

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *EX REL.*,
JACQUELINE KAY POTEET and JOHN DOE,

FILED UNDER
SEAL

Plaintiff,

-vs-

Case No. 07 CA 1 02 37 RGS

LAWRENCE G. LENKE, M.D., K. DANIEL
RIEW, M.D., REGIS HAID, M.D.,
GERALD E. RODTS, JR., M.D.,
MATHEW F. GORNET, M.D., EDWARD S. PRATT, M.D.,
MAURICE SMITH, M.D., KEVIN T. FOLEY, M.D.,
VINCENT C. TRAYNELIS, M.D.,
GEORGE PICETTI, M.D., MITCHEL CAMPBELL, M.D.,
STEVEN GLASSMAN, M.D., JOHN R. JOHNSON, M.D.
ROLANDO M. PUNO, M.D., MICKEY MORGAN, M.D.,
TERRY TRAMMELL, M.D., DEAN KARAHALIOS, M.D.,
STEVEN HUMPHREYS, M.D., SCOTT HODGES, M.D.,
JAMES GUILLE, M.D., TIMOTHY A. GARNEY, M.D.,
BRADLEY T. ESTES, M.D., FRANCIS DENIS, M.D.,
JEFFREY E. DECKEY, M.D., JAMES L. CHAPUIS, M.D.,
CENTRAL OHIO NEUROSURGICAL GROUP P.C.,
CHARLES BRANCH, M.D., JOSEPH H. PERRA, M.D.,
MANUEL PINTO, M.D., DAVID POLLY, M.D.,
BERNARD A. RAWLINS, M.D., JAMES SCHWENDER, M.D.,
ENSER TRANSFELDT, M.D., FRANK SCHWAB, M.D.
AMIN MEHBED, M.D., SYLVAIN PALMER, M.D.,
ERIC PITTS, M.D., AMERICAN ORTHOPEDIC CONSULTANTS, LLC,
KENNETH J. BURKUS, M.D., JOHN DIMAR, M.D.,
LGL SPINE, LLC, SILBER PHYSICIANS, PC,
DAVID LEE SKAGGS, M.D., BRIAN SUBACK, M.D.,
STEPHEN ONDRA, M.D., SPINECO, INC,
JAMES HARROP, M.D., VIVEK KUSHWAHA, M.D.,
JOSEPH RIINA, M.D., HALLETT MATTHEWS, M.D.,
REGINALD KNIGHT, M.D., CHISTOPHER SHAFFREY, M.D.,
RONALD LEHMAN, M.D., ROBERT ISAACS, M.D.,
JEAN PIERRE MOBASSER, M.D., NEEL ANAND, M.D.,
GEORGE A. FREY, M.D., LUIS MIGNUCCI, M.D.,
PAUL PAGANO, M.D., MLADEN DJURASOVIC, M.D.,
MICHAEL GROF, M.D., DAVID B. KEE, M.D.,

**MICHAEL MACMILLAN, M.D., SAN FRANCISCO
SPINE INSTITUTE, JOHN SHIAN, M.D., STANLEY
SKINNER, M.D., DAVID ROUBEN, M.D., HUAN BAE, M.D.,
JAMES OGILVIE, M.D., GEORGE PICETTI, M.D.,
HAL SILCOX, III, M.D., CHRISTIAN PUTTLITZ, M.D.,
KAUSHIK DAS, M.D., DONALD KUCHARZYK, M.D.,
JOHN BENDO, M.D., DENNIS CRANDALL, M.D.,
PERRY J. ARGIRES, M.D., DAENOC, LLC,
TODD BONVALLET, M.D., THE BOSTON
SPINE GROUP, GREG D. ANDERSON, M.D.,
CHRISTOPHER COMEY, M.D., ROBERT MYLES, M.D.,
THOMAS KLEEMAN, M.D., LOUIS G. JENIS, M.D.,
CHRISTIAN FRAS, M.D., FREDERICK MARCIANO, M.D.,
RANDALL BETZ, M.D., JOSEPH FLYNN, JR., M.D.
TAI FRIESAM, M.D., BERNARD RAWLINS, M.D.,
SEAN SALEHI, M.D., JEAN PIERRE FARCY, M.D.,
TIMOTHY A. GARVEY, M.D., SERENA HU, M.D.,
KEITH BRIDWELL, M.D., JEFFREY M. SPIVAK, M.D.,
RICK SASSO, M.D., TODD LANMAN, M.D.,
GIRARD GIRASOLE, M.D., STEVEN HEIM, M.D.,
MICHAEL D. KASTEN, M.D., GARY BLOOMGARDEN, M.D.,
DARRELL BRODKE, M.D., GEORGE TEITELBAUM, M.D.,
SCOTT BODEN, M.D., EDWARD GOLDBERG, M.D.,
THOMAS SCHULER, M.D., RUSSELL TRAVIS, M.D.,
ROBERT WATKINS, M.D., LYTTON WILLIAMS, M.D.,
LANGSTON HOLLY, M.D., INNOVATIVE SPINE AND
BRAIN SURGEONS, PC, THOMAS NAJEEB, M.D.,
JASON HUBBARD, M.D., JAMES ROBINSON, M.D.,
ARTHUR CONLEY, M.D., THEODORE G. OBENCHAIN, M.D.,
EDWARD DOHRING, M.D., BARRY LONNER, M.D.,
MICHAEL SWANK, M.D., LUIS DUARTE, M.D.,
JOHN PELOZA, M.D., MUWAFFEK ABDULHAK, M.D.,
REGINALD DAVIS, M.D., BENTON BIOMEDICAL, INC.,
BIO-TEK MEDICAL, LLC, RAPP MEDICAL SYSTEMS, INC.,
MEDICRAFT SPINAL IMPLANTS, INC., NU MED
TECHNOLOGIES, INC., PRAXA MEDICAL, INC.,
SURGICAL SYSTEMS, INC., SPINAL ASSOCIATES, LTD.,
RUMMER MEDICAL, INC., MEDALLIANCE, INC.,
TEAM SPINE, INC. (MINNESOTA), TEAM SPINE, INC.
(WISCONSIN), FIRST CHOICE MEDICAL, INC.,
CAROLINA SPINE SYSTEMS, INC., GHM, LLC,
PRECISION MEDICAL, INC., VENTURE MEDICAL, INC.,
MOUNTAIN MEDICAL DISTRIBUTORS,
and JOHN DOE(S), M.D.**

Defendants.

AMENDED COMPLAINT

Introduction

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and ineligible claims made and presented by the defendants and/or their agents, employees and employers in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729, *et. seq.*, as amended (hereinafter, sometimes, “the Act”). The violations of the Act involve claims for reimbursement that defendants made against Medicare and Medicaid programs since at least 2002 which defendants knew were false, exaggerated and/or ineligible. In violation of their duty to report known errors resulting in ineligible federal payments, defendants likewise concealed such errors from Government agents in order to keep funds to which they were not entitled.

2. The Act provides that any person who knowingly submits or causes to be submitted a false, fraudulent or ineligible claim to the Government for payment or approval is liable for a civil penalty of up to \$10,000.00 for each such claim submitted or paid, plus three times the amount of the damages sustained by the Government. Liability attaches both when a defendant knowingly seeks payment that is unwarranted from the Government and when false records or statements are knowingly created or caused to be used to conceal, avoid or decrease an obligation to pay or transmit money to the Government. The Act allows for any person having information regarding a false or

fraudulent claim against the Government to bring an action for himself (the “relator”) and for the Government, and to share in any recovery. The complaint is filed under seal for sixty (60) days (without service on the defendants during that period) to enable the Government: (a) to conduct its own investigation without the defendant’s knowledge, and (b) to determine whether to join the action.

3. Based on those provisions, plaintiff/relator seeks to recover damages and civil penalties arising from defendants’ presentation of false records, claims, and statements to the United States Government and its agents in connection with defendants’ claims for reimbursement for medical services provided to patients under the Medicare and Medicaid programs in violation of the Federal Anti-Kickback Statute 42 U.S.C.A. § 1320a-7b(b), §1877 of the Social Security Act, often referred to as the “Stark law and the Act. Plaintiff/relator also seeks to recover damages arising from defendants’ unlawful practice of permitting records that defendants have discovered, learned and knew contained erroneous or ineligible information to be relied upon by the Government as the basis upon which to pay defendants unqualified and prohibited reimbursement from federal funds.

Parties

4. Plaintiff and relator, Jacqueline Kay Poteet, is a resident of Memphis, Shelby County, Tennessee and is a former employee of Medtronic Sofamor Danek U.S.A., Inc. (“MSD”), a manufacturer and seller of spinal implants and other medical devices. Plaintiff/relator, Jacqueline Kay Poteet was employed by Medtronic Sofamor Danek, Inc., a manufacturer of spinal implant devices, from March 13, 1995 until August,

2003. She served as the Senior Manager for Travel Services, a position she held from 1998 until her departure. As such, her job responsibilities included the supervision of eight subordinate travel agents and planners and the administration of a ten million dollar (\$10,000,000.00) annual budget for employee and non-employee (physician) travel. Moreover, Ms. Poteet was also intimately aware of the substantial financial relationships existing between her employer and many of its physician-customers. Since her retirement, Ms. Poteet has been furnished with documents and information that clearly indicate that (a) continuing unlawful payments and perquisites are provided to the named physician defendants and that (b) these payments have increased since her retirement. The nature and amount of these unlawful payments and perquisites, and the role played by Medtronic Sofamor Danek's distributors in doling out same, will be set forth in detail herein.

5. Ms. Poteet brings this action for violations of 31 U.S.C. §§ 3729 *et. seq.*, on behalf of herself and the United States Government pursuant to 31 U.S.C. § 3730(b)(1).

6. The plaintiff/relator John Doe comprises a number of unidentified people with direct knowledge of the information contained in the allegations herein, and who have provided same to Ms. Poteet.

7. All physician defendants are neurosurgeons or orthopedic surgeons (sometimes incorporated) (a) who are customers of Medtronic Sofamor Danek, Inc., (b) who practice medicine within the United States and (c) who participate in Medicare and/or Medicaid programs as follows:

8. The defendant Mitch Campbell is a physician residing and practicing in Louisville, Kentucky.

9. The defendant Vincent Traynelis is a physician residing and practicing in Iowa City, Iowa.

10. The defendant Maurice Smith is a physician residing and practicing in Memphis, Tennessee.

11. The defendant Steven Glassman is a physician residing and practicing in Louisville, Kentucky.

12. The defendant John R. Johnson is a physician residing and practicing in Louisville, Kentucky.

13. The defendant Rolando M. Puno is a physician residing and practicing in Louisville, Kentucky.

14. The defendant Mickey Morgan is a physician residing and practicing in Frisco, Texas.

15. The defendant Terry Trammell is a physician residing and practicing in Indianapolis, Indiana.

16. The defendant Dean Karahalios is a physician residing and practicing in Chicago, Illinois.

17. The defendant Steven Humphreys is a physician residing and practicing in Chattanooga, Tennessee.

18. The defendant Scott Hodges is a physician residing and practicing in Chattanooga, Tennessee.

19. The defendant James Guille is a physician residing and practicing in Pottstown, Pennsylvania.
20. The defendant Timothy Garvey is a physician residing and practicing in Minneapolis, Minnesota.
21. The defendant Bradley T. Estes is a physician residing and practicing in Durham, North Carolina.
22. The defendant John Dorchak is a physician residing and practicing in Columbus, Georgia.
23. The defendant Francis Denis is a physician residing and practicing in Minneapolis, Minnesota.
24. The defendant Jeffrey E. Deckey is a physician residing and practicing in San Francisco, California.
25. The defendant James L. Chappuis is a physician residing and practicing in Atlanta, Georgia.
26. The defendant Central Ohio Neurosurgical Group is a legal association of neurosurgeons residing and practicing in Columbus, Ohio.
27. The defendant Charles Branch is a physician residing and practicing in Winston-Salem, North Carolina.
28. The defendant Joseph H. Perra is a physician residing and practicing in Minneapolis, Minnesota.
29. The defendant Manuel Pinto is a physician residing and practicing in St. Paul, Minnesota.

30. The defendant David Polly is a physician residing and practicing in Minneapolis, Minnesota.

31. The defendant Bernard A. Rawlins is a physician residing and practicing in New York, New York.

32. The defendant James Schwender is a physician residing and practicing in Minneapolis, Minnesota.

33. The defendant Enser Transfeldt is a physician residing and practicing in Minneapolis, Minnesota.

34. The defendant Frank Schwab is a physician residing and practicing in New York, New York.

35. The defendant Amir Mehbed is a physician residing and practicing in Minneapolis, Minnesota.

36. The defendant Sylvain Palmer is a physician residing and practicing in Mission Viejo, California.

37. The defendant Eric Potts is a physician residing and practicing in Indianapolis, Indiana.

38. The defendant American Orthopedic Consultants is an unincorporated association of one or more orthopedic physicians of unknown location.

39. The defendant Kenneth J. Burkus is a physician residing and practicing in Atlanta, Georgia.

40. The defendant John Dimar is a physician residing and practicing in Louisville, Kentucky.

41. The defendant LGL SPINE, LLC is a limited liability company comprising one or more neurosurgeons in an unknown location.
42. The defendant Silber Physicians PC is an incorporated physician group comprising physicians in Great Neck, New York. Its principal is Jeffrey S. Silber, M.D., also of Great Neck, New York.
43. The defendant David Lee Skaggs is a physician residing and practicing in Los Angeles, California.
44. The defendant Brian Suback is a physician residing and practicing in Reston, Virginia.
45. The defendant Stephen Ondra is a physician residing and practicing in Chicago, Illinois.
46. The defendant SPINECO, INC. is an incorporated association of surgeons residing and practicing in an unknown location.
47. The defendant James Harrop is a physician residing and practicing in Philadelphia, Pennsylvania.
48. The defendant Vivek Kushwaha is a physician residing and practicing in Bellaire, Texas.
49. The defendant Joseph Riina is a physician residing and practicing in Indianapolis, Indiana.
50. The defendant Hallett Matthews is a physician residing and practicing in Williamsburg, Virginia.
51. The defendant Reginald Knight is a physician residing and practicing in Kirkland, Washington.

52. The defendant Christopher Shaffrey is a physician residing and practicing in Charlottesville, Virginia.

53. The defendant Ronald Lehman is a physician residing and practicing in Silver Spring, Maryland.

54. The defendant Robert Isaacs is a physician residing and practicing in Durham, North Carolina.

55. The defendant Jean Pierre Mobasser is a physician residing and practicing in Indianapolis, Indiana.

56. The defendant Neel Anand is a physician residing and practicing in Los Angeles, California.

57. The defendant George A. Frey is a physician residing and practicing in Englewood, Colorado.

58. The defendant Luis Mignucci is a physician residing and practicing in McKinney, Texas.

59. The defendant Paul Pagano is a physician residing and practicing in Canfield, Ohio.

60. The defendant Mladen Djurasovic is a physician residing and practicing in Louisville, Kentucky.

61. The defendant Michael Grof is a physician residing and practicing in Indianapolis, Indiana.

62. The defendant David B. Kee is a physician residing and practicing in Myrtle Beach, South Carolina.

63. The defendant Michael MacMillan is a physician residing and practicing in Gainesville, Florida.

64. The defendant San Francisco Spine Institute is a legal association of surgeons residing and practicing in San Francisco, California.

65. The defendant John Shian is a physician residing and practicing in Staten Island, New York.

66. The defendant Stanley A. Skinner is a physician residing and practicing in Indianapolis, Indiana.

67. The defendant David Rouben is a physician residing and practicing in Louisville, Kentucky.

68. The defendant Hyun Bae is a physician residing and practicing in Santa Monica, California.

69. The defendant George Picetti is a physician residing and practicing in Sacramento, California.

70. The defendant Hal Silcox, III is a physician residing and practicing in Atlanta, Georgia.

71. The defendant Christian Puttlitz is a physician residing and practicing in Fort Collins, Colorado.

72. The defendant Kaushik Das is a physician residing and practicing in New York, New York.

73. The defendant Donald Kucharzyk is a physician residing and practicing in Demotte, Indiana.

74. The defendant John Bendo is a physician residing and practicing in New York, New York.

75. The defendant Dennis Crandall is a physician residing and practicing in Phoenix, Arizona.

76. The defendant Perry J. Argires is a physician residing and practicing in Ephrata, Pennsylvania.

77. The defendant DAENOC, LLC is a limited liability company composed of surgeons of unknown location.

78. The defendant Todd Bonvallet is a physician residing and practicing in Chattanooga, Tennessee.

79. The defendant Greg D. Anderson is a physician residing and practicing in Philadelphia, Pennsylvania.

80. The defendant Christopher Comey is a physician residing and practicing in Springfield, Massachusetts.

81. The defendant Robert Mylo is a physician residing and practicing in Hurst, Texas.

82. The defendant Thomas Kleeman is a physician residing and practicing in Bedford, New Hampshire.

83. The defendant Louis G. Jenis is a physician residing and practicing in Boston, Massachusetts.

84. The defendant Christian Fras is a physician residing and practicing in Philadelphia, Pennsylvania.

85. The defendant Frederick Marciano is a physician residing and practicing in Scottsdale, Arizona.

86. The defendant Randall Betz is a physician residing and practicing in Philadelphia, Pennsylvania.

87. The defendant Joseph Flynn, Jr. is a physician residing and practicing in Orlando, Florida.

88. The defendant Tai Friesem is a physician residing and practicing in Cleveland, Ohio.

89. The defendant Bernard Rawlins is a physician residing and practicing in New York, New York.

90. The defendant Sean Salehi is a physician residing and practicing in Maywood, Illinois.

91. The defendant Jean Pierre Farcy is a physician residing and practicing in New York, New York.

92. The defendant Timothy A. Garvey is a physician residing and practicing in Minneapolis, Minnesota.

93. The defendant Serema Hu is a physician residing and practicing in San Francisco, California.

94. The defendant Keith Bridwell is a physician residing and practicing in St. Louis, Missouri.

95. The defendant Jeffrey M. Spivak is a physician residing and practicing in New York, New York.

96. The defendant Rick Sasso is a physician residing and practicing in Indianapolis, Indiana.
97. The defendant Todd Lanman is a physician residing and practicing in Los Angeles, California.
98. The defendant Gerard Girasole is a physician residing and practicing in Trumbull, Connecticut.
99. The defendant Steven Heim is a physician residing and practicing in Warrenville, Illinois.
100. The defendant Michael D. Kasten is a physician residing and practicing in Kalamazoo, Michigan.
101. The defendant Gary Bloomgarden is a physician residing and practicing in New Haven, Connecticut.
102. The defendant Darrell Brodke is a physician residing and practicing in Salt Lake City, Utah.
103. The defendant George Teitelbaum is a physician residing and practicing in Los Angeles, California.
104. The defendant Scott Boden is a physician residing and practicing in Atlanta, Georgia.
105. The defendant Edward Goldberg is a physician residing and practicing in Chicago, Illinois.
106. The defendant Thomas Schuler is a physician residing and practicing in Reston, Virginia.

107. The defendant Russell Travis is a physician residing and practicing in Lexington, Kentucky.

108. The defendant Robert Watkins is a physician residing and practicing in Los Angeles, California.

109. The defendant Lytton Williams is a physician residing and practicing in Los Angeles, California.

110. The defendant Kevin Foley is a physician residing and practicing in Memphis, Tennessee.

111. The defendant Innovative Spine and Brain Surgeons is a legal association of neurosurgeons residing and practicing in Nashville, Tennessee.

112. The defendant Thomas Najeeb is a physician residing and practicing in Metairie, Louisiana.

113. The defendant Jason Hubbard is a physician residing and practicing in Nashville, Tennessee.

114. The defendant James Robinson is a physician residing and practicing in Atlanta, Georgia.

115. The defendant Arthur Conley is a physician residing and practicing in Oklahoma City, Oklahoma.

116. The defendant Edward Dohring is a physician residing and practicing in Phoenix, Arizona.

117. The defendant Theodore G. Obenchain is a physician residing and practicing in Los Angeles, California.

118. The defendant Edward Pratt is a physician residing and practicing in Memphis, Tennessee.

119. The defendant Barry Lonner is a physician residing and practicing in New York, New York.

120. The defendant Michael Swank is a physician residing and practicing in Cincinnati, Ohio.

121. The defendant Luis Duarte is a physician residing and practicing in San Angelo, Texas.

122. The defendant John Pelosa is a physician residing and practicing in Dallas, Texas.

123. The defendant Boston Spine Group is a legal association of orthopedic surgeons residing and practicing in Boston, Massachusetts.

124. The defendant Muwaffak Abdulhak is a physician residing and practicing in Detroit, Michigan.

125. The defendant Regis Haid is a physician residing and practicing in Atlanta, Georgia.

126. The defendant Daniel Riew is a physician residing and practicing in St. Louis, Missouri.

127. The defendant Lawrence Lenke is a physician residing and practicing in St. Louis, Missouri.

128. The defendant Gerald Rodts is a physician residing and practicing in Atlanta, Georgia.

129. The defendant Matthew Gornet is a physician residing and practicing in St. Louis, Missouri.

130. The defendant Benton Biomedical, Inc. is a distributor of medical devices and is located in Scottsdale, Arizona.

131. The defendant Bio-Tek Medical is a distributor of medical devices and is located in Memphis, Tennessee.

132. The defendant Rapp Medical Systems, Inc. is a distributor of medical devices and is located in Indianapolis, Indiana.

133. The defendant Medcraft Spinal Implants, Inc. is a distributor of medical devices and is located in Atlanta, Georgia.

134. The defendant Nu Med Technologies, Inc. is a distributor of medical devices and is located in Tulsa, Oklahoma.

135. The defendant Praxa Medical, Inc. is a distributor of medical devices and is located in Glen Allen, Virginia.

136. The defendant Surgical Systems, Inc. is a distributor of medical devices and is located in Birmingham, Alabama.

137. The defendant Spinal Associates, LTD is a distributor of medical devices and is located in Mineola, New York.

138. The defendant Rummer Medical, Inc. is a distributor of medical devices and is located in Plano, Texas.

139. The defendant Medalliance, Inc. is a distributor of medical devices and is located in Glenside, Pennsylvania.

140. The defendant Team Spine Minnesota, Inc. is a distributor of medical devices and is located in St. Louis Park, Minnesota.

141. The defendant Team Spine Wisconsin, Inc. is a distributor of medical devices and is located in Brookfield, Wisconsin.

142. The defendant First Choice Medical, Inc. is a distributor of medical devices and is located in Nashville, Tennessee.

143. The defendant Carolina Spine Systems is a distributor of medical devices and is located in Raleigh, North Carolina.

144. The defendant GHM, LLC is a distributor of medical devices and is located in Houston Texas.

145. The defendant Mountain Medical Distributors is a distributor of medical devices and is located in Anchorage, Alaska.

Jurisdiction and Venue

146. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

147. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. 3732(a), which provides that “any action under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act prescribed by § 3729 occurred.” § 3732(a) also authorizes nationwide service of process. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because some of the defendants can be found in, reside in, or transact business in the District of Massachusetts.

Factual Allegations

148. In order to prevent waste, fraud and abuse, the Medicare program restricts the types of drugs and medical devices which may be paid for with federal funds. Additionally, federal regulations prohibit certain marketing practices which have a propensity to lead to the unnecessary and ineffective prescription or use of these drugs and medical devices. These regulatory schemes are designed to insure that Medicare only pays for drugs and medical devices which are found to be safe and effective for their prescribed uses, and to insure that physicians who prescribe such items do not have ulterior motives for prescribing drugs or devices that will be purchased with federal funds.

149. In this *qui tam* action Relators allege that the defendant physicians and distributors knowingly and deliberately colluded with Medtronic Sofamor Danek, Inc. (“MSD”) and engaged in conduct they knew would lead to the violations of federal Medicare and other statutes and regulations designed to restrict Medicare reimbursement for MSD products. The defendants did not directly provide MSD products to the Medicare program. Instead, the defendants embarked on a course of unlawful conduct that they knew would lead to the submission by physicians (or their hospitals) of thousands of Medicare claims for MSD products when such products were not eligible for Medicare reimbursement. Although some of the third-party physicians may have been unaware that their Medicare claims were ineligible for reimbursement, the defendants knew their actions would inevitably cause these Medicare providers to submit false claims to the federal government. Relators, in the name of the United States, seek to hold

the defendants liable for knowingly causing these false claims to be presented to the United States for payment in violation of 31 U.S.C. §3729.

THE REGULATORY SETTING

150. New pharmaceutical drugs or medical devices may not be marketed in the United States until the sponsor of the drug or device has proven to the Food and Drug Administration (FDA) that the drug or device is safe and effective for specific indications at specified dosages. The indications and dosages (if applicable) approved by the FDA are set forth in the product's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to use devices for indications or at dosages different than those set forth in a product's labeling, The Food Drug and Cosmetic Act prohibits medical device companies from marketing or promoting approved devices for uses other than those set forth in the device's approved labeling. This regulatory scheme protects patients and consumers by insuring that medical companies do not promote drugs or devices for uses other than those found to be safe and effective by an independent, scientific governmental body.

151. The Medicare program also relies on the FDA's findings regarding what uses for approved drugs are safe and effective. In 1990, Congress passed the Budget Reconciliation Act which limited reimbursement for drugs or devices to "covered outpatient drugs"¹. Covered outpatient drugs and devices only include drugs and devices used for "medically accepted indications." A medically accepted indication is a use which has been approved by the FDA or one which is supported by specific compendia set forth

¹ The same policy considerations would apply with equal emphasis to known dangers associated with off-label use of medical devices.

in the Medicare statutes. Until August, 1997 none of the compendia referenced in the statute supported off-label usage of any approved drugs or devices. Even after August 1997, off-label usage was significantly restricted.

152. *Off-label* use of a medical product refers to the occasion when a physician prescribes or uses a product other than in the manner approved by the FDA. Although since the passage in November, 1997 of the Food and Drug Administration Modernization Act (“FDAMA”) manufacturers may provide off label studies to the medical community provided certain conditions are met, a manufacturer still may not legitimately promote off label uses through physician studies when the investigating physician is not truly independent or impartial, nor if the physician is in fact an *agent* of the manufacturer based on significant financial relationships.

153. The Medicare and Medicaid anti-kickback laws, 42 U.S.C. 1320a-7b(b) also regulate drug and device marketing in order to prevent over-utilization of medication or medical devices. Under the anti-kickback laws, companies may not offer or pay any remuneration, in cash or kind, to induce physicians or others to order or recommend drugs or devices which may be paid for by a federal healthcare program such as Medicare or Medicaid. These regulations not only prohibit outright bribes and rebate schemes, but prohibit any payment by a company to a physician which has as one of its purposes the inducing of the physician to use the company's products.

154. In addition to the anti-kickback laws, §1877 of the Social Security Act, often referred to as the "Stark law," provides that a physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (designated health services) (3) if there is a direct or indirect financial relationship between the referring physician (or an immediate family

member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations. For purposes of the Stark law, DHS includes durable medical equipment and supplies. Unlike the Medicare Anti-Kickback Statute, which is a criminal statute requiring at least some measure of criminal intent, the Stark Statute is a civil statute requiring strict compliance. Intent to violate or substantial compliance has no bearing on whether an activity is or is not legal. Violation, no matter how unintentional or technical, is sufficient to invoke the Stark Statute. Lastly, if a prohibited referral occurs under Stark, the DHS entity may not file or cause to be filed a claim under Medicare or Medicaid or a bill to any individual, third party payer or other entity for the designated health services provided.

155. As described below, the defendants have since 2002 through the present, knowingly and intentionally violated the regulatory schemes described above in both their purchase and marketing of MSD products. When they intentionally colluded with MSD and decided to participate in improper marketing practices to promote MSD products, the defendants knew or should have known that thousands of physicians (chiefly through their hospitals under applicable DRG's) would routinely and necessarily file false claims with the federal government when they sought federal reimbursement for MSD' products. But for defendants' actions most, if not all, of the false claims for the purchase of MSD products would never have been filed. Although they did not directly contract with the federal government, the defendants were the indirect beneficiaries of all of the false claims described herein.

156. The unlawful practices described below encompass a multiplicity of prohibited behaviors including (a) the improper *on-label* purchase and promotion of MSD products made and effected through the use of kickbacks in the form of consulting fees, bogus royalty payments, research grants and fellowships, free travel, lodging, entertainment, gifts and other perquisites, (b) the improper *off-label* promotion of MSD products through the use of the same types of incentives described in (a) but also including the skewed results of suspect clinical trials performed by financially interested physicians, the withholding of adverse data, the publication of favorable off-label data and studies in medical journals and websites authored by MSD's most highly compensated physicians, the promotion of off-label use of MSD products at CME seminars, VIP meetings, and training sessions at the M.E.R.I. Clinic at Memphis, and (c) unlawful self-referral by virtue of the receipt of consulting fees, grants and royalties paid in an amount determined precisely by the value and volume of purchases made or effected by, or to be expected to be made from the efforts of, each defendant physician.

While **all** on-label and off-label sales made or effected by the defendants receiving unlawful kickbacks or engaging in improper self-referral cause false claims to be filed, the unlawful promotion of *off-label* uses of MSD products provides an additional, independent and, under the circumstances, far more urgent basis for the government to interdict this activity, i.e., the public health is at risk.

KICKBACKS RECEIVED BY THE PHYSICIAN DEFENDANTS

157. All of the following individual and corporate physician defendants have been paid sham "consulting fees" in 2006. None of these defendants performed *bona fide*

consulting services for MSD. All of these payments constitute kickbacks for purchases made or effected by each physician and/or for the agreement to perform unlawful promotional activities for on-label and off-label sales of MSD products. Specific examples of the type of purported “consulting services” for which these kickbacks have been paid will be identified below. The payments were made as follows:

158. The defendant Mitch Campbell has received sham consulting fees in 2006 totaling at least \$212,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

159. The defendant Steven Glassman has received sham consulting fees in 2006 totaling at least \$200,300.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

160. The defendant John R. Johnson has received sham consulting fees in 2006 totaling at least \$.162,750.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

161. The defendant Rolando M. Puno has received sham consulting fees in 2006 totaling at least \$.106,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

162. The defendant Mickey Morgan has received sham consulting fees in 2006 totaling at least \$15,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

163. The defendant Terry Trammell has received sham consulting fees in 2006 totaling at least \$159,450.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

164. The defendant Dean Karahalios has received sham consulting fees in 2006 totaling at least \$88,834.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

165. The defendant Steven Humphreys has received sham consulting fees in 2006 totaling at least \$151,937.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

166. The defendant Scott Hodges has received sham consulting fees in 2006 totaling at least \$129,427.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

167. The defendant James Guille has received sham consulting fees in 2006 totaling at least \$40,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

168. The defendant Timothy Garvey has received sham consulting fees in 2006 totaling at least \$2,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

169. The defendant Bradley T. Estes has received sham consulting fees in 2006 totaling at least \$34,550.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

170. The defendant John Dorchak has received sham consulting fees in 2006 totaling at least \$5,850.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

171. The defendant Francis Denis has received sham consulting fees in 2006 totaling at least \$29,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

172. The defendant Maurice Smith has received sham consulting fees in 2006 in an indeterminate amount. Dr. Smith receives compensation in the form of stock and other perquisites that are not listed as consulting fees. Dr. Smith is and has been and remains one of the most highly compensated among the MSD physicians.

173. The defendant Vincent Traynelis has received sham consulting fees in 2006 totaling at least \$40,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

174. The defendant Jeffrey E. Deckey has received sham consulting fees in 2006 totaling at least \$68,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

175. The defendant James L. Chappuis has received sham consulting fees in 2006 totaling at least \$72,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

176. The defendant Central Ohio Neurosurgical Group has received sham consulting fees in 2006 totaling at least \$12,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

177. The defendant Charles Branch has received sham consulting fees in 2006 totaling at least \$154,900.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

178. The defendant Joseph H. Perra has received sham consulting fees in 2006 totaling at least \$39,250.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

179. The defendant Manuel Pinto has received sham consulting fees in 2006 totaling at least \$28,900.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

180. The defendant David Polly has received sham consulting fees in 2006 totaling at least \$344,375.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

181. The defendant Bernard A. Rawlins has received sham consulting fees in 2006 totaling at least \$55,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

182. The defendant James Schwender has received sham consulting fees in 2006 totaling at least \$84,250.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

183. The defendant Enser Transfeldt has received sham consulting fees in 2006 totaling at least \$253,750.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

184. The defendant Frank Schwab has received sham consulting fees in 2006 totaling at least \$94,937.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

185. The defendant Amir Mehbed has received sham consulting fees in 2006 totaling at least \$25,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

186. The defendant Sylvain Palmer has received sham consulting fees in 2006 totaling at least \$8750.00, but that it is believed far more was paid but is not discoverable.

187. The defendant Eric Potts has received sham consulting fees in 2006 totaling at least \$48,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

188. The defendant American Orthopedic Consultants has received sham consulting fees in 2006 totaling at least \$56,000.00. Plaintiff alleges that it received similar amounts in the preceding 2 years.

189. The defendant Kenneth J. Burkus has received sham consulting fees in 2006 totaling at least \$416,775.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

190. The defendant John Dimar has received sham consulting fees in 2006 totaling at least \$192,300.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

191. The defendant LGL SPINE, LLC has received sham consulting fees in 2006 totaling at least \$474,475.00. Plaintiff alleges that it received similar amounts in the preceding 2 years. A list of all payments made to this LLC is attached hereto as Exhibit "1".

192. The defendant Silber Physicians PC has received sham consulting fees in 2006 totaling at least \$55,050.00. Plaintiff alleges that it received similar amounts in the preceding 2 years.

193. The defendant David Lee Skaggs has received sham consulting fees in 2006 totaling at least \$93,025.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

194. The defendant Brian Suback has received sham consulting fees in 2006 totaling at least \$34,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

195. The defendant Stephen Ondra has received sham consulting fees in 2006 totaling at least \$92,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

196. The defendant SPINECO, INC. has received sham consulting fees in 2006 totaling at least \$47,750.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

197. The defendant James Harrop has received sham consulting fees in 2006 totaling at least \$5,100.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

198. The defendant Vivek Kushwaha has received sham consulting fees in 2006 totaling at least \$4,325.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

199. The defendant Joseph Riina has received sham consulting fees in 2006 totaling at least \$208,325.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

200. The defendant Hallett Matthews has received sham consulting fees in 2006 totaling at least \$375,000.00. Plaintiff alleges that he received triple these amounts in the preceding 2 years.

201. The defendant Reginald Knight has received sham consulting fees in 2006 totaling at least \$62,600.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

202. The defendant Christopher Shaffrey has received sham consulting fees in 2006 totaling at least \$8,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

203. The defendant Ronald Lehman has received sham consulting fees in 2006 totaling at least \$2,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

204. The defendant Robert Isaacs has received sham consulting fees in 2006 totaling at least \$42,300.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

205. The defendant Jean Pierre Mobasser has received sham consulting fees in 2006 totaling at least \$11,375.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

206. The defendant Neel Anand has received sham consulting fees in 2006 totaling at least \$13,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

207. The defendant George A. Frey has received sham consulting fees in 2006 totaling at least \$377,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

208. The defendant Luis Mignucci has received sham consulting fees in 2006 totaling at least \$14,475.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

209. The defendant Paul Pagano has received sham consulting fees in 2006 totaling at least \$18,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

210. The defendant Mladen Djurasovic has received sham consulting fees in 2006 totaling at least \$55,900.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

211. The defendant Michael Grof has received sham consulting fees in 2006 totaling at least \$2,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

212. The defendant David B. Kee has received sham consulting fees in 2006 totaling at least \$6,200.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

213. The defendant Michael MacMillan has received sham consulting fees in 2006 totaling at least \$23,200.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

214. The defendant San Francisco Spine Institute has received sham consulting fees in 2006 totaling at least \$54,625.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

215. The defendant John Shian has received sham consulting fees in 2006 totaling at least \$14,250.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

216. The defendant Stanley A. Skinner has received sham consulting fees in 2006 totaling at least \$47,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

217. The defendant David Rouben has received sham consulting fees in 2006 totaling at least \$109,300.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

218. The defendant Hyun Bae has received sham consulting fees in 2006 totaling at least \$6,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

219. The defendant George Picetti has received sham consulting fees in 2006 totaling at least \$33,750.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

220. The defendant Hal Silcox, III has received sham consulting fees in 2006 totaling at least \$49,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

221. The defendant Christian Puttlitz has received sham consulting fees in 2006 totaling at least \$7,700.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

222. The defendant Kaushik Das has received sham consulting fees in 2006 totaling at least \$2,800.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

223. The defendant Donald Kucharzyk has received sham consulting fees in 2006 totaling at least \$8,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

224. The defendant John Bendo has received sham consulting fees in 2006 totaling at least \$8,100.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

225. The defendant Dennis Crandall has received sham consulting fees in 2006 totaling at least \$16,800.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

226. The defendant Perry J. Argires has received sham consulting fees in 2006 totaling at least \$14,480.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

227. The defendant DAENOC, LLC has received sham consulting fees in 2006 totaling at least \$86,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

228. The defendant Todd Bonvallet has received sham consulting fees in 2006 totaling at least \$75,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

229. The defendant Greg D. Anderson has received sham consulting fees in 2006 totaling at least \$5,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

230. The defendant Christopher Comey has received sham consulting fees in 2006 totaling at least \$5,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

231. The defendant Robert Mylo has received sham consulting fees in 2006 totaling at least \$18,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

232. The defendant Thomas Kleeman has received sham consulting fees in 2006 totaling at least \$37,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

233. The defendant Louis G. Jenis has received sham consulting fees in 2006 totaling at least \$3,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

234. The defendant Christian Fras has received sham consulting fees in 2006 totaling at least \$11,175.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

235. The defendant Frederick Marciano has received sham consulting fees in 2006 totaling at least \$5,700.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

236. The defendant Randall Betz has received sham consulting fees in 2006 totaling at least \$60,000.00. Plaintiff alleges that he received greater amounts in the preceding 2 years.

237. The defendant Joseph Flynn, Jr. has received sham consulting fees in 2006 totaling at least \$75,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

238. The defendant Tai Friesem has received sham consulting fees in 2006 totaling at least \$46,874.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

239. The defendant Bernard Rawlins has received sham consulting fees in 2006 totaling at least \$8,625.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

240. The defendant Sean Salehi has received sham consulting fees in 2006 totaling at least \$2,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

241. The defendant Jean Pierre Farcy has received sham consulting fees in 2006 totaling at least \$31,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

242. The defendant Timothy A. Garvey has received sham consulting fees in 2006 totaling at least \$3,750.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

243. The defendant Serema Hu has received sham consulting fees in 2006 totaling at least \$7,500.00. Plaintiff alleges that she received similar amounts in the preceding 2 years.

244. The defendant Keith Bridwell has received sham consulting fees in 2006 totaling at least \$10,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

245. The defendant Jeffrey M. Spivak has received sham consulting fees in 2006 totaling at least \$52,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

246. The defendant Rick Sasso has received sham consulting fees in 2006 totaling at least \$150,000.00. Plaintiff alleges that he received far greater amounts in the preceding 2 years.

247. The defendant Todd Lanman has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

248. The defendant Gerard Girasole has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

249. The defendant Steven Heim has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

250. The defendant Michael D. Kasten has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

251. The defendant Gary Bloomgarden has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

252. The defendant Darrell Brodke has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

253. The defendant George Teitelbaum has received sham consulting fees in 2006 totaling at least \$36,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

254. The defendant Scott Boden has received sham consulting fees in 2006 totaling at least \$75,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

255. The defendant Edward Goldberg has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

256. The defendant Thomas Schuler has received sham consulting fees in 2006 totaling at least \$40,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

257. The defendant Russell Travis has received sham consulting fees in 2006 totaling at least \$36,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

258. The defendant Robert Watkins has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

259. The defendant Lytton Williams has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

260. The defendant Kevin Foley has received sham consulting fees in 2006 totaling at least \$145,000.00. Plaintiff alleges that he received far greater amounts in the preceding 2 years. Foley has been paid royalties and consulting fees exceeding \$27,000,000.00 since 2001.

261. The defendant Innovative Spine and Brain Surgeons has received sham consulting fees in 2006 totaling at least \$25,000.00. Plaintiff alleges that it received similar amounts in the preceding 2 years.

262. The defendant Thomas Najeeb has received sham consulting fees in 2006 totaling at least \$25,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

263. The defendant Jason Hubbard has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

264. The defendant James Robinson has received sham consulting fees in 2006 totaling at least \$15,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

265. The defendant Arthur Conley has received sham consulting fees in 2006 totaling at least \$125,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

266. The defendant Edward Dohring has received sham consulting fees in 2006 totaling at least \$25,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

267. The defendant Theodore G. Obenchain has received sham consulting fees in 2006 totaling at least \$150,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

268. The defendant Edward Pratt has received sham consulting fees in 2006 totaling at least \$80,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

269. The defendant Barry Lonner has received sham consulting fees in 2006 totaling at least \$60,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

270. The defendant Michael Swank has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

271. The defendant Luis Duarte has received sham consulting fees in 2006 totaling at least \$49,500.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

272. The defendant John Peloza has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

273. The defendant Boston Spine Group has received sham consulting fees in 2006 totaling at least \$50,000.00. Plaintiff alleges that it received similar amounts in the preceding 2 years.

274. The defendant Muwaffak Abdulhak has received sham consulting fees in 2006 totaling at least \$30,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

275. The defendant Regis Haid has received sham consulting fees in 2006 totaling at least \$50,000.00 disguised and mischaracterized as royalty payments. Plaintiff alleges that he received similar amounts in the preceding 2 years.

276. The defendant Daniel Riew has received sham consulting fees in 2006 totaling at least \$80,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

277. The defendant Lawrence Lenke has received sham consulting fees in 2006 totaling at least \$175,000.00 in the form of grants and fellowships. Plaintiff alleges that he has indirectly received similar amounts in the preceding 2 years.

278. The defendant Gerald Rodts has received sham consulting fees in 2006 totaling at least \$80,000.00. Plaintiff alleges that he received similar amounts in the preceding 2 years.

279. The defendant Matthew Gornet has received sham consulting fees in 2006 totaling at least \$50,000.00 in disguised forms. Plaintiff alleges that he received similar amounts in the preceding 2 years.

280. Therefore, sham payments in 2006 alone to *known* physician consultants to MSD exceeded \$8,000,000.00. Plaintiff alleges that there are numerous other John Doe physician customers whose identities and payment amounts have been hidden by MSD through the use of multiple ledger accounting, disguised forms of payments and reimbursements, and other such artifice.

281. Plaintiff alleges that these bribes and kickbacks constitute violations of 42 U.S.C. § 1320a-7b(b), commonly known as the Federal Anti-Kickback Statute. These bribes and kickbacks distorted and continue to distort the defendants' medical decision-making, cause over-utilization of MSD products, increase costs, and result in unfair competition by freezing out competitors who are unwilling to pay kickbacks. Further, these kickbacks adversely affect the quality of patient care as the defendant physicians

order or recommend medical devices based on profit motive rather than the patients' best medical interests.

282. Plaintiff alleges that after accepting remuneration for purchasing goods and medical devices from MSD and for recommending the purchase of MSD goods to other physicians, the defendant physicians, or their respective employers, in fact purchased or recommended the purchase of medical devices for which payment or reimbursement may be made in whole or in part under a federal healthcare program. Plaintiff alleges that the individual defendants, or their employers, thereafter actually submitted false claims for reimbursement for such devices for which payment was made in whole or in part under a federal healthcare program.

283. Plaintiff alleges that the individual defendants, or their employers, by submitting claims for reimbursement under federal healthcare programs, implicitly stated and represented to the Government that they had complied with all statutes, rules, and regulations governing the Medicare act, including the Federal Anti-Kickback Statute. Plaintiff further alleges that by failing to comply with the dictates of the Federal Anti-Kickback Statute, the individual defendants, or their employers, submitted fraudulent and ineligible claims in violation of the False Claims Act 31 U.S.C. §§ 3729-3733.

284. Plaintiff alleges that the course of conduct represented by the payment of illegal remuneration in return for the purchasing and recommending of MSD products involves tens of thousands of Medicare claims. At the present time, and without preliminary discovery, it is impossible to plead the fraud perpetrated upon the United States with respect to every false claim filed with greater particularity than furnished herein. Further, where the facts relating to the false filing of Medicare claims are

peculiarly within the individual defendants' or their employers' possession or knowledge, plaintiff should be entitled to conduct discovery prior to any requirement that she plead the fraud herein with more particularity.

**KICKBACKS; UNLAWFUL MARKETING FOR THE PROMOTION OF
OFF-LABEL SALES OF MSD PRODUCTS**

285. In July, 2002, the FDA, upon the application of MSD, approved the use of a product called INFUSE™ for *single level lumbar* spinal fusion operations only when contained in a wedged cage, implanted into the vertebral interbody space, and by means *only* of an anterior surgical approach, i.e., an approach to the spine made only through the abdomen (“ALIF”). The amount of INFUSE™ tested and approved for use was ≤ 10 m.g. for single level lumbar fusion. Substantially increased dosages, use of different cages, or other types of surgeries or approaches to the spine (non-ALIF) would be *off-label*.

286. The composition of INFUSE™, a bio-engineered product, is actually much closer in nature to that of a drug than to that of a device², and it is potentially far more harmful if misused. INFUSE™ includes a genetically engineered protein known as rhBMP-2 (“BMP” is the acronym for Bone Morphogenetic Protein) which is produced by way of molecular cloning. Strands of human DNA are inserted into chromosomes extracted from Chinese hamsters. The process is termed “recombination”. Cell division results in the production of great quantities of rhBMP-2 (*a million times more potent than*

² Relators are aware that the FDA has classified BMP as a Class III medical device and not as a drug; however, the profound concerns raised by Committee members over the **known** potential hazards posed by off-label use of BMP (as opposed to mere “unknowns” concerning a drug’s other potential off-label benefits) impels the conclusion that off-label uses of BMP would not be reimbursed by CMS if all the facts were known.

found as a natural product in the human body; this compound will turn flesh into bone), which induces transformation of undifferentiated cells into osteoblasts (a cell from which bone develops; a bone-forming cell) which results in the formation of bone. With this advanced technology, the need to remove and import bone from the patient's hip (as is typically done) to the spine, requiring an ancillary operative procedure, would be eliminated. This new technology was potentially revolutionary, but highly volatile and with many unknowns still remaining.

287. A transcript of the FDA Advisory Committee hearing where the initial PMA (pre-market approval) of INFUSE was sought by MSD was made in January of 2002. The transcript makes it clear that the principal concern of the Committee members was that INFUSE™ *should not be used for off label uses* due to its high potential for injury. The only use for which INFUSE™ was ultimately approved by the Committee was for *single level lumbar* spinal fusions *only, and only then* when contained in a wedged cage and implanted into the vertebrae space through an anterior surgical approach, i.e., through the abdomen and not through a posterior approach. Several Committee members expressed profound concern that any use of INFUSE™ through an approach other than anterior would potentially cause exuberant growth of bone into the spinal canal, thus ossifying the neural elements of the spine and injuring the patient in a significant number of cases. It should be noted that according to the FDA transcript of the Committee meeting leading to the initial approval of INFUSE™ for ALIF procedures *only*, Committee member Stephen Li, Phd., remarked that nine (9) clinical investigators with a financial interest in the product had reported success with INFUSE™ more often

than investigators without a financial interest “almost by a factor of two.” The identity of all nine of these investigators is not apparent from the transcript.

288. MSD consultants Drs. Zdeblick, Mathews³, and Boden, three of MSD’s most highly paid consultants and royalty recipients, were present and testified on behalf of MSD at the hearing and assured the Committee (particularly through Dr. Boden) that the only approval sought, i.e., use of INFUSE™ for the single level lumbar anterior approach, would prevent leakage of the BMP into the neural elements of the spine. At the time of this hearing, Dr. Zdeblick was a consultant making \$400 thousand per year for 8 days’ consulting (not including royalties), Dr. Boden was receiving at least \$100 thousand per year in consulting fees for the same work (not including royalties), and Dr. Mathews was making an average of at least \$250 thousand per year in consulting fees for the same amount of work. Drs. Polly, Burkus, and Branch were all listed by MSD as *resources* for this hearing, and were presumably present, but did not speak (all receive consulting and/or royalty payments).

289. Six months after this initial hearing, the Committee on July 2, 2002, voted unanimously to approve INFUSE™ but *only with a wedged cage in a single level lumbar anterior approach* (a wedged cage cannot practically be implanted from a posterior or posterior/lateral approach). Any surgical approach other than the anterior requires the posterior barrier to the spinal canal to be intentionally compromised. In spite of these assurances from Drs. Zdeblick and Boden, and the limited use permitted by the Committee, available literature estimates that INFUSE™ is used at least 75% off label. The anterior approach is risky, more costly, and requires a vascular or general surgeon to

³ Relators have learned that Dr. Hallett Mathews became an MSD employee in early 2006.

assist in the operation due to the abdominal approach to the spine. Physicians interviewed by Relators estimate that the ALIF procedure may account for less than 10% of all procedures utilizing INFUSE™. Yearly sales of INFUSE™ by MSD may currently top \$1 billion with associated surgical costs and expenses likely tripling this figure when reimbursement is sought.

290. Although INFUSE™ was conditionally approved for use only in ALIF procedures, MSD's consultants (and surgeons awarded patent interests in MSD products) immediately (July, 2002) initiated a coordinated campaign through the authorship of off-label studies, through off-label promotion of the product by the defendant consultants at VIP meetings and CME meetings, and through personal instruction at the M.E.R.I. clinic in Memphis, to expand the market for INFUSE™ beyond the comparatively rare ALIF procedure to the majority of spinal fusion procedures, of which there occur 250,000 or more per year in the United States (see attached Exhibit "2", p. 3). These include one of four (4) approaches: TLIF procedures, ALIF procedures, posterolateral fusions, and PLIF procedures; only the ALIF procedure obtained FDA approval, and even then only on the condition of use with a wedged cage in single level procedures (a wedged cage cannot be used in other surgical approaches to the spine). None of the off label studies or investigations, to Relators knowledge, had been conducted by physicians other than those receiving millions of dollars annually from MSD in consulting fees and/or royalties.

291. The following physicians, among the most highly compensated by MSD, and most serving as clinical investigators of MSD products, have performed studies published in journals or on websites promoting off label uses of INFUSE™ as follows:

Todd Lanman: cervical, multiple level cervical, multiple level TLIF, and TLIF.

David Polly: Multiple level, TLIF

Stephen Glassman: Posterolateral

Scott Boden: Posterolateral

Kenneth Burkus: PLIF procedures, multiple level fusions

Charles Branch: PLIF procedures

Kevin Foley: posterolateral procedures on cadavers (M.E.R.I. clinic instruction)

Regis Haid: TLIF procedures, PLIF procedures, cervical fusions.

Keith Bridwell: spinal deformity; multiple level fusions with up to 40 m.g. of BMP per level.

Promotion of these patently off label uses of INFUSE™ through these highly compensated physicians does not meet the exacting criteria of the FDAMA, viz., these studies are neither independent nor reliable as they are unsupported by valid scientific opinion, i.e., legitimate peer-reviewed literature, or some other unbiased authoritative text.

PATENTS AS KICKBACKS

292. To date there have been six randomized clinical trials of rhBMP-2 in single level lumbar spinal fusions published in “peer-reviewed” journals. (Exhibit “2”). The first was reported by Scott Boden *et al.* (2002), the second by Scott Boden *et al.*, the third by Burkus, Gornet, *et al.*, the fourth by Burkus, Transfeldt *et al.*, the fifth by Burkus, Dorchak *et al.* and the sixth by Haid *et al.* Each of these physicians is a major consultant and/or grantee of patent interests from MSD.

293. After determining the identity of the physicians responsible for these initial studies, Relators, who already knew the amount of consulting fees received by each of these physicians, determined the MSD patent interests held (a) by the initial INFUSE™ clinical investigators, and (b) by physicians appearing on behalf of MSD at the INFUSE™ FDA hearing in January, 2002, as well as (c) by Drs. Foley and Smith, who principally lead INFUSE™ (and other) off-label teaching clinics at the M.E.R.I (Medical Education and Research Institute) in Memphis for hundreds if not thousands of physicians each year.

294. Relators have determined and allege that the principal clinical investigators of BMP: Drs. Boden, Burkus, Haid, and Dorchak, for the period 1998 through 2004, collectively were awarded *41 patents* relating to MSD products. Prior to 1998, the approximate date of the inception of the INFUSE™ clinical investigations (the FDAMA was enacted in November, '97, allowing *legitimate* off-label promotion) none of these physicians had invented or patented anything at all in the 61 years of their collective practice.

295. Relators have also determined and allege that Dr. Smith received 19 MSD patents after 1998, none before. Dr. Zdeblick received 31 patents since 1998; he received only 2 patents in the preceding 17 years of his practice. Lastly, Dr. Foley has received **79 patents** since 1998, having earned only two (2) patents in the preceding 19 years of his practice. Thus, the six (6) physicians identified above received 151 patents after 1998 with no *material* history of ever having invented anything prior to that year.

296. Approximately *90%* of the interests in the patents described above are co-held by these physicians with the Medtronic engineers/inventors who in fact (Relators

contend) invented these devices alone. Dr. Foley, through his consulting fees and royalties, has alone received \$27 million from MSD since 2001.

297. Other clinical investigators of INFUSE™ who hold no royalty interests, such as Drs. Transfeldt and Polly, who evidently practice together in Minneapolis, each receive over \$250 and \$340 thousand annually, respectively, in consulting fees. Other surgeons who have clinically investigated MSD products and who hold patents with MSD engineers include defendant Drs. Sasso, Heim (who also owns stock in MSD for “consulting” services), Crandall, Frey, and Papadopoulos.

297. While the FDA initially approved the use of INFUSE™ for anterior lumbar procedures based upon a clinical study indicating a successful 94.5% fusion rate on 143 patients⁴ after 2 years (See Exhibit “2”, Burkus, Gornet, et al. (2002)), a finding which still enjoys widespread acceptance, unpublished documents available at the FDA will instead indicate that the 143 patients who received INFUSE showed a 46.2% overall failure rate, with 49 of the 143 patients requiring secondary surgeries and with a total of 289 adverse events reported among the 143 patients. This adverse data has never been published, and cannot be reconciled with the report of Burkus, Gornet et al. (2002) concerning an overall fusion rate (“FDA success” rate) of 94.5% after 24 months.

298. The original FDA PMA given to MSD on July 2, 2002 was for the INFUSE™ Bone Graft/LT Cage Lumbar Tapered Fusion Device, indicated only for lumbar fusion spinal procedures in skeletally mature patients with degenerative disc disease at level L4 to S1. The only modification ever made to this FDA approval was

⁴ A sample of 143 patients in the experimental group is an extraordinarily low sample from which medical conclusions of this magnitude might be derived, particularly where the clinical investigators are financially interested in the outcomes.

made in 2004 when the levels of lumbar use were extended to L2-S1. No approval for use in the thoracic vertebrae was ever applied for or received, for it would never be approved.

DR. DAVID POLLY

299. Until November 2003, Dr. David Polly was an orthopedic physician serving as a Lieutenant Colonel in the U.S. Army. While *still on active duty* with the U.S. Army, Dr. Polly published the first economic cost analysis of BMP (INFUSE™) in October, 2003, in the magazine *Orthopedics*. It also appears that each of his co-authors (Drs. Shaffrey and later Burkus) in this study were either highly paid MSD consultants and/or held patent interests in MSD products (which were in fact invented by MSD engineers alone). In this highly favorable article, Dr. Polly, who was then department head of orthopedics at Walter Reed Hospital, states that his cost analysis work was performed as “part of his official duties in the U.S. Army”.

300. Relator Kay Poteet personally booked international flights for Dr. Polly on behalf of MSD while Polly was still in active military service. MSD (through Hank Pelegrin) always offered Dr. Polly 1st class passage for each flight, but Ms. Poteet specifically recalls that Dr. Polly insisted on flying coach class since he was still on active military service. Relators allege that on Dr. Polly’s *curriculum vitae*, it is stated that during the 2-year period from July 2001 through August 2003 (for a year prior to the FDA’s approval of INFUSE™), Dr. Polly traveled promoting his BMP Cost Analysis to medical conferences in the Bahamas, San Diego, Baltimore, Switzerland, Chicago, Rome, Montreal, and Seattle. All costs associated with this international promotion were

paid by MSD. Ms. Poteet personally arranged and handled all of Dr. Polly's international travel.

301. In addition to promoting his favorable (low cost) BMP (INFUSE™) and misleading cost analysis while on active duty, Dr. Polly also authored a presentation representing that INFUSE™ patients (wounded soldiers) reported less pain at the site of an operation when INFUSE™ was used than otherwise. Dr. Polly also conducted off-label experiments on soldiers wounded in Afghanistan and Iraq, publishing the results of these investigations in the magazine *Neurological Focus* (in February, 2004, only 3 months after leaving active service, and after receiving the first of his MSD consulting payments). Moreover, MSD listed Dr. Polly as a *resource* before the FDA Advisory Committee that considered the INFUSE™ application for approval in January, 2002, almost 2 years before Polly left military service.

302. Dr. Polly also authored the attached article appearing in *Minnesota Medicine* (Exhibit "3"). Relators contend that this article, which cites no legitimate studies nor presents any scientific findings, is unadulterated MSD promotional material, again touting that his work was associated with Walter Reed Hospital, giving his "findings" unique credibility. It is contended that the aim of articles such as this and those previously cited is to promote off label uses of INFUSE™ using highly paid consultants (Dr. Polly and others) rather than relying on truly independent sources and reliable peer-reviewed studies to promote legitimate off label uses of the product.

303. Despite the fact that Dr. Polly was uniquely positioned to know of the limited, approved uses for INFUSE™, he continued to conduct, at MSD's urging and financial support, experiments on civilian patients as soon as he left the military. In

November, 2003, within a month after leaving military service, Dr. Polly joined an orthopedic group in Minneapolis that included other highly paid MSD “consultants”. He immediately began operating on patients using INFUSE™ for off-label procedures, with disastrous results. It appears from the medical records that on December 8, 2003, with two MSD “observers” and two other MSD physician “consultants” in attendance, Dr. Polly, upon a preoperative diagnosis of adult scoliosis, degenerative disc disease, kyphosis and facet arthrosis, had chosen to perform a procedure known as transforaminal lumbar interbody fusion (“TLIF”) to accomplish the spinal fusion on portions of the patient’s lumbar and thoracic spine, using interbody spacers known as Hydrosorb™ Boomerang™ and Hydrosorb™ Mesh *Cylindrical Cages* (emphasis added) and applying INFUSE™ to the lumbar and thoracic vertebrae. Thus, Dr. Polly knowingly used INFUSE™ for an unapproved TLIF procedure affecting the thoracic spine, using unapproved cylindrical cages; the failed fusion operation rendered his patient paraplegic. (The post-operative report is attached hereto as Exhibit “4”). Despite inflicting life-altering injuries of this kind, Dr. Polly and the legion of MSD consultants continue to promote this and other off-label uses at MSD’s expense and with its explicit support. The two (2) “consultants” listed on post-operative report as assisting in this surgery included Dr. Enser Transfeldt, (*See infra* ¶ 183, alleging \$252 thousand received in 2006 as consulting fees) and Dr. James D. Schwender (*See infra* ¶ 182 indicating \$84 thousand received in 2006 as consulting fees).

304. Relators allege that all of the individual and corporate physician defendants named herein required, as a condition of their agreement to purchase and promote on-label and off-label spinal implant products from MSD, unlawful payments,

i.e., kickbacks, in the form of “consulting” fees, bogus patent interests, and other disguised fees and reimbursed “expenses”. The variable amount of the “consulting fee”, “expense”, etc. paid by MSD to each physician is directly related to the gross purchases of spinal implants and other MSD medical products made or effected by each such physician.

VIP MEETINGS

305. VIP meetings have doubled since 2004. At these meetings, the most highly paid consultants travel to Memphis at MSD expense to promote on and off-label uses of MSD products to new candidate physicians, whose trips are also paid for (airfare, entertainment, lodging (The Peabody Hotel), ground transportation, food and beverage, and excursions, if desired, to Tunica, MS. Casinos).

306. VIP meetings are provided at the expense of MSD exclusively to allow its principal Key Opinion Leaders (“KOL’s”) to instruct new physicians in the potential benefits of on-label and off-label use (INFUSE™) of MSD products. These meetings occur continuously throughout the year in Memphis, Tennessee at the cost of many millions of dollars per year. The purpose of these meetings is solely for the promotion of MSD products. MSD KOL’s that participate regularly in these promotional activities include:

Kenneth Burkus

Steven Humphreys

Scott Hodges

Steven Glassman

Thomas Zdeblick
George Frey
James Schwender
Hallett Mathews
Matthew Gornet
Gary Bloomgarden
Lawrence Lenke
Todd Bonvallet
John Dorchak
Dennis Crandall
Kevin Foley
Curtis Dickman
David Polly
Najeeb Thomas
Scott Boden
Harvinder Sandhu
Stephen Papadopoulos
Terry Trammell
Charles Branch
Vincent Traynellis
John Johnson
Mitch Campbell
John Dimar

Mladen Djurasovic

Stephen Ondra

Maurice Smith

Regis Haid

Rick Sasso

Thomas Kleeman

Darrel Brodke

Gerald Rodts

Edward Pratt

Dean Karahalios

Christopher Shaffrey

and a host of international physicians who teach foreign doctors.

All consulting fees paid to physicians conducting VIP meetings are paid solely for the promotion and recommendation of the use of on-label and off-label MSD products, particularly including INFUSE™, the sole MSD product responsible for MSD's 30% yearly increase in gross profits since 2002. There is no other purpose of the VIP meeting.

THE M.E.R.I. CLINIC

307. The M.E.R.I Clinic (Medical Education and Research Institute) a 501(c)(3) entity, is a state-of-the-art "research" facility in Memphis, Tennessee where Drs. Foley, Branch, Thomas, Dorchak, Gornet, Smith and others regularly teach orthopedic surgeons and neurosurgeons the latest techniques in on and off-label spinal fusion techniques (using cadavers) to physicians flown in from all over the country, all at Medtronic's expense. Dr. Foley controls the activities of the M.E.R.I. Clinic through

Janice Hepler, executive director of MERI. According to Dr. Foley: "From inception to application, MERI is involved in all phases of a product's life." The success of the M.E.R.I. Clinic as an instrument of MSD product development (which also uses NIH grants to fund its activities) is the principal reason why Dr. Foley has been compensated by MSD in the amount of \$27 million since 2001 through generous consulting fees and the award of 79 MSD patents on products he did not invent.

Thus, off-label "research" and product development for MSD's financial benefit is being conducted at a U.S. tax-exempt organization. This indirect use of public funds by MSD is in addition to its utilization of public (DoD) funds when MSD induced Dr. Polly to experiment with INFUSE™ on wounded soldiers at Walter Reed, i.e., an off-label clinical trial conducted on soldiers without informed consent at a U.S. Army flagship installation.

308. Typically, these M.E.R.I. clinic teaching sessions are one-on-one training in the use of MSD products and techniques to use the product. These training sessions occur most often on Fridays and Saturdays. As with the VIP meetings, there is no purpose served other than the paid training of candidates in the use of MSD products. After a product is approved by the FDA, MSD immediately invites scores of physicians to the M.E.R.I. Clinic for training by MSD consultants. The scale of the training is enormous. With respect to a recently invented Medtronic stent device, Ms. Hepler, executive director of M.E.R.I., observed: "If the product is approved by the FDA for marketing for this use, physicians from around the country will come to MERI for training, bringing in about 20,000 physicians over six months."

MSD DISTRIBUTORS

309. Beginning in mid-2004, in order to avoid prospective government detection of its illegal programs of providing unlawful gifts and perquisites to thousands of existing and potential physician customers, MSD shifted the responsibility for its unlawful gift and perquisite programs to its distributors. Each of these distributors has been named as defendant herein.

310. Beginning in mid-2004, the distributors began a program of giving expensive gifts to physicians, the cost of which collectively has totaled several hundreds of thousands of dollars per year. For example, MSD's distributors were given discretion to purchase medical texts and other items each worth several thousands of dollars and give it to a physician, a physician's group, or a hospital. After paying for same, the distributor would then send evidence of payment for the gift to MSD's accounting office. Upon receipt of same, MSD would charge the cost of the item to a newly created (2004) account under the name of "Doug King". The distributor would then later be reimbursed by MSD by increasing its next commission check in an amount equal to the cost of the gift. As a result of this intentional artifice, MSD's participation in the unlawful gift program is no longer readily apparent. Documents evidencing this unlawful practice are attached as collective Exhibit "5" hereto.

311. Each year, thousands of MSD physician customers (neurosurgeons and orthopedic surgeons), including the physician defendants herein, attend hundreds of lavish meetings all over the world sponsored not only by MSD, but also by many other medical associations, most relating to spinal surgery issues. In each such case, the entire cost of the physician customer's travel, lodging, food, beverage, and entertainment is

defrayed by MSD's distributors, and not by MSD. The yearly cost of these unlawful perquisites totals in the high nine figure millions of dollars. Unlike gifts, these expenses are not reimbursed to the distributor(s) by MSD.

312. In 2005 and 2006, MSD distributors accounted for approximately 57% of total MSD sales of spinal devices in each such year. Distributor commissions in 2005 totaled \$150,020,000.00, and in 2006 totaled \$161,293,629.04. Since commissions represent approximately 20% of gross sales, gross MSD sales attributable to distributors totaled approximately \$750,000,000.00 in 2005, and \$806,468,810.00 in 2006. A copy of the distributor commissions is attached hereto as Exhibit "6".

313. Plaintiff alleges that these unlawful payments made by the distributor defendants on behalf of its physician customers are nothing more than bribes and kickbacks which constitute violations of 42 U.S.C. § 1320a-7b(b), commonly known as the Federal Anti-Kickback Statute. These bribes and kickbacks distorted and continue to distort the defendants' medical decision-making, cause over-utilization of MSD products, increase costs, and result in unfair competition by freezing out competitors who are unwilling to pay kickbacks. Further, these kickbacks adversely affect the quality of patient care as the defendant physicians order or recommend medical devices based on profit motive rather than the patients' best medical interests.

314. Plaintiff alleges that after accepting remuneration for purchasing goods and medical devices from MSD and for recommending the purchase of MSD goods to other physicians, many client or prospective customer physicians, or their respective employers, in fact purchased or recommended the purchase of medical devices for which payment or reimbursement may be made in whole or in part under a federal healthcare

program. Plaintiff alleges that many such client and prospective customer physicians, or their employers, thereafter actually submitted false claims for reimbursement for such devices for which payment was made in whole or in part under a federal healthcare program.

315. Plaintiff alleges that the these distributor client physicians, or their employers, by submitting claims for reimbursement under federal healthcare programs, implicitly stated and represented to the Government that they had complied with all statutes, rules, and regulations governing the Medicare act, including the Federal Anti-Kickback Statute. Plaintiff further alleges that by failing to comply with the dictates of the Federal Anti-Kickback Statute, these physicians, or their employers, submitted fraudulent and ineligible claims in violation of the False Claims Act 31 U.S.C. §§ 3729-3733.

316. Plaintiff alleges that the course of distributor conduct represented by the payment of illegal remuneration in return for the purchasing and recommending of MSD products involves tens of thousands of Medicare claims. At the present time, and without preliminary discovery, it is impossible to plead the fraud perpetrated upon the United States with respect to every false claim filed with greater particularity than furnished herein. Further, where the facts relating to the false filing of Medicare claims are peculiarly within the individual defendants' or their employers' possession or knowledge, plaintiff should be entitled to conduct discovery prior to any requirement that she plead the fraud herein with more particularity.

COUNT I

FALSE CLAIMS CAUSED BY PAYMENT OF KICKBACKS IN VIOLATION OF THE MEDICARE ANTI-KICKBACK PROVISIONS

317. Relator realleges and incorporates by reference the allegations made in paragraphs 1 through 316 of this Complaint.

318. This is a claim for treble damages and forfeitures under the False Claim Act, 31 U.S.C. §§ 3729-32 as amended.

319. Through the acts described above, all of which violate the terms of the Medicare Anti-Kickback Statutes, defendants and their agents, employers, and employees knowingly presented and caused to be presented to the United States Government and state governments participating in the Medicaid programs, false, fraudulent, and ineligible claims in order to obtain reimbursements for healthcare items and devices provided under Medicare and/or Medicaid.

320. Through the acts described above and otherwise, defendants and their agents, employers and employees, knowingly made, used and/or caused to be made or used false statements and implied certifications of compliance with applicable laws in order to be reimbursed for such false claims for the approval of the United States Government.

321. Through the acts described above and otherwise, defendants and their agents, employers, and employees knowingly made, used, and caused to be made or used false records, certifications, and statements to conceal, avoid and/or decrease defendants'

obligation to repay money to the United States Government that the defendants improperly and/or fraudulently received. Defendants also failed to disclose to the Government material facts that would have resulted in substantial repayment by them to the federal and state governments.

322. The United States and the state Medicaid programs, unaware of the falsity or ineligibility of the records, statements and claims made or submitted by defendants and their agents and employees paid and continue to pay defendant for claims that would not be paid if the truth were known.

323. Plaintiff United States and the state Medicaid programs, unaware of the falsity of the records, statements, and claims made or submitted by defendants, have not recovered Medicare and Medicaid funds that would have been recovered otherwise.

324. By reason of the defendants false claims and certifications and their omissions, the United States and the state Medicaid programs have been damaged in the amount of many million of dollars in Medicare and Medicaid funds.

COUNT II

FALSE CLAIMS CAUSED BY KNOWING PROMOTION OF OFF-LABEL SALES INELIGIBLE FOR MEDICAID REIMBURSEMENT

325. Relator repeats and re-alleges each and every allegation contained in Paragraphs 1 through 324 as if alleged herein.

326. Defendants have caused the submission of hundreds of thousands of false claims by knowingly purchasing and promoting to Medicare providers sales of INFUSE™ for off-label uses which were not eligible for Medicare reimbursement. Every sale of INFUSE™ which was not made for an FDA unapproved use that was

submitted to Medicare, constitutes a false claim. Defendants are liable, pursuant to 31 U.S.C. §3729, for each of those false claims which would not have been made but for defendant's off-label promotion of INFUSE™. At the time they engaged in such unlawful promotional activities, defendants knew that off-label uses of INFUSE™ were ineligible for Medicare reimbursement and that their activities would, in fact cause numerous ineligible claims to be submitted to Medicare. Had defendants not engaged in such promotions, federal funds would not have been used to pay for unapproved uses of INFUSE™ that were not qualified to be reimbursed by Medicare.

327. In order to cause ineligible claims to be submitted to Medicare, defendants colluded with MSD and engaged in a systematic and extensive course of fraudulent conduct. This conduct included deliberate disregard of FDA regulations concerning off-label promotion (and conduct designed to hide such disregard from the regulatory authorities), deliberate misrepresentations to physicians of the evidence regarding the safety and efficacy of off-label usage of INFUSE™; deliberate payment of tens of thousands of kickbacks to encourage physicians to order INFUSE™, and deliberate creation of publications designed to appear to be written by neutral independent researchers, when in fact such publications were created and written by the specifically named defendants, and were the products of substantial undisclosed monetary compensation.

328. Relator cannot identify at this time all of the false claims which were caused by defendants' conduct. The false claims were submitted by many physicians with whom the Relators had no dealings and the records of the false claims are not within the Relator's control. Indeed, specification of the vast number of false claims would be

burdensome to the Court and the parties. Given the vast number of false claims, their scope and complexity, Realtor is excused from the requirement of specifying each false claim. The time period of the false claims, however was from 2002 to the present. Such claims were made across the entire United States.

329. As a result of defendants' actions, the United States has paid directly or indirectly tens of thousands of false claims and spent hundreds of millions of dollars on off-label uses of INFUSE™. Congress, the federal government, and the individual states never intended to make such payments and would have never made such payments but for the conduct of the defendants in collusion with MSD. Although defendants did not submit the false claims and did not directly receive the payments from the states and the United States, the defendants have been the significant beneficiaries of this pattern of unlawful conduct.

COUNT III

FALSE CLAIMS FILED AS THE RESULT OF UNLAWFUL SELF-REFERRAL

330. Relators repeat and re-allege each of the allegations set forth in Paragraphs 1 through 329 herein.

331. All of the defendant physicians have been compensated for their purchase or promotion of MSD products in the form of some or all of the following conduits: consulting fees, patent interests, expense reimbursements, MSD stock, grants and fellowships and other hidden forms of remuneration, all greatly in excess of fair market value. In each instance, the excessive payments, in whatever form, are based directly on

the value and volume of purchases made or effected by each physician defendant. As such, each purchase and sale effected by any such referral constitutes a violations of 42 U.S.C. §1395nn, often referred to as the "Stark law," which provides that a physician cannot (a) refer patients to an entity (2) for the furnishing of DHS (designated health services) (3) if there is a direct or indirect financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity.

332. The defendants have caused the submission of false claims in violation of the Stark law by referring their own patients and the patients of other physicians to DHS entities (the hospitals where the surgeries are performed) with whom the defendants have indirect compensation arrangements, and who are paid money by MSD, the manufacturer. Had defendants not received these excessive payments based on the value and volume of referrals, they would not have referred their patients or the patients of other physicians to the DHS entities involved, and no false certifications of compliance with the Stark law, express or implicit, would have been made. Relators allege that those physicians enjoying either bogus royalty arrangements or own stock in MSD (Smith and Heim) are clearly violating the Stark law.

333. Relator cannot identify at this time all of the false claims which were caused by defendants' above-described conduct. The false claims were submitted by many physicians with whom the Relators had no dealings and the records of the false claims are not within the Relator's control. Indeed, specification of the vast number of false claims would be burdensome to the Court and the parties. Given the vast number of false claims, their scope and complexity, Realtor is excused from the requirement of specifying each false claim. The time period of the false claims, however was from 2002

to the present. Such claims were made across the entire United States.

334. As a result of defendants' actions, the United States has paid directly or indirectly tens of thousands of false claims and spent hundreds of millions of dollars on surgeries performed as the result of unlawful self-referral. Congress, the federal government, and the individual states never intended to make such payments and would have never made such payments but for the conduct of the defendants in collusion with MSD. Although defendants did not submit the false claims and did not directly receive the payments from the states and the United States, the defendants have been the significant beneficiaries of this pattern of unlawful conduct.

Prayer for Relief

WHEREFORE, plaintiff/relator prays for judgment against defendants as follows:

1. That defendants cease and desist violations of 31 U.S.C. § 3729, *et. seq.*
2. That the Court enter judgment against defendants in an amount equal to three times the amount of damages the United States have sustained as a result of defendants actions, as well as a civil penalty against each defendant of \$10,000.00 for each violation of 31 U.S.C. § 3729;
3. That plaintiff/relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal Civil False Claims Act;
4. That plaintiff/relator be awarded all costs and expenses of this action, including attorneys fees; and
5. That the United States and plaintiff/relator receive all such other relief as the Court deems just and proper.

Jury Demand

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiff hereby demands trial by jury.

Respectfully submitted,

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