U.S. Department of
JUSTICE

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"); Bard Peripheral Vascular, Inc. ("BPV"), C. R. Bard, Inc., and Becton, Dickinson and Company (collectively, "Defendants"); and Robert Kane and Franklin W. West (collectively, "Relators"), hereafter collectively referred to as "the Parties," through their authorized representatives.

RECITALS

A. BPV is a medical device manufacturer and distributor headquartered in Tempe, Arizona. BPV is subsidiary of Becton, Dickinson and Company, which acquired BPV's parent company, C. R. Bard, Inc., in December 2017.

B. BPV distributed the FloChec and QuantaFlo devices ("the Devices"), which were developed and manufactured by Semler Scientific ("Semler"), to medical providers throughout the United States from August 2012 through approximately September 2022.

C. On December 7, 2016, Relators filed a *qui tam* action in the United States District Court for the Middle District of Florida captioned *United States ex rel. Kane v. Semler Scientific, Inc.*, Case No. 3:16-CV-1516, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) ("the Civil Action").

D. Defendants received credit under the Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual §4-4.112.

E. The United States contends that Defendants caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").

F. The United States contends that it has certain civil claims against Bard arising from the following conduct, which is referred to below as the "Covered Conduct." Paragraphs F.i and F.ii are contentions by the United States. Defendants admit the facts set forth only in paragraph F.iii.

The United States contends that from August 2012 through September 2022, Defendants violated the False Claims Act, 31 U.S.C. §§ 3729-3733, by knowingly causing, and conspiring to cause, the submission of false claims to Medicare Part B for tests performed using the FloChec and QuantaFlo devices.

i. Peripheral Arterial Disease and Relevant Regulations

The Devices use a single clip-on light sensor, similar to a pulse oximeter, that is attached to the fingers and toes to generate a photoplethysmographic waveform. Neither device is approved by the Food and Drug Administration to diagnose peripheral arterial disease ("PAD").

PAD in the legs or lower extremities is the narrowing or blockage of the vessels that carry blood between the heart and legs.

To be reimbursable, plethysmographic testing for PAD must satisfy Current Procedural Terminology ("CPT") codes 93922, 92923, or 93924. All three codes require that a provider perform an ankle brachial index ("ABI") ***plus*** certain enumerated additional testing. To conduct an ABI, a healthcare professional measures the patient's blood pressure in both arms and both ankles using an inflatable cuff and a hand-held ultrasound device that is pressed on the skin. By comparing the pressure in the arms against the pressure in the ankles, the healthcare professional can estimate the severity of PAD in a patient's limbs and recommend a course of treatment. The Devices do not satisfy CPT codes 93922, 93923, or 93924 because they do not perform an ABI.

The Devices also fail to satisfy Medicare reimbursement requirements because they use photoplethysmography, also known as photoelectric plethysmography, to generate a waveform. National Coverage Determination ("NCD") 20.14 and the Local Coverage Determinations ("LCDs") that incorporate it prohibit reimbursement for noninvasive vascular tests that use photoplethysmography because of concerns about accuracy and reproducibility.

ii. FDA 510k Clearance of the Devices

On February 12, 2010, the FDA cleared Semler's "FloChec Photoplethysmography Device." In submissions to the FDA, the inventor compared FloChec to the predecessor device by describing it as "similar to the PPG [photoplethysmography] portion." Under "Non-photo plethysmographic functions," the inventor stated "none."

Semler later changed the trade name from "FloChec Photoplethysmography Device" to "Flochec Device" to obscure the underlying technology used in the device.

On March 5, 2015, the FDA cleared QuantaFlo to "aid clinicians in the diagnosis and monitoring of Peripheral Arterial Disease." During the approval process, Semler classified QuantaFlo as a "Hydraulic, pneumatic, or photoelectric plethysmograph[]." Semler also represented to FDA that there were no material changes between FloChec and QuantaFlo. During the 510k approval process, FDA employees told Semler that QuantaFlo was a photoplethysmography device, did not perform an ABI, and could not be called a "digital ABI." Semler did not share these communications from the FDA with Bard.

iii. Bard's Marketing of the Devices

From August 2012 through September 2022, Bard marketed and distributed the Devices to customers throughout the United States pursuant to distribution agreements with Semler.

Semler and Bard discussed whether tests performed using the Devices were reimbursable under certain CPT codes. Semler also provided Bard with certain marketing materials concerning the Devices. Under the distribution agreement, any promotional materials created by Bard that were "inconsistent with [Semler's] approved literature and/or labeling," were required to be provided to Semler, and Bard was not permitted to "use any such materials without obtaining [Semler's] prior written consent[.]"

Based in part on Semler's representations, Bard told its customers that CPT codes 93922, 93923, and/or 93924 may be applicable to tests performed using the Devices when considering reimbursement.

At least as early as August 2012, Bard was aware of statements from third-parties that tests performed using FloChec may not be reimbursable under any CPT codes. Certain Bard employees also questioned whether tests performing using the Devices met the requirements of CPT Code 93922. Bard discussed these reimbursement concerns with Semler and relied on Semler's representations regarding reimbursement for the tests and the codes. Bard also directed customers to Semler to address reimbursement questions.

In or around November 2012, Bard prepared a letter to address potential questions regarding reimbursement, which stated that "the FloChec digital ABI device is normally coded under CPT 93922 or potentially 93924 if stress testing is also performed." The letter also stated that BPV does not guarantee that the use of any particular code will ensure coverage or payment. Bard later prepared an updated letter with similar language concerning the QuantaFlo device.

In or around July 2022, Bard notified Semler that it was terminating the distribution agreement. The termination became effective in or around September 2022.

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

H. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' 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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants shall pay to the United States $7,200,000.00 ("Settlement Amount"), of which $3,600,000 is restitution, and interest on the Settlement Amount at a rate of 4.625% per annum from March 28, 2025 ("Interest"), no later than 7 business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States' receipt of the Settlement Amount, plus Interest due under Paragraph 1, and as soon as feasible after receipt, the United States shall pay $1,260,000 plus 17.5% of the Interest to Relator by electronic funds transfer ("Relators' Share").

3. Defendants shall pay Relators $140,000 no later than 7 business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by undersigned Relators' counsel (the "Statutory Fees Payment"). Defendants' payment of the Statutory Fees Payment will constitute full and complete satisfaction of their liability for Relators' statutory claims pursuant to 31 U.S.C. § 3730(d)(2) for reasonable attorneys' fees, expenses, and costs resulting from or related to the Civil Action.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus Interest due under Paragraph 1, the United States releases Defendants, together with their current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Upon the United States' receipt of the Settlement Amount, plus Interest due under Paragraph 1 and Relators' receipt of the Statutory Fees Payment due under Paragraph 3, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Defendants, together with their current and former officers, directors, and employees; current and/or former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, of any and all claims, whether in law or equity, whether known or unknown, that Relators have asserted or could have asserted against Defendants as of the Effective Date of this Agreement, including but not limited to claims related to the Covered Conduct, Relators' or the United States's investigations or prosecutions thereof, or Relators' original complaint(s) filed in the Civil Action.

6. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights 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. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, 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;

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

7. Relators and their 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 Relators' receipt of the Relators' Share, Relators and their 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.

8. Defendants waive and shall not assert any defenses Defendants 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.

9. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendants have 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 or the United States' investigation or prosecution thereof.

10. Defendants fully and finally release Relators and their agents, attorneys, successors, heirs, and assigns (the "Relator Releasees") from any and all claims, whether in law or equity, whether known or unknown (including but not limited to attorneys' fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, or could have asserted, against the Relator Releasees as of the Effective Date of this Agreement, including but not limited to claims related to the Civil Action, the Covered Conduct, or Relators' or the United States' investigations or prosecutions thereof.

11. 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 Defendants agree not to resubmit to any Medicare contractor or any state payer any

previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

12. Defendants agree 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, their 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) Defendants' 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 attorneys' fees);

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

(5) the payment Defendants make to the United States pursuant to this Agreement and any payments that Defendants may make to Relators, 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 by Defendants, and Defendants 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 Defendants or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement they 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 Defendants or any of their 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. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants 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 Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in

this paragraph) on Defendants or any of their 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 Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. Defendants agree to cooperate fully, truthfully, and actively with the United States regarding any matter about which Defendants have any knowledge or information relating to any ongoing investigation, litigation, trial, or other proceeding arising out of any ongoing federal investigation related to the Devices or Semler. Any refusal by Defendants to cooperate fully, truthfully, and actively will constitute a breach of this Agreement. Defendants' cooperation shall include:

a. Upon reasonable notice, Defendants shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall agree not to impair the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals;

b. Defendants agree to provide testimony, declarations/affidavits, or other information necessary to identify or establish the original location, authenticity, or other basis for admissibility into evidence documents or physical evidence as requested by the United States;

c. Defendants agree to furnish to the United States, upon request, complete and unredacted copies of non-privileged documents, reports, and records in their possession, custody, or control concerning the Devices or Semler that have not already been produced to the Department of Justice;

d. Defendants agree to furnish non-privileged documents, and upon request identify, and if possible facilitate the appearance of, additional witnesses concerning each of the topics set forth in the confidential email provided by the United States on February 12, 2025, along with any future topics identified by the United States concerning any ongoing investigation of the Devices or Semler.

14. 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 15 (waiver for beneficiaries paragraph), below.

15. Defendants agree that they waive 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.

16. Upon receipt of the payment described in Paragraph 1, above, the United States and Relators shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action only as to Defendants pursuant to Rule 41(a)(1).

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

19. 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 Middle District of Florida. 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.

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

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

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

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

24. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

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

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "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: 9/3/25 BY: _____

KRISTEN M. ECHEMENDIA
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/3/25 BY: _____

MARTHA GLOVER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: KELLEY HOWARD ALLEN Digitally signed by KELLEY HOWARD ALLEN Date: 2025.09.03 15:23:04 -04'00'

KELLEY HOWARD ALLEN
Assistant United States Attorney
Middle District of Florida

DATED: _____ BY: EDWARD WILSON Digitally signed by EDWARD WILSON Date: 2025.09.03 10:56:44 -04'00'

SUSAN E. GILLIN
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

DEFENDANTS

DATED: 8/29/25 BY: C. Camarata

Candace Camarata
Bard Peripheral Vascular, Inc.

DATED: 8/29/25 BY: C. Camarata

Candace Camarata
C.R. Bard, Inc.

DATED: 8/29/25 BY: C. Camarata

Candace Camarata
Becton, Dickinson and Company

DATED: 08/29/25 BY:

AMANDA SANTELLA
O'Melveny & Myers LLP
Counsel for Bard Peripheral Vascular, Inc.; C.R. Bard, Inc. and Becton, Dickinson and Company

RELATORS

DATED: _____ BY: _____
ROBERT KANE

DATED: 8/26/25 BY: _____
FRANKLIN W. WEST

DATED: 8/29/2025 BY: _____
DAN MILLER
Counsel for Relators Robert Kane and Franklin W. West

RELATORS

DATED: 8/26/25 BY: _____
ROBERT KANE

DATED: _____ BY: _____
FRANKLIN W. WEST

DATED: _____ BY: _____
DAN MILLER
Counsel for Relators Robert Kane and Franklin W. West