IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DISTRICT

UNITED STATES OF AMERICA
ex rel. *

EDITH I. SHLIAN, R.N *
35 Penny Lane
Baltimore, MD 21209 * Civil Action No.

Plaintiff-Relators, *

v. * **CIVIL FALSE CLAIMS ACT COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3729 *et seq.***

ABBOTT LABORATORIES, INC. *
(individually and as successor in interest
to GUIDANT CORPORATION, *

and *

WESTERN INSTITUTIONAL REVIEW *
BOARD

*

and

*

CARDIOVASCULAR RESEARCH
FOUNDATION, *
55 East 59th Street
New York, NY 10022 *

and *

MIDATLANTIC CARDIOVASCULAR *
ASSOCIATES, P.A.,
1838 Greene Tree Road, Suite 535 *
Baltimore, Maryland, 21208,

*

Serve on: **DO NOT PLACE IN PRESS BOX.**
James S. Jacobs, Esquire * **DO NOT ENTER IN PACER.**
One South Street
Suite 1910, Commerce Place *
Baltimore, Maryland 21202
Resident Agent *

and *

MARK MIDEI, M.D. *
1838 Greene Tree Road, Suite 250
Baltimore, Maryland 21208 *

and *

ST. JOSEPH MEDICAL CENTER, INC. *
7601 Osler Drive
Towson, Maryland 21204 *

Serve On: *
The Corporation Trust Incorporated
351 West Camden Street *
Baltimore, Maryland 21201
Resident Agent *

Defendants. *

* * * * * * * * * * * *

COMPLAINT AND JURY DEMAND

Plaintiff-Relator, by and through her undersigned counsel, brings this qui tam action in the name of the United States of America and the State of Maryland against the above named Defendants (hereinafter collectively referred to as "Defendants").

1. This is an action to recover damages and civil penalties arising from the following activities:

a. False statements and claims for reimbursement from the United States Government for federally funded medical care under the Medicare, Medicaid, and Tri-Care programs in violation of the False Claims Act, 31 U.S.C. § 3729 et. seq.

b. False statements and claims for reimbursement from the State of Maryland for state-funded medical care in violation of the Maryland False Claims Act, Md. Code Ann. (Health General) § 2-602 et seq. (2010).

c. Defendants' agreement to offer and to accept remuneration, directly and indirectly, overtly and covertly to ensure the completion of the clinical trials and to allow for the future sales of Defendant Abbott Laboratories medical devices in violation of 42 U.S.C. §§ 1320a-7a and 1320a-7b and 42 U.S.C. § 1395.

d. Defendants' scheme to falsify clinical data and violate subjects' rights in order to receive clinical approval from the Food and Drug Administration for their medical devices so that they could then market and sell those devices to beneficiaries of state and federally funded health care programs.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 because this action arises under the laws of the United States. This Court has pendent jurisdiction over the State False Claims Act claims pursuant to 28 U.S.C. § 3732(a).

3. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a).

4. Venue is proper in this District because Defendants resided, transacted business, and can be found in this judicial district.

PARTIES

5. Plaintiff-Relator is a registered nurse with a license to practice nursing in Maryland. From 1996 through October 2010 she was employed as a Clinical Research Coordinator for Midatlantic Cardiovascular Associates, P.A.

6. Defendant Abbott Laboratories, Inc. is the successor in interest to Guidant Corporation and its subsidiary Advanced Cardiovascular Systems, Inc. (hereinafter collectively

referred to as "Abbott"). Abbott manufactured and marketed a variety of stents for use in patients with cardiovascular disease.

7. Defendant Western Institutional Review Board ("WIRB") is an institutional review board that, among other things, assists medical researchers in creating and approving protocols and "Informed Consent" forms for experimentation of medical devices in human subjects.

8. Defendant Cardiovascular Research Foundation ("CRF"), is an independent angiographic core lab, contracted by Abbott to assist in the collection, review, confirmation and dissemination of data captured by Abbott's study research facilities. A key CRF duty was verifying the accuracy of angiographic data submitted by the study facilities.

9. Midatlantic Cardiovascular Associates, P.A. ("MACVA") is a professional medical association organized under the laws of the State of Maryland, with its principal place of business in Baltimore County, Maryland. MACVA, through a series of mergers and acquisitions, became the dominant cardiology practice in the Baltimore metropolitan area.

10. Defendant Midei is an interventional cardiologist who practiced at St. Joseph Medical Center ("SJMC"). Defendant Midei, acting as principal investigator, participated in a number of studies that collected clinical data for Abbott.

11. Defendant SJMC is a community acute care hospital possessing a Certificate of Need issued by the State of Maryland authorizing them to perform cardiac surgery and percutaneous coronary intervention in the Metropolitan Baltimore Regional Service Area. SJMC agreed to serve as a clinical site for testing of various Abbott stents.

12. Plaintiff-Relator is the "original source" of the information contained in the complaint within the meaning of 31 U.S.C. § 3730(e) (4) and has personal knowledge of the false records and statements presented to the United States by, or on behalf of, Defendants.

13. The violations of the State and Federal False Claims Acts arise because Defendants have submitted claims to, and received funds from, the federal and state funded health care programs based on claims, which the Defendants knew were false claims.

BACKGROUND

14. This case centers on Defendant Abbott's plan to significantly increase its market share of the future sales of stents identified by the brand name "Xience."

15. In order to sell these stents, Abbott first had to receive FDA approval for use of the stents in human subjects. Abbott engaged in a scheme to recruit physicians to participate in the study in order to gain a significant market share for their stents.

16. Abbott had no desire to participate in a meaningful scientific study of the efficacy of the Xience stents. Instead, Abbott wanted to gain FDA approval of the stents so that it could begin marketing them for off-label uses for a broader population base. Further, by paying physicians like Dr. Midei to participate in the studies, Abbott used the studies as a tool to build "goodwill" with doctors and thereby increase sales of its stents.

17. During the studies discussed herein, Defendants individually and collectively falsified data used in the study (or allowed falsified data to be included in the study), failed to provide subjects with proper informed consent about the financial payments being made to the researchers, failed to provide subjects with proper informed consent about the medical risks and alternate treatments that were available to the subjects, and filed claims for reimbursement for medically unnecessary procedures.

THE ABBOTT-SPONSORED STUDIES

18. On or about 2005, Abbott became the primary sponsor for a number of FDA-approved clinical trials of drug eluting coronary stents. In its role, Abbott sponsored three key interventional trials: The Spirit III trial, The Spirit IV trial, and the Xience V Post Market USA study.

19. In 2004, Abbott, through its predecessor in interest, Guidant, approached Dr. Midei, MACVA, and SJMC to participate in a National Spirit III clinical trial. This trial enrolled a total of 1071 subjects at 65 sites, of which 110 were enrolled at SJMC.

20. The Spirit III clinical trial began in 2005 as a clinical evaluation of the Xience V™ everolimus eluting coronary stent for the treatment of patients with up to two *de novo* coronary artery lesions.

21. In 2006, Abbott, through its predecessor-in-interest, Guidant, approached Dr. Midei, MACVA, and SJMC to participate in the national Spirit IV clinical trial. This trial enrolled a total of 3690 subjects at 66 sites, of which 196 were enrolled at SJMC.

22. The Spirit IV clinical trial began in 2006 and was a clinical evaluation of the Xience V ™ everolimus eluting coronary stent system for the treatment of patients with up to three *de novo* coronary artery lesions.

23. Abbott's primary purpose for asking these parties to participate in the Spirit III and Spirit IV studies were market-based, not scientific.

24. The Xience V USA study began in 2008 and was a post-approval study of the Xience V™ everolimus eluting coronary stent system to evaluate clinical outcomes in a group of 8000 patients who received stents during commercial use by a variety of physicians with a range of experience in implanting stents in patients.

25. During all three studies, Abbott contracted with physicians in various geographical markets to participate as "investigators" in the studies. In Baltimore, Maryland, Dr. Midei was one of the physicians Abbott chose as a principal investigator.

26. Abbott's primary motivation in contracting with Dr. Midei was to promote the success of the Xience stents for FDA approval and for future sales.

A. Lack of Informed Consent for Subjects

27. Under FDA-mandated rules for testing medical devices on human subjects, investigators are required to provide participants adequate information about the study. The FDA classifies study stents as a "Significant Risk Device." Investigators are further required to provide potential human subjects adequate time to reflect on the information provided to them so that they can give meaningful informed consent of their participation as a human test subject.

28. Among other things, investigators must provide subjects information about the study, the nature of the study, alternative medical treatments available to the subjects, a full analysis of risks associated with participating in the study, and that the study doctor will be receiving payment from the sponsor to conduct the research.

29. Abbott, WIRB, MACVA, Dr. Midei, and SJMC, individually and corporately, failed to provide subjects with adequate informed consent about the risks of stents and the potential alternative treatments available to the subjects, as well as information disclosing payments they received for participating in the studies.

B. Lack of Informed Consent: Waiting Periods

30. Under the terms of the Spirit IV Consent Form that was approved by the FDA, WIRB mandated on May 5, 2006, that subjects must be provided copies of the consent form at

least 24 hours prior to undergoing the procedure so that they might have adequate time to reflect on whether or not they wished to participate in the study.

31. Dr. Midei, speaking for himself, MACVA and SJMC, initially stated to Abbott that he would not participate in the Spirit IV study because the informed consent procedures gave the patients too much time to decide. Defendants' common practice was to insert stents at the time of the diagnostic catheterization procedure, and they did not want to delay trial enrollment.

32. Because Abbott viewed the studies as a marketing tool, not legitimate research, Abbott and Dr. Midei approached WIRB and requested that WIRB waive the 24-hour informed consent rules.

33. On May 10, 2006, WIRB denied Dr. Midei's and Abbott's request, stating, in pertinent part:

> The federal regulations state: "An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." (21 CFR 50.20).
>
> The Board continued to express concern that subjects would be expected to read and agree to participate in a research study at a time when they are under stress, are feeling anxious because they are about to undergo a surgical procedure, and may be unduly influenced to agree to be in the study.

34. Abbott knew that it could not engender the sort of "goodwill" necessary to insure Dr. Midei's, MACVA's and SJMC's business without the payments and income provided by its studies. Thus, Abbott continued to put pressure on WIRB to modify the 24-hour waiting period. On June 6, 2006, WIRB relented, and removed the 24-hour wait period for Dr. Midei's patients.

35. In making the change, though, WIRB warned Defendants that subjects must still be given an adequate opportunity to reflect on whether or not they wished to participate in the study. Among other things, WIRB stated:

> The Board rescinded its requirement that subjects be consented 24 hours prior to treatment. However, the Board requires that a potential subject be given sufficient time to consider the research and, if the subject appears distracted or unable to understand the research, the consent process must be stopped and the subject will no longer be considered for the research.

36. After receiving WIRB's authorization, Defendants MACVA and Dr. Midei, with the consent of SJMC, proceeded to enroll subjects in the study without providing them a thorough informed consent form or an adequate opportunity to decide whether or not they wished to participate as a human subject in a clinical trial.

37. Rather than providing patients informed consent, MACVA and Dr. Midei, with the consent of SJMC, established a procedure whose primary goal was to increase study enrollment and revenue.

38. Under the procedure, when a patient presented to the hospital for a cardiac problem, Dr. Midei, or a member of MACVA's staff, usually referred to as a "clinical coordinator", examined the subject's chart to determine if the subject met the initial eligibility requirement for participation in the study.

39. If the subject met the initial study criteria, a representative of Defendants would tell the subject that, if they required a stent, they might be eligible for participation in a stent study, and would then provide the subject an informed consent form to sign. Most of the patients presented with these forms were not in a position or state of mind to provide actual informed consent because they were usually in the emergency room or waiting to enter the SJMC

catheterization lab. Some were even sedated. Nonetheless, Defendants asked the subject to sign the form.

40. The conduct of Defendants was in direct violation of WIRB's warnings to Dr. Midei, MACVA, and SJMC.

41. As a result of the aggressive pursuit of trial subjects, SJMC became one the leading participants in the studies. Indeed, its participation rate exceeded even that of large academic medical institutions such as Columbia University Medical Center, Johns Hopkins, and Vanderbilt University Medical Center.

C. Lack of Informed Consent: Alternative Treatments

42. Abbott and WIRB together drafted and approved the informed consent forms that were provided to subjects at SJMC. In creating these forms, Abbott, WIRB, and SJMC omitted critical data that would fully inform the subjects of the risks of the stents.

43. Among other things, Defendants failed to provide subjects adequate information regarding alternative medical treatments such as the use of medication in lieu of the implantation of a stent.

44. In addition, Defendants failed to alert subjects that the study authorized the use of stents in subjects with a blockage that was significantly lower than the recommendations for stenting issued by the American College of Cardiology.

45. Under the guidelines provided by the American College of Cardiology, stents are recommended for subjects with 70 percentage of arterial blockage. The Abbott-sponsored studies, however, used a lower threshold, accepting subjects with $\geq$ 50 percentage of arterial blockage. Subjects, however, were never informed of this deviation from the American College of Cardiology recommendations.

46. In fact, throughout the course of the Spirit III and Spirit IV studies, Abbott and WIRB engaged in a concerted practice to "water down" the language of the informed consent forms so that subjects were not informed of alternative medical treatments available to them.

D. Lack of Informed Consent: Source of Funding

47. In the 2005 Spirit III study Consent Form, subjects were advised that, "Your study doctor is paid by the sponsor, Advanced Cardiovascular Systems, Inc.; a subsidiary of Guidant Corporation, to conduct this research."

48. Subjects in the 2006 Spirit IV study Consent Form, subjects were never informed that the study doctor was paid by the sponsor to conduct the research. This is in violation under the American Medical Association Guidelines.

49. The informed consent forms further failed to alert subjects who were enrolled in the Spirit III study from January 12, 2006 through February 28, 2006 that the doctor would receive a $1,000 incentive payment for each enrolled subject.

50. The informed consent forms further failed to alert subjects who were enrolled in the Spirit IV study from May 2008 through June 2008 that the doctor would receive a $1,000 incentive payment for each enrolled subject.

E. Falsification of Data and Improper Review of Data

51. Abbott, CRF, Dr. Midei, MACVA and SJMC engaged in a scheme to defraud the Government and subjects by implanting stents in subjects who did not meet the study eligibility requirements established by the American College of Cardiology.

52. In order to meet the eligibility requirements, the Abbott studies' eligibility protocol required that subjects present to the hospital with new lesions that were $\geq$ 50 percent.

53. Dr. Midei routinely ignored these requirements and implanted stents in subjects with blockages that did not meet the study criteria.

54. During the Abbott trials, CRF was tasked with the legal responsibility for review and analysis of the procedural films associated with the studies. Yet, despite this duty, CRF never informed SJMC, MACVA, or Plaintiff-Relator, the data coordinator, that some of Dr. Midei's subjects did not meet the protocol criteria and were, therefore, ineligible to participate in the studies. Moreover, upon information and belief, CRF approved the data submitted by Dr. Midei's site and allowed the data to remain in the Abbott study.

55. Abbott knew, or reasonably could be expected to know, that the data submitted by Dr. Midei and reviewed by CRF was false. Yet it nonetheless certified the data and allowed it to be submitted to the FDA.

F. Payment of Kickbacks and Inducements to Enroll Subjects

56. In an attempt to complete the Spirit III enrollment as early as possible, Abbott paid sites cash rewards as an enticement.

57. In 2006, Abbott and Guidant created what they termed the "4.0 Fast Enrollment Compensation Plan."

58. Under the terms of the plan, as announced by Nicole Haratani of Guidant, Guidant paid sites a bounty of $1,000 for each subject they enrolled in the Trial for the period from January 12, through February 28, 2006.

59. Abbott created a similar kickback scheme to induce physicians to participate in the Spirit IV study. On May 23, 2008, Barbara Nishimoto of Abbott sent an email entitled "Spirit IV – Compensation." As in the Spirit III study, Abbott paid physicians a $1,000 bounty for each subject they enrolled from the period from May 2008 through June 2008.

60. These rewards were not based on any actual services performed by the physicians, but were, instead, disguised kickbacks designed to ensure the timely completion of the enrollment for Spirit IV, and therefore advance the time frame for submission to the FDA for approval of the device for marketing.

COUNT ONE
(Violation of the Self-Referral and Anti-Kickback Laws)

61. Plaintiff-Relators incorporate the foregoing paragraphs as if fully set forth herein.

62. By virtue of the acts described herein, Defendants have knowingly submitted, or caused to be submitted, false or fraudulent claims for payment to officials of the United States Government and the State of Maryland in violation of the Federal False Claims Act, 31 U.S.C. § 3729 et seq., and the State of Maryland's False Claims Act, Md. Code Ann. (Health General) § 2-601 et. seq., by knowingly and willfully soliciting remuneration, directly and indirectly, overtly and covertly, in cash and in kind, in order to induce CHI, SJMC, MACVA, and the Physician Defendants to purchase stents for which payments for part the cost of such stents were made in whole and in part under state and federal health care programs, all in violation of 42 U.S.C. § 1320a-7a(a)(7) and 1320a-7b(1)(A),

63. Plaintiff the United States, and the State of Maryland, unaware of the foregoing circumstances and conduct of Defendant, and in reliance on the accuracy of said false or fraudulent claims, made payments to Defendants, which resulted in the United States and the State of Maryland being damaged in an amount to be established at trial or upon motion.

COUNT TWO
(31 U.S.C. § 3729(a)(1) False Claims Act)
(Knowingly Presenting a False or Fraudulent Claim)

64. Plaintiff-Relator incorporates the foregoing paragraphs as if fully set forth herein.

65. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to officers, employees, or agents of the United States Government false or fraudulent claims for payment or approval.

66. Defendants knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false. These claims were, therefore, false or fraudulent claims submitted for payment or approval to the United States in violation of 31 U.S.C. Section 3729(a) (1).

67. Plaintiff, the United States, unaware of the foregoing circumstances and conduct of Defendants, and in reliance on the accuracy of said false or fraudulent claims, made payments to Defendants, which resulted in the United States being damaged in an amount to be established at trial or upon motion.

COUNT THREE
(31 U.S.C. Sec. 3729(a)(1) False Claims Act)
(Knowingly Making, Using, or Causing to be Made or Used, a False Record or Statement)

68. Plaintiff-Relator incorporates by reference the preceding paragraphs as if fully set forth herein.

69. By virtue of the acts described above, Defendants made, used, or caused to be made or used, false records and statements to get the false and fraudulent claims allowed and paid.

70. The United States, unaware of the foregoing circumstances and conduct of Defendants, and unaware of the falsity of the records and or statements made, used, or caused to be made or used by Defendants, and in reliance on the accuracy thereof, paid the false or

fraudulent claims submitted it, which resulted in the United States being damaged in an amount to be established at trial or upon motion.

COUNT FOUR
(31 U.S.C. Section 3729(a)(3) and Md. Code Ann. (Health General) § 2-602(a)(3)) (Knowingly Engaging in a Conspiracy in Violation of the False Claims Act)

71. Plaintiff-Relator incorporates the foregoing paragraphs as if fully set forth herein.

72. As a result of their illegal business and financial arrangements, and illegal conduct, Defendants conspired to obtain payments wrongfully from the United States in violation of 31 U.S.C. Section 3729(a)(3) and Md. Code Ann. (Health General) § 2-603(a)(3).

73. As a consequence of this illegal conspiracy, the United States and the State of Maryland have suffered substantial damages in an amount to be determined at trial or upon motion.

COUNT FIVE
(Md. Code Ann. (Health General) § 2-602 Maryland False Claims Act) (Knowingly Presenting a False Claim)

74. Plaintiff-Realtor incorporates the foregoing paragraphs as if fully set forth herein.

75. The Maryland False Claims Act, Md. Code Ann. (Health-General) § 2-602(A) (1) (2010), prohibits knowingly presenting or causing to be presented false or fraudulent claims for approval.

76. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to officers, employees, or agents of the State of Maryland false or fraudulent claims for payment or approval.

77. Defendants knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of said claims or acted in reckless

disregard of whether said claims were true or false. These claims were, therefore, false or fraudulent claims submitted for payment or approval to the State of Maryland in violation of the Maryland False Claims Act, Md. Code Ann. (Health-General) § 2-602(A)(1) (2010),

78. The State of Maryland, unaware of the foregoing circumstances and conduct of Defendant, and in reliance on the accuracy of said false or fraudulent claims, made payments to Defendant, which resulted in the State of Maryland being damaged in an amount to be established at trial or upon motion.

COUNT SIX
(Md. Code Ann. (Health General) § 2-602(A)(2)
Maryland False Claims Act)
(Knowingly Making, Using or Causing to be Made or Used a False Record or Statement)

79. Plaintiff- Realtor incorporates the foregoing paragraphs as if fully set forth herein.

80. The Maryland False Claims Act, Md. Code Ann. (Health-General) § 2-602(A)(2) (2010), prohibits knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.

81. By virtue of the acts described above, Defendants made, used or caused to be made or used, false records and statements to get the false and fraudulent claims allowed and paid.

82. Defendants knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of said claims or acted in reckless disregard of whether said claims were true or false. These claims were, therefore, false or fraudulent claims submitted for payment or approval to the State of Maryland in violation of the Maryland False Claims Act, Md. Code Ann. (Health-General) § 2-602(A)(1) (2010),

83. The State of Maryland, unaware of the foregoing circumstances and conduct of Defendant, and in reliance on the accuracy of said false or fraudulent claims, made payments to Defendant, which resulted in the State of Maryland being damaged in an amount to be established at trial or upon motion.

WHEREFORE, Plaintiff-Relator, on behalf of herself, the United States of America and the State of Maryland, demand judgment against Defendants as follows:

A. All Counts:

(a) Treble the amount of damages sustained by the United States, in an amount to be established at trial equal to the amount of false claims submitted by Defendants;

(b) Assessment of a civil penalty of $10,000 for each false or fraudulent claim that Defendants made or caused to be made to the government;

(c) All other necessary and proper relief, including the costs of this action.

In addition, Plaintiff-Relator on her behalf further demands:

(a) That, in the event that the United States of America or the State of Maryland proceed with this action or otherwise settles these claims, the Court award to Plaintiff-Relator, an amount of the proceeds of this action or settlement of these claims of not less than 15% and as much as 25% pursuant to 31 U.S.C. § 3730(d) and Md. Code Ann., Health General, § 2-605(A)(I), together with an amount of reasonable expenses incurred by

Plaintiff-Relator, plus reasonable attorneys' fees and all costs and expenses incurred by the Plaintiff-Relator in bringing this action.

(b) That in the event that the United States of America does not proceed with this action, the Court award to Plaintiff-Relator, an amount of the proceeds of this action or settlement of claims of not less than 25% and as much as 30% pursuant to 31 U.S.C. 3730 (together with an amount of reasonable expenses incurred by Plaintiff-Relator, plus reasonable attorneys' fees and all costs and expenses incurred by the Plaintiff-Relators in bringing this action.

(c) Such other and further relief that this Court deems just and proper.

Jury Demand

Pursuant to Fed. R. Civ. P. 38, Plaintiff-Relator demands trial by jury.

Dated: 7-13-11

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