

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) (collectively the "United States"), defendants C.R. Bard, Inc. and Proseed, Inc. ("Bard"), and relator Julie Darity (the "Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

- A. C.R. Bard, Inc. is a multinational company that develops, manufactures and markets medical devices, including, but not limited to, brachytherapy seeds.
- B. On January 30, 2006, Relator filed a *qui tam* action in the United States District Court for the District of the Northern District of Georgia captioned *United States ex rel. Julie Darity v. C.R. Bard, Inc. and Proseed, Inc.*, Civil Action File No. 1:06-cv-0208-SCJ, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action). It involves allegations that C.R. Bard, Inc. and its wholly-owned subsidiary, ProSeed, Inc. (collectively, "Bard") provided illegal remuneration to customers and/or physicians to induce those customers and/or physicians to purchase items for which payment may be made in whole or in part under a federal health care program.
- C. The United States contends that Bard submitted or caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1.
- D. The United States contends that it has certain civil claims against Bard for engaging in the following conduct during the period from 1998 through 2006: Bard caused the presentation of false claims to Medicare in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733 (FCA),

as a result of illegal remuneration to customers and physicians in violation of 42 U.S.C. § 1320a-7b(b); specifically, this illegal remuneration was paid by Bard to one or more customers and/or physicians who performed prostate cancer treatment procedures using Bard's brachytherapy seeds. This illegal remuneration took the form of certain grants, guaranteed minimum rebates, conference fees, marketing assistance and/or free medical equipment, to secure and maintain sales of brachytherapy seeds. The conduct in this Paragraph shall hereinafter be referred to as the "Covered Conduct."

E. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to have Bard pay Relator's reasonable expenses, attorneys' fees and costs.

F. This Agreement is neither an admission of facts or liability by Bard 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. Bard shall pay to the United States Forty-Eight Million, Two-Hundred Sixty Thousand Dollars (\$48.26 million) (Settlement Amount), as well as interest on the Settlement Amount at an annual rate of 1.625% to accrue from May 1, 2012 to the date of payment, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Northern District of Georgia no later than seven (7) days after the Effective Date of this Agreement.

2. Conditioned upon the United States receiving the Settlement Amount from Bard and as soon as feasible after receipt, the United States shall pay \$10,134,600 plus twenty-one

percent (21%) of the interest accrued on the Settlement Amount pursuant to paragraph 1, above, to Relator by electronic funds transfer as Relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d).

3. Bard shall separately negotiate with Relator concerning Relator's expenses, and attorney's fees and costs under 31 U.S.C. § 3730(d), and/or for discrimination and wrongful termination claims under subsection 3730(h), which claims Relator does not release pursuant to this Agreement.

4. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon Bard's full payment of the Settlement Amount, the United States releases Bard, together with Bard's predecessors, current and former parents, affiliates, subsidiaries, divisions, transferees, successors and assigns, and all of their current and former directors, officers and employees (hereinafter, collectively "Bard Releasees"), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R., Part O, Subpart I, Section 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Conditioned upon Bard's full payment of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Bard Releasees from any claim the Relator has on behalf of the United States for the Covered Conduct including any claim Relator has on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Bard and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion) based upon the Covered Conduct.

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

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. any criminal liability;
- c. except as explicitly stated in this Agreement, any administrative liability, including mandatory 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 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;
- h. any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
- i. any liability of individuals except otherwise identified in paragraph 4.

8. Relator and her 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 2, Relator and her 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.

9. Bard waives and shall not assert any defenses Bard may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

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

11. To the extent applicable, 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 carrier or

intermediary or any state payer, related to the Covered Conduct; and Bard agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

12. Bard 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 Bard, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and the non-prosecution agreement;
- (2) the United States' audit(s) and civil and criminal investigations of the matters covered by this Agreement;
- (3) Bard's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigations in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and the non-prosecution agreement;
- (5) the payment Bard makes to the United States pursuant to this Agreement and any payments that Bard may make to Relator, including costs and attorneys fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:

- (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
- (ii) prepare and submit reports to the OIG-HHS,

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).

However, nothing in this paragraph 13.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Bard.

- b. Future Treatment of Unallowable Costs: To the extent applicable, Unallowable Costs shall be separately determined and accounted for by Bard, and Bard 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 Bard or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: To the extent applicable, Bard 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,

legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

15. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal With Prejudice as to the Relator, and a Joint Stipulation of Dismissal as to the United States that is With Prejudice as to the Covered Conduct and Without Prejudice as to all other claims pursuant to Rule 41(a)(1), except that Relator shall not dismiss her personal claims for relief as set forth in Paragraph 3, above.

16. Except as set forth in Paragraph 3, above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17. 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.

18. 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 Northern District of Georgia . 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.

19. This Agreement constitutes the complete agreement between the Parties related to the matters addressed herein. This Agreement may not be amended except by written consent of the Parties.

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

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

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

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

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

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

(signatures continue on next page)

THE UNITED STATES OF AMERICA

DATED: BY: _____

ROBERT MCAULIFFE
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: BY: _____

SALLY QUILLIAN YATES
United States Attorney
NEELI BEN-DAVID
Assistant United States Attorney
Northern District of Georgia

DATED: BY: _____

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
United States Department of Health and Human Services

(signatures continue on next page)

C.R. BARD, INC. and PROSEED, INC. – Defendants

DATED: BY: _____
[Name]
[Title]
C.R. Bard, Inc. and ProSeed, Inc.

DATED : BY: _____
JOHN C. DODDS
Counsel for C.R. Bard, Inc. and ProSeed, Inc.

DATED: BY: _____
CHRISTOPHER A. WRAY
Counsel for C.R. Bard, Inc. and ProSeed, Inc.

(signatures continue on
next page)

JULIE DARITY – Relator

DATED: BY: _____
JULIE DARITY

DATED: 7/24/13 BY: _____
MARLAN WILBANKS
Counsel for Julie Darity

DATED: BY: _____
PETER W. CHATFIELD
Counsel for Julie Darity

DATED: BY: _____
CHARLES E. COX, JR.
Counsel for Julie Darity