and costs resulting from the Civil Action pursuant to 31 U.S.C. § 3730(d).

15. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, except to the extent that Relator has reserved his right to seek attorneys' fees, expenses and costs under 31 U.S.C. § 3730(d), and to the extent AngioDynamics has reserved its rights to challenge such claims as set forth above.

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 Western District of Texas. 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 AngioDynamics' successors, transferees, heirs, and assigns.

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

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

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

[SIGNATURE PAGES FOLLOW]

THE UNITED STATES OF AMERICA

Dated: 7/10/18

By: _____
Colin M. Huntley
Assistant Director
Commercial Litigation Branch, Civil Division
United States Department of Justice

Dated: 6/26/2018

By: _____
Susan Strawn
Assistant United States Attorney
Western District of Texas

Dated: _____

By: _____
Lisa 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 UNITED STATES OF AMERICA

Dated: _____ By: _____
Colin M. Huntley
Assistant Director
Commercial Litigation Branch, Civil Division
United States Department of Justice

Dated: _____ By: _____
Susan Strawn
Assistant United States Attorney
Western District of Texas

Dated: 06/21/2018 By: _____
Lisa 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

ANGIODYNAMICS, INC.

Dated: 7/9/2018

By: Stephen A. Trowbridge
Stephen A. Trowbridge
Senior Vice President & General Counsel
AngioDynamics, Inc.

Dated: 7/9/2018

By: Anne K. Walsh
Anne K. Walsh
Hyman Phelps & McNamara P.C.

Counsel for AngioDynamics, Inc.

RELATOR RYAN BLISS

Dated: 6-18-18

By: Ryan Bliss
Ryan Bliss

Dated: 6-18-2018

By: _____
W. Paul Lawrence, II
Waters & Kraus, LLP

Counsel for Ryan Bliss

Dated: _____

By: _____
Jeffrey A. Newman
Law Offices of Jeffrey A. Newman

Counsel for Ryan Bliss

RELATOR RYAN BLISS

Dated: _____ By: _____
Ryan Bliss

Dated: _____ By: _____
W. Paul Lawrence, II
Waters & Kraus, LLP

Counsel for Ryan Bliss

Dated: 6/18/18 By: _____
Jeffrey A. Newman
Law Offices of Jeffrey A. Newman

Counsel for Ryan Bliss