

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; ev3, Inc., formerly known as Fox Hollow Technologies, Inc. (collectively “Defendants”); and Amanda Cashi (“Relator”) through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

RECITALS

A. During the period January 1, 2006, through October 7, 2007, Fox Hollow Technologies, Inc. (“Fox Hollow”) was a California corporation headquartered in Redwood City, California that manufactured and sold a device known as the SilverHawk Plaque Excision System (the “SilverHawk”). The SilverHawk is an FDA-approved medical device used in atherectomy, a minimally-invasive surgical procedure that uses a small cutting device attached to a catheter to remove atherosclerotic plaque from blood vessels in the body. On October 7, 2007, ev3, Inc. (“ev3”) acquired Fox Hollow, and thereafter the SilverHawk was manufactured and sold by ev3. In July 2010, Covidien plc acquired ev3 and now operates ev3 as a wholly-owned subsidiary of Covidien plc.

B. On December 16, 2009, Relator filed a *qui tam* action in the United States District Court for the Western District of New York captioned *United States ex rel. Cashi v. Fox Hollow Technologies, Inc., et al.*, Civ. No. 09-CV-01066-S, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”).

C. The United States contends that Defendants 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, for minimally-invasive atherectomy procedures in which the SilverHawk was used.

D. The United States contends that it has certain civil claims against Defendants arising from the following conduct: During the time period January 1, 2006, through December 31, 2007, Defendants, through their respective reimbursement departments and sales personnel, knowingly caused certain hospital providers to submit false claims to Medicare for certain inpatient atherectomy procedures that were correctly billable only as outpatient procedures due to the absence of medical necessity for an inpatient level of service.

More specifically, throughout 2006 and 2007, the Fox Hollow reimbursement department advised existing and prospective hospital customers that the hospitals should classify SilverHawk atherectomy procedures as inpatient claims, as opposed to outpatient claims, in order to increase the profitability of the procedure. In order to persuade hospitals to classify more SilverHawk atherectomy procedures as higher-paying inpatient claims, Fox Hollow personnel provided hospitals with false and misleading “national benchmarks” indicating that atherectomy procedures in which SilverHawk was used were classified as inpatient claims 80% of the time, when, in fact, the actual percentage was considerably lower than figures cited by Fox Hollow. In addition, Fox Hollow personnel distributed SilverHawk economic models that contained information relating only to inpatient codes and which emphasized the profitability of inpatient claims.

As a result of the foregoing conduct, the United States alleges that Defendants knowingly caused false or fraudulent claims to be submitted to Medicare by the hospitals

identified in Attachment A. This conduct is collectively referred to below as the “Covered Conduct.”

E. This Agreement is made in compromise of disputed claims. Defendants expressly deny the United States’ allegations in Paragraph D and the Relator’s allegations in the Civil Action. This Settlement Agreement is neither an admission of liability by Defendants, nor a concession by the United States that its claims are not well founded.

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. 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. Defendants shall pay to the United States the sum of \$1,250,000 (the “Settlement Amount”). The Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than thirty (30) calendar days after the Effective Date of this Agreement.

2. Conditioned upon the United States receiving the Settlement Amount from Defendants and as soon as feasible after receipt, the United States shall pay \$250,000.00 to Relator by electronic funds transfer.

3. On or about the Effective Date of this Agreement, Defendants and Relator will enter into a separate agreement with respect to the payment by Defendants of Relator's reasonable attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

4. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Settlement Amount, the United States releases Defendants, together with their current and former parent corporations; current and former directors, officers, employees, and agents; direct and indirect subsidiaries; brother or sister corporations; divisions; and the successors and assigns of any of them, 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.

5. Conditioned upon Defendants' full payment of the Settlement Amount and the amount referred to in Paragraph 3, above, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, release Defendants, together with their current or former direct and indirect parent and member corporations; direct and indirect subsidiaries; direct or indirect brother or sister corporations; divisions; current or former owners; and officers, directors, and affiliates; agents, servants, and employees; and the successors and assignees of any of them, from any civil monetary claim the Relator has or may have on her own behalf or on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, or any other legal theory.

6. 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:

- (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 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 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.

7. Relator and her 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 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.

8. Conditioned upon Defendants' full payment of the Settlement Amount and the amount referred to in Paragraph 3, above, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Defendants, and their officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

9. 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. 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. Defendants fully and finally release the United States and its agencies, officers, agents, employees, and servants, from any claims (including attorney's 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 and its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. Defendants fully and finally release Relator and her attorneys and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against Relator or her attorneys and agents related to the filing of the Civil Action or the investigation and prosecution the Civil Action.

12. 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, and agree not to appeal any such denials of claims.

13. 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. §§ 1395-1395kkk-1 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' audits 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 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 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.

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. After payment of the Federal Settlement Amount, the United States and Relator shall file a joint stipulation of dismissal in the Civil Action as follows:

(a) the joint stipulation of dismissal shall be with prejudice as to the United States' and Relator's claims as to the Covered Conduct pursuant to and consistent with the terms and conditions of this Agreement; and

(b) the joint stipulation of dismissal shall be without prejudice as to the United States and with prejudice as to Relator as to all other claims.

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 in to 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 Western District of New York. 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 Relator's 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 ("Effective Date of this Agreement"). Facsimiles and .pdf versions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

COLIN M. HUNTLEY
Senior Trial Counsel
Commercial Litigation Branch, Civil Division
United States Department of Justice

DATED: _____

BY: _____

GRETCHEN L. WYLEGALA
Assistant U.S. Attorney
United States Attorney's Office
Western District of New York

DATED: _____

BY: _____

ROBERT K. DECONTI
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

EV3, INC., formerly known as FOX HOLLOW TECHNOLOGIES, INC.

DATED: _____

BY: _____

Michael Cowhig, Esq.
Vice President & General Counsel
Vascular Therapies
Covidien plc

On behalf of ev3, Inc.

DATED: _____

BY: _____

BRIEN T. O'CONNOR
JAMES DOWDEN
AARON KATZ
Ropes & Gray LLP

Counsel for ev3, Inc.

RELATOR AMANDA CASHI

DATED: _____

BY: _____
AMANDA CASHI

DATED: _____

BY: _____
TIMOTHY McCORMACK
LARRY ZOGLIN
Phillips & Cohen LLP

Counsel for Amanda Cash

ATTACHMENT A

Hospital	City, State
Altoona Regional Health System	Altoona, PA
Archbold Memorial Hospital	Thomasville, GA
Buffalo General Hospital-Kaleida Health	Buffalo, NY
Community Hospital – Community Hospital System	Munster, IN
Frankfort Regional Medical Center	Frankfort, KY
OhioHealth Grant Medical Center	Columbus, OH
Saint Alphonsus Medical Center Nampa	Nampa, ID
The Methodist Hospitals, Inc.	Gary, IN
St. Joseph Hospital Kokomo – St. Vincent Health	Kokomo, IN
St. Luke’s Boise Medical Center	Boise, ID
St. Thomas-West Hospital	Nashville, TN
Washington Regional Medical Center	Fayetteville, AR