

## SETTLEMENT AGREEMENT

### I. PARTIES

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"); and Arizona Heart Hospital ("AHH") and Dr. Edward Diethrich (collectively "the Defendants"), through their authorized representatives.

### II. PREAMBLE

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

A. The Defendants are health care providers in the Phoenix, Arizona area who 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. §§ 1395-1395hhh.

B. The United States contends that it has certain civil claims, as specified in Paragraph 2, below, against the Defendants for submitting claims or causing claims to be submitted to Medicare Part A between June 1998 and October 2002 for services provided to Medicare beneficiaries involving the implantation of endoluminal graft devices for treatment of thoracic and abdominal aortic aneurysms that had not received final marketing approval from the Food & Drug Administration and were either implanted without an approved Investigational Device Exemption ("IDE") or were implanted outside of the approved IDE protocol (hereinafter "the Covered Conduct").

C. The United States also contends that it has certain administrative claims against the Defendants for engaging in the Covered Conduct, as specified in Paragraphs 2 and 3, below.

D. The Defendants deny that they engaged in any wrongdoing or illegal conduct, and specifically deny the allegations set forth in paragraph B, above.

E. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below. This Agreement is neither an admission of liability by the Defendants nor a concession by the United States that its claims are not well founded.

### III. TERMS AND CONDITIONS

1. The Defendants agree to pay to the United States \$5,820,412 (the "Settlement Amount"). The Defendants agree to pay the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office in Phoenix, Arizona. The Defendants agree to make this electronic funds transfer within 14 days of the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 4, below, in consideration of the obligations of the Defendants set forth in this Agreement, conditioned upon the Defendants' full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release the Defendants from any civil or administrative monetary claim the United States has or may have 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; the common law theories of payment by mistake, unjust enrichment, and fraud, for the Covered Conduct.

3. In consideration of the obligations of AHH set forth in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and AHH, conditioned upon the Defendants' full payment of the Settlement Amount, the OIG-HHS agrees to release

and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against AHH under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 4, below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude the Defendants from Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including the Defendants) are the following:

a. Any civil, criminal, or administrative 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 and permissive exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f) under 42 U.S.C. § 1320a-7(a) and 42 U.S.C. § 1320a-7(b));

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

- e. Any liability based upon such obligations as are 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 of individuals, other than Dr. Diethrich, as specified in Paragraph 2, above.

5. The Defendants waive and shall not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses 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.

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

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

8. The Defendants agree to the following:

a. Unallowable Costs Defined: that 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. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with the following shall be “unallowable costs” on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):

- (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) The 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 attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment the Defendants make to the United States pursuant to this Agreement, including any 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.

However, nothing in this Paragraph 8.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 the Defendants. (All costs described or set forth in this Paragraph 8.a. are hereafter “unallowable costs.”)

b. Future Treatment of Unallowable Costs: These unallowable costs shall be separately determined and accounted for by the Defendants, and the 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 the 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: The 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 the 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. The Defendants agree that the United States, at a minimum, shall be entitled to recoup from the 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 the Defendants or any of their subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this Paragraph) on the Defendants or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

9. 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 10, below.

10. The Defendants 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 payers based upon the claims defined as Covered Conduct.

11. The Defendants warrant that they have reviewed their financial situation and that they currently are solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following their payment to the United States of the

Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to the Defendants, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which the Defendants were or became indebted, on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

12. 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.

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

14. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the District of Arizona, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

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

16. The individuals signing this Agreement on behalf of the Defendants represent and warrant that they are authorized by the Defendants to execute this Agreement. The



United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

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

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

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

20. 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.

**THE UNITED STATES OF AMERICA**

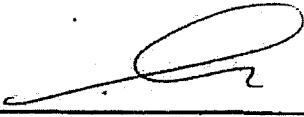
DATED: 11/5/07, 2007

BY: David T. Cohen  
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U.S. Department of Justice

DATED: October 17, 2007

BY: Jon R. Leavitt  
LON R. LEAVITT  
Assistant United States Attorney  
District of Arizona

DATED: Nov 15<sup>th</sup>, 2007

BY:   
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DR. EDWARD DIETRICH

DATED: Oct. 17, 2007

BY:   
DR. EDWARD DIETRICH

DATED: Oct. 17, 2007

BY: Debra A Hill  
DEBRA A. HILL, ESQ.  
Counsel for Dr. Diethrich

ARIZONA HEART HOSPITAL

DATED: \_\_\_\_\_, 2007

BY: \_\_\_\_\_  
DOLARES HORVATH  
Acting President

DATED: \_\_\_\_\_, 2007

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DR. EDWARD DIETRICH

DATED: 10-23-07, 2007

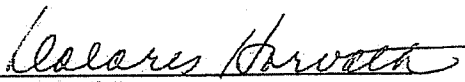
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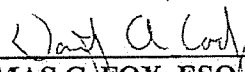
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ARIZONA HEART HOSPITAL

DATED: 10-23, 2007

*DOLORÉS* BY:   
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Acting President

DATED: Oct 26, 2007

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