

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"), and Mark H. Heinicke (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Mark H. Heinicke, M.D. (Dr. Heinicke) was a practicing physician specializing in Internal Medicine and Rheumatology. During the time period relevant to this investigation, Dr. Heinicke maintained a private medical practice in Louisville, Kentucky.

B. The United States contends that Dr. Heinicke 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.

C. The United States contends that it has certain civil claims against Dr. Heinicke arising from the following conduct which occurred from December 1, 2010, through April 19, 2012:

Dr. Heinicke purchased Rituxan, Actemra, Remicaid, Aclasta, Prolia, and Synvisc (collectively referred to as the "Products") from foreign distributors that obtained the Products from foreign sources. These foreign Products, with labeling in foreign languages, were not approved by the United States Food and Drug Administration ("FDA") for distribution or administration to patients in the United States. These foreign, non-FDA approved Products cost significantly less than FDA-approved versions. Dr. Heinicke used these foreign, non-FDA approved Products on Medicare recipients and did not inform those recipients that they were receiving non-FDA approved Products. Dr. Heinicke thereafter submitted or caused to be submitted false claims to Medicare, seeking payment for the

Products as if they were FDA-approved versions and seeking payment for the administration of the Products, in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733. Medicare made payments to Dr. Heinicke based upon these claims.

Said conduct is referred to below as the Covered Conduct.

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. Dr. Heinicke shall pay to the United States the sum of THREE HUNDRED THIRTY-EIGHT THOUSAND FOUR-HUNDRED NINETY-THREE DOLLARS AND THIRTY CENTS (\$338,493.30) (“Settlement Amount”) no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Western District of Kentucky.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Dr. Heinicke’s full payment of the Settlement Amount, the United States releases Dr. Heinicke 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.

3. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Dr. Heinicke and/or officers, directors, and employees of his practice 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).

4. Notwithstanding the release given in paragraph 2 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;
- 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 (including current or former directors, officers, employees, agents, or shareholders of Dr. Heinicke) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted or charged, or who enter into a plea agreement, related to the Covered Conduct.

5. Dr. Heinicke waives and shall not assert any defenses Dr. Heinicke 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.

6. Dr. Heinicke 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 Dr. Heinicke has asserted, could have asserted, or may assert in the future against the United States, and 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 contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Dr. Heinicke 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.

8. Dr. Heinicke 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 Dr. Heinicke, his present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Dr. Heinicke's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and any plea agreement; and
- (5) the payment Dr. Heinicke 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 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 Dr. Heinicke, and Dr. Heinicke 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 Dr. Heinicke or any of his subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Dr. Heinicke further agrees that within 90 days of the Effective Date of this Agreement he 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 Dr. Heinicke or any of his 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. Dr. Heinicke agrees that the United States, at a minimum, shall be entitled to recoup from Dr. Heinicke 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 Dr. Heinicke or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dr. Heinicke or any of his 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 Dr. Heinicke's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of 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 (waiver for beneficiaries paragraph), below.

10. Dr. Heinicke agrees that he 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.

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

12. 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.

13. 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 Kentucky. 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.

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

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

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

17. This Agreement is binding on Dr. Heinicke's successors, transferees, heirs, and assigns.

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

19. 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

JOHN E. KUHN, JR.
Acting United States Attorney, Western District of Kentucky

DATED: _____

BY: _____
Benjamin S. Schecter
Assistant United States Attorney

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

MARK H. HEINICKE, M.D.

DATED: _____

BY: _____
Mark H. Heinicke, M.D.

DATED: _____

BY: _____
David Lambertus
Tricia Lister
Counsel for Mark H. Heinicke, M.D.