

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), and the Department of Defense¹ (collectively the "United States"), and LifeScan, Inc. and Johnson & Johnson, Co. (collectively "LifeScan" or the "Defendants"); and relators Robert Konrad and John Pumphrey (collectively the "Relators"), (all of whom are hereafter referred to as "the Parties"), through their authorized representatives.

II. PREAMBLE

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

A. LifeScan, a California corporation, headquartered in Milpitas, California, is a wholly owned subsidiary of Johnson & Johnson, Co., a New Jersey corporation headquartered in New Brunswick, New Jersey. LifeScan develops, designs, manufactures, distributes and sells medical devices called blood glucose monitoring systems, which included a blood glucose meter and related products such as a lancet and chemically treated white melenix test strips.

B. On October 31, 1997, relators Robert Konrad and John Pumphrey (the "Relators") filed *USA, ex rel. Konrad, et al. v. LifeScan, Inc. et al*, C 00-20478 JF, a *qui tam* action, in the United States District Court for the District of Columbia, which in turn -- on or about February 24, 2000 -- was transferred to the Northern District of California, San Jose Division (hereinafter "the Civil Action"). Relator Konrad, M.D., a board certified clinical pathologist, was employed

¹ TRICARE Management Activity ("TMA")(formerly the Office of Civilian Health and Medical Program of the Uniformed Services ("OCHAMPUS")), a field activity of the Office of the Secretary of Defense, the United States Department of Defense.

as the Director of Clinical Research at LifeScan from March 4, 1996, through January 2, 1998; Relator Pumphrey, a chemist, was employed by LifeScan from June 1, 1995 through December 19, 1997, first as Director of Reagent Operations, and then as Director of Advanced Reagent Development.

C. LifeScan is entering a misdemeanor plea of guilty to an Information alleging, in part, that it introduced and delivered into interstate commerce an adulterated and misbranded medical device in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), in a matter captioned *United States of America v. LifeScan, Inc.*, No. CR 00-^{20356 JF} (Filed in the Northern District of California, December 15, 2000).

D. 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. §§ 1395-1395ggg; the TRICARE Program (also known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)), 10 U.S.C. §§ 1071-1109; the Veterans Affairs Program, 38 U.S.C. §§ 1701-1743; and the Medicaid Program, 42 U.S.C. §§ 1396-1396v.

E. The United States contends that it has certain civil claims against Defendants under the False Claims Act, 31 U.S.C. §§ 3729-3733, and/or the common law theories as specified in Paragraph D above and Paragraph 2 b. below, for introducing and delivering into interstate commerce between July 1, 1996 and June 30, 1998 an adulterated and misbranded medical device, namely the SureStep blood glucose monitoring system, for which federal and state health care programs subsequently were caused to pay, which conduct is described more specifically

and fully in the complaint in the Civil Action and in paragraphs 2 and 6 of the Plea Agreement entered into by LifeScan in the matter captioned *United States v. LifeScan*, CR 00-20356 JF, a copy of which attached hereto as Exhibit A and is hereinafter referred to as the "Covered Conduct".

F. The United States also contends that it has certain administrative claims against Defendants for engaging in the Covered Conduct, as specified in Paragraph E above.

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. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

1. Defendants agree to pay to the United States \$30,350,000 (the "Settlement Amount"). The United States agrees to pay \$6,253,790 of the Settlement Amount to the relators. Defendants further agree to pay Relators' counsel \$250,000 for expenses and attorney's fees and costs. The foregoing payments shall be made as follows:

a. Defendants agree to pay the full Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the Financial Litigation Unit, United States Attorney's Office, Northern District of California. Defendants agree to make this electronic funds transfer within 24 hours of the time that the United States District Court for the Northern District of California ("District Court") imposes sentence on LifeScan in accordance with the Plea Agreement, a copy of which is attached hereto as Exhibit

A. In the event that the District Court does not accept the Plea Agreement, and/or does not impose the sentence agreed to in the Plea Agreement, Defendants may, in their discretion, within seven days of the Court's dispositive action on the Plea Agreement, declare this agreement null and void. Of the Settlement Amount, the United States will make a portion available to state Medicaid programs that choose to participate.

b. Contingent upon the United States receiving the Settlement Amount from Defendants and as soon as feasible after receiving the Settlement Amount from Defendants, the United States agrees to pay \$3,126,895 to Relator Robert Konrad and \$3,126,895 to Relator John Pumphrey pursuant to instructions to be provided by the Relators' counsel.

c. Defendants agree to pay \$250,000 to relators' counsel representing attorney's fees and costs within 24 hours of the time that the District Court imposes sentence on LifeScan in accordance with the Plea Agreement, as set forth in subsection a.

2. Releases:

a. 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) which 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.

b. Subject to the exceptions in Paragraph 3 below, in consideration of the obligations of Defendants set forth in this Agreement, conditioned upon Defendants' full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents,

agencies, and departments) agrees to release Defendants and their current and former directors, officers, shareholders, employees, agents, successors and assigns (collectively the “Released Parties”) 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; or the common law theories of payment by mistake, unjust enrichment, breach of contract, and fraud, for the Covered Conduct.

c. In consideration of the obligations of Defendants set forth in this Agreement and the Defendants’ execution of the Corporate Compliance Agreement (“CCA”), attached as Exhibit B, which is incorporated into this Agreement by reference, and conditioned upon Defendants’ payment in full of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Defendants under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the Covered Conduct. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude LifeScan from the Medicare, Medicaid or other Federal health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. The OIG-HHS acknowledges that the pleas to be entered under the Plea Agreement will not result in a mandatory exclusion of the released parties. Nothing in this Paragraph precludes the OIG-HHS from taking action against

entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3, below.

d. In consideration of the obligations of Defendants set forth in this Agreement, conditioned upon Defendants' full payment of the Settlement Amount, and subject to Paragraph 3, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative or any action seeking exclusion from the TRICARE Program against the Released Parties under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 3, below. Nothing in this Paragraph precludes the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3, below.

e. Conditioned upon receipt of the payment described in Paragraph 1(b), the Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, agree to release the United States, its officers, agents, and employees, from any claims pursuant to 31 U.S.C. § 3730 arising from the filing of the Civil Action, including 31 U.S.C. 3730(b), (c), (d), and (d)(1), and for a share of the proceeds of the Civil Action, and from any claims for a share of the Settlement Amount, and for a share of the proceeds of any proceeding involving an "alternate remedy" to the Civil Action as that term is used in 31 U.S.C. § 3730(c)(5), and for their attorney's fees and costs arising from the Civil Action. The Relators agree and confirm that the settlement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

f. Conditioned upon receipt of the payment described in Paragraph 1(c), the Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, agree to release the Released Parties from any liability to Relators arising from and all matters relating to the Covered Conduct, including but not limited to the claims related to the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.

3. 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 Defendants and Relators) are the following claims of the United States:

a. Any civil, criminal or administrative liability to the United States 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 claims of the United States based upon such obligations as are created by this Agreement;

g. Any claims of the United States for personal injury or for other consequential damages arising from the Covered Conduct; and

h. Any civil and administrative claims against individuals, including current or former directors, officers, employees, agents or shareholders of Defendants who are criminally

indicted or charged, or are convicted or who enter into a criminal plea agreement for the Covered Conduct.

4. LifeScan has entered into the CCA with OIG- HHS, attached as Exhibit B.

LifeScan will immediately upon execution of this Agreement implement its obligations under the CCA.

5. In connection with the execution and performance of this Agreement, Defendants waive and will not assert, in any criminal prosecution or administrative action relating to the Covered Conduct, any defenses 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 Settlement bars a remedy sought in such criminal prosecution or administrative action. Defendants agree that this settlement is not punitive in purpose or effect. 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 Settlement Amount will not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, TRICARE, or VA carrier or payer, or any State payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare carrier or intermediary, TRICARE, VA or other payer or any State payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

7. Defendants agree that all costs (as defined in the Federal Acquisition Regulations (FAR) § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations promulgated thereunder) incurred by or on behalf of Defendants, and their present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement and any related plea agreement or settlement agreement, (2) the Government's audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement, (3) Defendants' investigation, defense, and corrective actions undertaken in response to the Government's audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees) and CCA, (4) the negotiation and performance of this Agreement, the CCA and any related plea agreement or settlement agreement, and (5) the payment made pursuant to this Agreement by Defendants to the United States and to Relators, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, Veterans Affairs Program (VA), and Federal Employees Health Benefits Program (FEHBP) (hereafter, "unallowable costs"). If applicable, these unallowable costs will be separately estimated and accounted for by Defendants and Defendants will 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 its subsidiaries to the Medicare, Medicaid, TRICARE, VA, or FEHBP Programs. Defendants further agree that within 60 days of the effective date of this Agreement they will identify to applicable Medicare and TRICARE

fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA 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, and will 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 will be entitled to recoup from Defendants any overpayment 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 or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Defendants or any of their subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Defendants or any of their subsidiaries' 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.

8. This Agreement is intended to be for the benefit only of the United States, the Relators, and the Released Parties. The Parties do not release any claims against any other person or entity.

9. Defendants agrees that they will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Defendants waive any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

10. Upon receipt of the payments described in Paragraph 1(a) and (c) above, the United States shall promptly sign and file in the Civil Action a Notice of Intervention and, jointly with the Relators, a Stipulation of Dismissal with prejudice of the Civil Action pursuant to the terms of the Agreement.

11. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. 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 will be the United States District Court for the Northern District of California, except that disputes arising under the CCA shall be resolved exclusively under the dispute resolution provisions in the CCA.

13. This Agreement, the Plea Agreement, including the Special Conditions of Probation, and the CCA constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only LifeScan and OIG-HHS must agree in writing to modification of the CCA

14. The individuals signing this Agreement on behalf of Defendants represent and warrant that they are authorized by Defendants to execute this Agreement. The individual(s) signing this Agreement on behalf of the Relators represent and warrant that they are authorized by the Relators 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.

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

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

17. Relators hereby consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

18. This Agreement is effective on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

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THE UNITED STATES OF AMERICA

DAVID OGDEN
Assistant Attorney General

ROBERT S. MUELLER, III
United States Attorney
Northern District of California

DATED: 12-13-00

BY: 
JOANN M. SWANSON
Assistant U.S. Attorney

DATED: 12-13-00

BY: 
DANIEL R. ANDERSON
Senior Trial Counsel
Commercial Litigation Branch, Civil Division
U.S. Department of Justice

DATED: _____

BY: _____
LEWIS MORRIS
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
ROBERT L. SHEPHERD
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

THE UNITED STATES OF AMERICA

DAVID OGDEN
Assistant Attorney General

ROBERT S. MUELLER, III
United States Attorney
Northern District of California

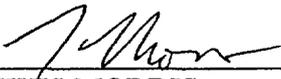
DATED: _____

BY: _____
Joann M. Swanson
Assistant U.S. Attorney

DATED: _____

BY: _____
Daniel R. Anderson
Senior Trial Counsel
Commercial Litigation Branch, Civil Division
U.S. Department of Justice

DATED: 12/13/00

BY: 
LEWIS MORRIS
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
ROBERT L. SHEPHERD
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

LIFESCAN, JOHNSON & JOHNSON - DEFENDANTS

DATED: 12/13/00 BY: 
JAN NIELSEN LITTLE
Keker & Van Nest
Attorneys for LifeScan, Inc.

DATED: 12/13/00 BY: 
JAN NIELSEN LITTLE
Keker & Van Nest
Attorneys for Johnson & Johnson

ROBERT KONRAD AND JOHN PUMPHREY - RELATORS

DATED: 12/13/00

BY: Robert Konrad
ROBERT KONRAD

Dated: _____

By: _____
JOHN PUMPHREY

Dated: _____

By: _____
ROBERT L. VOGEL
Attorney for Relators Konrad and Pumphrey

Dated: _____

By: _____
MICHAEL RUBIN
Attorney for Relators Konrad and Pumphrey

ROBERT KONRAD AND JOHN PUMPHREY - RELATORS

DATED: _____

BY: _____
ROBERT KONRAD

Dated: 12/13/00

By: John Pumphrey
JOHN PUMPHREY

Dated: _____

By: _____
ROBERT L. VOGEL
Attorney for Relators Konrad and Pumphrey

Dated: _____

By: _____
MICHAEL RUBIN
Attorney for Relators Konrad and Pumphrey

ROBERT KONRAD AND JOHN PUMPHREY - RELATORS

DATED: _____

BY: _____
ROBERT KONRAD

Dated: _____

By: _____
JOHN PUMPHREY

Dated: 12/13/00

By: Robert L. Vogel
ROBERT L. VOGEL
Attorney for Relators Konrad and Pumphrey

Dated: _____

By: _____
MICHAEL RUBIN
Attorney for Relators Konrad and Pumphrey

ROBERT KONRAD AND JOHN PUMPHREY - RELATORS

DATED: _____

BY: _____
ROBERT KONRAD

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By: _____
JOHN PUMPHREY

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By: _____
ROBERT L. VOGEL
Attorney for Relators Konrad and Pumphrey

Dated: 12/13/00

By: 
MICHAEL RUBIN
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