

SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement ("Agreement") is entered by and between the United States of America, acting through its Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, and on behalf of the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); the Office of Inspector General of the United States Railroad Retirement Board ("RRB-OIG"); the Office of the Civilian Health and Medical Program of the Uniformed Services ("Office of CHAMPUS") through the General Counsel, Office of CHAMPUS, a field activity of the Office of the Secretary of Defense, the United States Department of Defense; the Federal Employees Health Benefits Plan, administered by the United States Office of Personnel Management ("OPM-OIG"), through the United States Attorney's Office for the District of Columbia; SmithKline Beecham Clinical Laboratories, Inc. ("SBCL"), a corporation organized under the laws of the State of Delaware; and Robert J. Merena, Glenn Grossenbacher, Dr. Charles Robinson, C. Jack Dowden, Kevin Spear, and the Berkeley Community Law Center (the "Relators"). Collectively, all of the above will be referred to as "the Parties."

PREAMBLE

A. WHEREAS, this Agreement addresses the United States civil claims against SBCL based on the conduct described in Preamble Paragraphs H through Q below including the conduct alleged in United States ex rel. Robert J. Merena v. SmithKline Beecham Corporation, Civil Action No. 93-CV-5974 (Eastern District of Pennsylvania) (filed November 12, 1993, and amended on August 31, 1995); United States ex rel. Dr. Charles Robinson and Glenn Grossenbacher v. SmithKline Beecham Clinical Laboratories, Inc., Civil Action No. 95-CV-6953 (Eastern District of Pennsylvania) (originally filed December 15, 1993 in the Western District of Texas as Civil Action SA-93-CA-1070, amended on August 29, 1995); and United States ex rel. Kevin Spear, C. Jack Dowden and Berkeley Community Law Center v. SmithKline Beecham Clinical Laboratories, Civil Action No. 95-6551 (Eastern District of Pennsylvania) (originally filed February 13, 1995 in the Northern District of California as Civil Action No. C-95-0501) (collectively these three suits will be referred to as the "Civil Actions");

B. WHEREAS, at relevant times, SBCL owned and operated a national system of clinical laboratories, draw stations, satellite laboratories, branch operations, and laboratory and patient service centers, including regional clinical laboratories in the following metropolitan areas: Atlanta, Georgia; Baltimore, Maryland; Boston, Massachusetts; Chicago, Illinois; Cleveland, Ohio; Dallas, Texas; Detroit, Michigan; Honolulu, Hawaii; Houston, Texas; Lexington,

Kentucky; Los Angeles, California; Louisville, Kentucky; Miami, Florida; Minncapolis, Minnesota; Nashville, Tennessee; New Orleans, Louisiana; New York City, New York; Philadelphia, Pennsylvania; Phoenix, Arizona; San Antonio, Texas; San Diego, California; San Francisco, California; Seattle, Washington; St. Louis, Missouri; Syosset, New York; Tallahassee, Florida; Tampa/Orlando, Florida, and Van Nuys, California;

C. WHEREAS, SBCL submitted or caused to be submitted claims for payment to the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., which is administered by the United States Department of Health and Human Services;

D. WHEREAS, SBCL submitted or caused to be submitted claims for payment to the Railroad Retirement Medicare program, Railroad Retirement Act of 1974, 45 U.S.C. § 231 et seq., which is administered by the United States Railroad Retirement Board ("RRB");

E. WHEREAS, SBCL submitted or caused to be submitted claims for payment to the Civilian Health and Medical Program for the Uniformed Services ("CHAMPUS"), 10 U.S.C. §§ 1071-1106, which is administered by the United States Department of Defense through its component agency, the Office of CHAMPUS ("OCHAMPUS");

F. WHEREAS, SBCL submitted or caused to be submitted claims for payment to the Federal Employees Health Benefits Program ("FEHBP"), which is administered by the Office of Personnel Management ("OPM") pursuant to 5 U.S.C. §§ 8901 et seq.

G. WHEREAS, SBCL submitted or caused to be submitted claims for payment to the Medicaid programs, Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq., of the states of Alabama, Alaska, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin;

H. WHEREAS, the United States contends that SBCL violated federal statutes and/or common law doctrines, in connection with the marketing, sale, pricing and billing of its testing for serum ferritin (Current Procedural Terminology ("CPT") 82728), gamma glutamyl transpeptidase ("GGT") (CPT 82977), triglycerides ("Trig") (CPT 84478), serum iron (CPT 83545/83540), high-density lipoprotein cholesterol ("HDL") (83718), low-density lipoprotein cholesterol ("LDL") (CPT 83720), total iron binding capacity ("TIBC") (CPT 83550/83555), and serum magnesium tests (CPT 83735/83750) when performed routinely in conjunction with SBCL's ChemZyme and/or ChemZyme Plus profiles, or other SBCL chemistry profiles that included serial multichannel automated chemistry ("SMAC") tests (CPT 80002-80019 and codes G0058-60); these services were billed by and paid to SBCL;

I. WHEREAS, the United States contends that SBCL violated federal statutes and/or common law doctrines in connection with its testing and billing for Urinalysis tests (CPT 81000/81002/81003/

by routinely performing Urinalysis with microscopy and routinely billing for Urinalysis with microscopy when a urinalysis was ordered; these services were billed by and paid to SBCL;

WHEREAS, the United States contends that SBCL violated state statutes and/or common law doctrines in connection with its practice of billing for Prostate Specific Antigen tests ("PSA") (CPT 84153) and Thyroid Stimulating Hormone tests ("TSH") (CPT 80070) by performing these tests as screening tests and improperly inserting a diagnosis code to obtain payment, specifically diagnosis code 799 when submitting claims to the Medicare carrier in Lexington, Kentucky; these services were billed by and paid to SBCL;

WHEREAS, the United States contends that SBCL violated state statutes and/or common law doctrines in connection with its practice of and billing for Complete Blood Count ("CBC"), one or more additional indices (CPT 85029/85030), when these indices were ordered by doctor-clients; these services were billed by and paid to SBCL;

WHEREAS, the United States contends that SBCL violated state statutes and/or common law doctrines in connection with its practice of billing for Pap Smears (CPT 88150/88151/88155/88156/88157/88160/P3000/P3001) by improperly inserting diagnosis codes to obtain payment; these services were billed by and paid to SBCL;

WHEREAS, the United States contends that SBCL violated state statutes and/or common law doctrines in connection with its practice of billing for SMAC tests (CPT 80002-80019) and individual clinical

laboratory tests for End Stage Renal Disease ("ESRD") patients (1) by billing Medicare Part B for the same tests included in the composite rate paid to ESRD facilities under Medicare Part A, and (2) by billing the Medicare program for tests for ESRD patients when such tests were not necessary for the diagnosis or treatment of illness or injury; these services were billed by SBCL and paid to SBCL;

N. WHEREAS, the United States contends that SBCL violated federal statutes and/or common law doctrines, including the Medicare Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), in connection with the provision to physicians and/or other referral sources of free or discounted tests; free or discounted tests to certain patients affiliated with managed care organizations; the provision in client facilities of computers and computer-related equipment, fax machines, refrigerators, or other laboratory-related equipment; the placement of phlebotomists in clients' offices; or the payment of rent to referring clients;

O. WHEREAS, the United States contends that SBCL violated federal statutes and/or common law doctrines in connection with its billing for tests that were neither reported nor performed ("TNRP") due to specimen integrity or other technical problems but that were billed by and paid to SBCL, and these tests were billed by and paid to SBCL;

P. WHEREAS, the United States contends that SBCL violated federal statutes and/or common law doctrines in connection with allegations not specified in Preamble Paragraphs H through O above but which are set forth in the Civil Actions referenced in Preamble

Paragraph A; these allegations resulted in tests that were billed by and paid to SBCL;

Q. WHEREAS, the United States contends that the practices described in Preamble Paragraphs H through P resulted in the submission of false claims actionable under the False Claims Act, 31 U.S.C. § 3729, et seq., between January 1, 1989, and September 16, 1996, to the Medicare program, the Railroad Retirement Medicare program, the CHAMPUS program, the Federal Employees Health Benefits Program, and the Medicaid programs in the states listed in Preamble Paragraph G above, which enabled SBCL to improperly collect federal Medicare payments, Railroad Retirement Medicare program payments, CHAMPUS payments, Federal Employees Health Benefits Program payments, and Medicaid program payments from the states listed in Preamble Paragraph G above;

R. WHEREAS, SBCL contends that its marketing, sales, pricing, and billing practices, including those specifically referenced in Preamble Paragraphs H through Q above, including those alleged in the Civil Actions, were appropriate and lawful and did not result in any violations of federal law, common law doctrines or state law;

S. WHEREAS, SBCL denies the contentions of the United States and the Relators as set forth in Preamble Paragraphs H through Q above, including those alleged in the Civil Actions;

T. WHEREAS, SBCL specifically denies any wrongdoing or liability in connection with the contentions of the United States and the Relators set forth in Preamble Paragraphs H through Q above, including those alleged in the Civil Actions;

U. WHEREAS, SBCL has entered into a Corporate Integrity Agreement with HHS-OIG, attached as Exhibit 1, which is hereby incorporated into this Settlement Agreement and Release by reference as though fully presented herein; and,

V. WHEREAS, in order to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final compromise of the civil claims the United States has against SBCL pursuant to the statutes and terms set forth in Paragraph 2 below and based on the conduct alleged in Paragraphs H through Q of this Preamble including that alleged in the three Civil Actions referenced in Preamble Paragraph A above, except as reserved in Paragraph 3 below.

TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties hereby agree as follows:

1. SBCL agrees to pay to the United States and the states listed in Preamble Paragraph G above, collectively, the sum of three hundred twenty five million dollars (\$325,000,000) of principal (the "Settlement Amount"), which shall constitute a debt due and owing in accordance with a court order agreed to by the Parties and entered by the court ("the Court Order").

2. Subject only to the conditions specified in Paragraph 3 below, on receipt of the payment described in Paragraph 1 above by the United States and the State Settlement Account, collectively, in accordance with the Court Order, the United States, on behalf of itself, its officers, agents, agencies, and departments, will release and will be deemed to have released for the time period of January 1, 1989, through September 16, 1996 (i) SBCL, its parents, affiliates, divisions, subsidiaries, (ii) their predecessors, successors, assigns, transferees, and (iii) any of their current or former directors, officers, and employees, from any civil or administrative monetary claims (including recoupment claims) that the United States has or may have under the False Claims Act, 31 U.S.C. § 3729 et seq. (as amended); the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801 et seq.; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Anti-Kickback Act, 41 U.S.C. §§ 52 et seq.; Titles XVIII and XIX of the Social Security Act, 42 U.S.C. § 1395 et seq. and § 1396 et seq.; the FEHBP sanctions provision, 5 U.S.C. § 8902a (subject to Paragraph 6 below); any statutory provision applicable to the federally-funded programs in this Agreement for which the Civil Division, United States Department of Justice, has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, § 0.45(d) (1995); or common law for the conduct described in Paragraphs H through Q of the Preamble above including that alleged in the Civil Actions with respect to claims submitted or caused to be submitted during the relevant time period to the Medicare program, the Railroad Retirement Medicare program, the

CHAMPUS program, and/or the FEHBP, and to the Medicaid programs of the states listed in Preamble Paragraph G above.

3. Notwithstanding any other provision in this Agreement, the United States specifically does not release SBCL or any other entity or individual under this Agreement from (a) any potential criminal liability arising from the subject matter of this Agreement; (b) any potential criminal, civil or administrative claims arising under Title 26 U.S. Code (Internal Revenue Code); (c) any potential liability to the United States (or any agencies thereof) for any conduct other than that identified in Preamble Paragraphs H through Q above including that alleged in the Civil Actions; (d) any claims against individuals, including current or former directors, officers, and employees of SBCL who are criminally convicted of an offense related to the conduct alleged in Preamble Paragraphs H through Q above (the term "convicted" shall have the meaning set forth in 42 U.S.C. § 1320a-7(i)); (e) claims arising at any laboratory owned or operated by SBCL but not referenced in Preamble Paragraph B above; (f) conduct by any laboratory owned in whole or in part by SBCL which occurred prior to such ownership; (g) any conduct by any laboratory performing services under contract with SBCL and billing federally-funded programs using non-SBCL provider (or other identifying) number(s); (h) any civil or administrative claims for the recoupment of overpayments for TNRP's for services billed by and paid to SBCL during the period July 1, 1992, through September 16, 1996; (i) any obligations created by this Agreement; (j) any claims for defective or deficient services.

4. On receipt of the payment described in Paragraph 1 above by the United States and the State Settlement Account, collectively, in accordance with the Court Order, the Office of Inspector General of HHS agrees to release and refrain from instituting, directing, or maintaining any administrative claim or any action seeking exclusion from the Medicare program or State health care programs (as defined in 42 U.S.C. § 1320a-7(h)) against SBCL, its parents, affiliates, divisions, subsidiaries, their predecessors, successors, assigns, transferees or any of their present or former directors, officers, employees, or agents under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law); 31 U.S.C. §§ 3801-3812 (Program Fraud Civil Remedies Act); or 42 U.S.C. § 1320a-7(b) (permissive exclusion) for the conduct described in Preamble Paragraphs H through Q above including that alleged in the Civil Actions, except as reserved in Paragraph 3 above. The Office of Inspector General of HHS expressly reserves all rights and statutory obligations to exclude SBCL, or any of its parents, affiliates, divisions, subsidiaries, successors, or assigns, or any of its present or former officers, directors, employees, from the Medicare program or a State health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion). Nothing in this Paragraph precludes the Office of Inspector General of HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 above.

5. On receipt of the payment described in Paragraph 1 above by the United States and the State Settlement Account, collectively, in accordance with the Court Order, OCHAMPUS agrees to release and refrain from instituting, directing, or maintaining any administrative claim or any action seeking exclusion from the CHAMPUS program against SBCL, its parents, affiliates, divisions, subsidiaries, their predecessors, successors, assigns, transferees or any of their present or former directors, officers, employees, or agents under 32 C.F.R. § 199.9, or 31 U.S.C. §§ 3801-3812 (Program Fraud and Civil Remedies Act) for the conduct described in Preamble Paragraphs H through Q above including that alleged in the Civil Actions, except as reserved in Paragraph 3 above. OCHAMPUS expressly reserves all rights and statutory obligations to exclude SBCL, or any of its parents, affiliates, divisions, subsidiaries, successors, or assigns, or any of its present or former officers, directors, employees, from the CHAMPUS program under its mandatory exclusion authority, set forth at 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), (f)(1)(iii). Nothing in this Paragraph precludes OCHAMPUS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 above.

6. On receipt of the payment described in Paragraph 1 above by the United States and the State Settlement Account, collectively, in accordance with the Court Order, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative claim or any action seeking exclusion from the FEHBP program against SBCL, its parents, affiliates, divisions,

subsidiaries, their predecessors, successors, assigns, transferees or any of their present or former directors, officers, employees, or agents, under 5 U.S.C. § 8902a, 5 C.F.R. Part 970 or 31 U.S.C. §§ 3801-3812 (Program Fraud and Civil Remedies Act) for the conduct described in Preamble Paragraphs H through Q above including that alleged in the Civil Actions, except if excluded by the Office of Inspector General of HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 above.

7. SBCL hereby agrees that it will waive and will not assert any defense, which may be based in whole or in part on the Double Jeopardy Clause of the Constitution as set forth in the holding or principles in United States v. Halper, 490 U.S. 435 (1989), in any criminal prosecution based on the conduct alleged in Preamble Paragraphs H through Q above including that alleged in the Civil Actions.

8. The Relators agree that the settlement of claims in the Civil Actions is fair, adequate and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). The Relators will release, on receipt of the payment described in Paragraph 1 above by the United States and the State Settlement Account, collectively, in accordance with the Court Order, SBCL, its parents, affiliates, divisions, subsidiaries, joint ventures, managed laboratories, their predecessors, successors, assigns, transferees, and any of their current or former directors, officers, employees, shareholders, and agents from any and all

claims that may arise under or relate to any of the allegations in the Civil Actions and/or the conduct described in Paragraph 2 above, except as they relate to a claim for attorneys' fees, costs, and expenses, pursuant to 31 U.S.C. § 3730(d).

9. After this Agreement is executed, the United States and the Relators will notify the court that all Parties have stipulated that the three Civil Actions be dismissed with prejudice effective on receipt of the payment described in Paragraph 1 above by the United States and the State Settlement Account, collectively, in accordance with the Court Order, pursuant to and consistent with the terms of this Agreement. The Parties also will request in that notification to the Court that the United States District Court for the Eastern District of Pennsylvania specifically retain jurisdiction with respect to any unresolved issues, including attorneys' fees, costs, expenses, and relators' shares of the settlement proceeds, and specifically retain jurisdiction with respect to enforcement of the Corporate Integrity Agreement.

10. The payment from SBCL to the United States under Paragraph 1 above shall not be offset by any claims for payment now being withheld from payment by any Medicare carrier or intermediary, or by any CHAMPUS or FEHBP carrier or payor, related to serum ferritin, TIBC, iron, GGT, magnesium, HDL, or LDL tests; and SBCL agrees not to resubmit any claims to a Medicare carrier or intermediary that have been denied for tests billed between January 1, 1989, and September 16, 1996, and agrees not to appeal such denials of claims, where such denial resulted from the practices described in Preamble Paragraphs H through Q above including that

alleged in the Civil Actions. Nothing in this Paragraph shall be construed to bar SBCL from contesting any payment denial where such denial is not based on the practices described in Preamble Paragraphs H through Q above including those alleged in the Civil Actions.

11. For government contracting purposes and for Medicare, Railroad Retirement Medicare, CHAMPUS, and state Medicaid purposes, SBCL agrees to treat as unallowable all costs (as defined in the Federal Acquisition Regulations ("FAR") §31.205.47(a)) incurred by SBCL on behalf of SBCL and/or its current or former officers, directors, owners, agents, employees, shareholders, parents, subsidiaries, divisions, predecessors and successors in connection with (a) the performance of this Agreement; (b) the Government's audit and investigation of the matters covered by this Agreement, (c) SBCL's investigation, defense, and corrective actions; (d) the negotiation and performance of this Agreement; and (5) the payments made to the United States provided for in this Agreement. These amounts shall be separately estimated and accounted for by SBCL, and SBCL will charge such costs directly or indirectly to any contracts with the United States, or to any cost report submitted to the Medicare, Railroad Retirement Medicare, CHAMPUS, or state Medicaid programs.

12. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the amounts paid thereunder for purposes of any proceeding under Title 26 of the Internal Revenue Code.

13. The Parties agree that this Agreement does not constitute an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact. The Parties also agree that the performance under this Agreement of any of the obligations of SBCL, its parents, affiliates, divisions, subsidiaries, their predecessors, successors, assigns, transferees, and any of their released (pursuant to Paragraph 2 above) current or former directors, officers, employees or agents, shall not constitute nor be construed as an admission by any person or entity, with respect to any issue of law or fact.

14. This Agreement shall be binding upon the Parties, their successors, assigns, and heirs.

15. The undersigned SBCL and Berkeley Community Law Center signatories represent and warrant that they are signing this Agreement in their official capacity and are fully empowered and authorized by their Board of Directors to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacity and they are fully empowered and authorized to do so.


16. This Agreement shall become final and binding only on signing by each party hereto, and in accordance with the Court Order.


17. This Agreement may not be changed, altered or modified, except in writing signed by all parties.


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


19. This Agreement is effective on the date signed by the last signatory.


UNITED STATES OF AMERICA


By:  Dated: 9/27/96
JAMES G. SNEEHAN
Assistant United States Attorney
Eastern District of Pennsylvania


By:  Dated: 9/27/96
LAURENCE J. FREEDMAN
Civil Division
United States Department of Justice

By:  Dated: 9/27/96
DARA A. CORRIGAN
Assistant United States Attorney
District of Columbia

By:  Dated: 9/27/96
LEWIS MORRIS
Assistant Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services

By:  Dated: 9/27/96
ROBERT D. SEAMAN
General Counsel
Office of CHAMPUS

By:  Dated: 9/27/96
LUCRETIA F. MYERS
Assistant Director For Insurance Programs
United States Office of Personnel Management

By:  Dated: 9/27/96
MARTIN J. DICKMAN
Inspector General
Railroad Retirement Board

SMITHKLINE BEECHAM CLINICAL LABORATORIES, INC.

By: *Teitoku Yamada* Dated: 9/26/96
TEITOKU YAMADA, M.D.

Chairman
SmithKline Beecham Clinical Laboratories, Inc.

By: *Thomas H. Lee II* Dated: 9/26/96
THOMAS H. LEE, II, ESQ.

Dechert Price & Rhoads
Counsel to SmithKline Beecham Clinical Laboratories, Inc.

By: *S. Craig Holden III* Dated: 9/26/96
S. CRAIG HOLDEN, ESQ.

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A Professional Corporation
Counsel to SmithKline Beecham Clinical Laboratories, Inc.

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By: 151 Dated: 9/27/96
ROBERT J. MERENA

By: 151 Dated: 9/27/96
MARC S. RASPANTI, ESQ.
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By: 151 Dated: 9/27/96
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By: 151 Dated: 9/27/96
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JOHN E. CLARK, ESQ.
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Counsel to Charles W. Robinson, Jr., M.D.,
and Glenn Grossenbacher

By: 151 Dated: 9/27/96
KEVIN SPEAR

By: 151 Dated: 9/27/96
C. JACK DOWDEN

By: 151 Dated: 9/27/96
BERNITA REAGAN
Director, Berkeley Community Law Center

By: 151 Dated: 9/27/96
MARY LOUISE COHEN, ESQ.
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Counsel to C. Jack Dowden,
Kevin Spear, and Berkeley Community Law Center