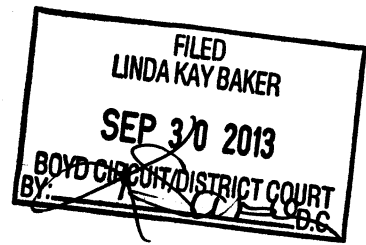


COMMONWEALTH OF KENTUCKY  
BOYD CIRCUIT COURT  
32<sup>ND</sup> JUDICIAL CIRCUIT  
DIVISION I  
CIVIL ACTION NO. 13.CI.841



ROBERT HURON and JANA HURON

PLAINTIFFS

v.

COMPLAINT

ASHLAND HOSPITAL CORPORATION  
d/b/a KING'S DAUGHTERS MEDICAL CENTER

Serve: Sheryl Mahaney  
2201 Lexington Avenue  
Ashland, Kentucky 41101

-and-

KENTUCKY HEART INSTITUTE, INC.  
P.O. Box 151  
Ashland, Kentucky 41101  
d/b/a COMPREHENSIVE HEART & VASCULAR ASSOCIATES, INC

Serve: Sheryl Mahaney  
2201 Lexington Avenue  
Ashland, Kentucky 41101

-and-

RICHARD E. PAULUS, M.D.  
613 23<sup>rd</sup> Street, Suite 230  
Ashland, Kentucky 41101

DEFENDANTS

\*\*\*\*\*

## INTRODUCTION

1. This case arises out of the pattern and practice by Defendants of performing, allowing to perform, and billing for hundreds of medically unnecessary and harmful cardiac procedures, such as percutaneous transluminal coronary angioplasty (“PTCA”) with stenting.

2. King’s Daughter’s cardiology service and physicians are currently under investigation by the United State Department of Justice for participating and facilitating the performance of unnecessary cardiac procedures.

3. PTCA with stenting is a procedure in which a cardiologist runs a catheter into the arteries of the heart in order to dilate a narrowed segment of the artery. This narrowing is known as stenosis. PTCA with stenting is only medically appropriate when the artery has stenosis of at least 70%, and the patient has certain other signs or symptoms of obstructed blood flow.

4. Defendants in this case routinely overstated the extent of the disease in the coronary arteries of patients in order to justify PTCA with placement of a stent—a small mesh-wire cylinder—into the arteries of the patient’s heart.

5. Unnecessary stenting has recently become a pervasive problem with cases arising in Kentucky, Texas, Tennessee, Maryland, and Pennsylvania. Ashland Hospital Corporation d/b/a King’s Daughters Medical Center has assisted and participated in this problem. [Exhibit 1]

6. The overstating of the extent of disease allows Defendant healthcare providers to bill health insurance companies, federal and state governments, and the patients themselves, for hundreds of unnecessary procedures.

7. Over the fiscal years 2007-2009, King’s Daughter’s Medical Center reports it increased angioplasty procedures by 22% and increased diagnostic cardiac procedures by 18.6%.

8. From 2006-2011, King's Daughter's Medical Center performed more angioplasty stenting procedures (MSDRG 247) than any other hospital in the Commonwealth of Kentucky.
9. In 2006, King's Daughters ranked first in the Commonwealth of Kentucky for the number of angioplasty stenting procedures (MSDRG 247), with 1,787 patients.
10. In 2007 King's Daughters ranked first in the Commonwealth of Kentucky for the number of angioplasty stenting procedures (MSDRG 247), with 1,595 patients.
11. In 2008 King's Daughters ranked first in the Commonwealth of Kentucky for the number of angioplasty stenting procedures (MSDRG 247), with 1,533 patients.
12. In 2009 King's Daughters purchased the medical practices of the two largest cardiology groups in Ashland.
13. In 2009, the number of angioplasty stenting procedures performed at King's Daughters (MSDRG 247) rose to 1,774.
14. In 2010, the number of angioplasty stenting procedures performed at King's Daughters (MSDRG 247) was 1,529.
15. By 2011, the number of angioplasty stenting procedures performed at King's Daughters (MSDRG 247) had fallen to 961.
16. By 2012, two years after the investigation began by the DOJ, the number of angioplasty stenting procedures performed at King's Daughters (MSDRG 247) had fallen to 513, a 70% decrease in the number of procedures performed prior to the investigation; however, KDMC still performed more of these procedures than all but one Kentucky hospital in 2012.



## JURISDICTION AND VENUE

17. The amount in controversy in this action exceeds the minimum jurisdictional limit of the Circuit Court of Boyd County, Kentucky, and jurisdiction and venue are proper in the Circuit Court of Boyd County, Kentucky.

18. Ashland Hospital Corporation, D/B/A King's Daughters Medical Center is a Kentucky corporation with a principal office located at P.O. Box 151 Ashland, Kentucky 41101.

19. Kentucky Heart Institute, Inc., D/B/A/ Comprehensive Heart and Vascular Associates, Inc., are both Kentucky Corporations with a principal office located at P.O. Box 151 Ashland, Kentucky 41101.

20. Richard Paulus, M.D. is a Kentucky physician with a principal office located at 613 23<sup>rd</sup> Street, Suite 230 Ashland, Kentucky 41101.

## FACTS COMMON TO ALL COUNTS

21. At all relevant times, Ashland Hospital Corporation owned and/or operated King's Daughters Medical Center.

22. At all relevant times, Defendant Richard Paulus, M.D. was an agent, ostensible agent, servant, or employee of the corporate defendants named in this Complaint.

23. Defendants employed various physicians to perform, and bill for, diagnostic testing, cardiac catheterizations, PTCA with stenting, and other cardiac procedures in the hospital, and provided them with staff and resources.

24. PTCA is a procedure whereby a narrowing or stenosis in a patient's coronary artery is expanded or opened. PTCA with stenting involves the additional use of a stent to stabilize previously narrowed arterial segment.

25. At all relevant times, PTCA with stenting generated significant revenue for Defendants.

26. According to well-established evidence-based guidelines promulgated by medical authorities including the American College of Cardiology and the American Heart Association, PTCA with stenting is not medically appropriate unless, among other things, the patient has a significant coronary artery stenosis of at least than 70%, along with other signs of impaired coronary blood flow.

27. PTCA with stenting entails significant risk to patients and does not confer any benefit on patients with stenosis of less than 70%. The risks include heart attack, stroke, damage to vessels and other structures, hematoma formation, bleeding, and required use of anticoagulant and anti-platelet medications that further increase the risk of bleeding.

28. As part of their businesses, Defendants held themselves and their actual and/or apparent employees out to Plaintiff and the general public as able, competent, and qualified medical professionals who rendered and provided health care, treatment, and other services within the ordinary standards of care in their respective fields, including the fields of cardiology and interventional cardiology. In so doing, the Defendants owed a duty to Plaintiff to exercise reasonable skill and care in performing interventional cardiology procedures and in monitoring, supervising, training, and evaluating the conduct, skills and competencies of their employees to ensure that they possessed and complied with that degree of skill and knowledge ordinarily possessed by those who devote special study and attention to the practice of their selected fields of health care. Defendants had a duty to periodically review all employed and non-employed physician's conduct and procedures to ensure they were performing medically necessary procedures.

29. Defendants also owed all of their patients, including Plaintiff Robert Huron, a duty to accurately and completely disclose all important medical information, including information regarding the degree of stenosis in a patient's coronary arteries.

30. From 2006-2011, Defendant Paulus performed, and the other Defendants allowed Paulus to perform, multiple unnecessary coronary PTCA with stent placements on Plaintiff Huron and, on information and belief, on hundreds of other patients.

31. In Robert Huron's case, and on information and belief, hundreds of others, Defendants dramatically misrepresented the extent of coronary artery stenosis in order to justify performance of PTCA with stenting.

32. Defendants knowingly subjected such patients, including Robert Huron, to significant medical risks with no countervailing benefit and procured consent to the procedure based on false representations that the procedure was necessary and based on fraudulent concealment of medical facts. No reasonable patient would consent to such a procedure if adequately informed about the risks, benefits and alternatives.

33. The nurses, technicians, and staff in the cardiac catheterization lab at King's Daughters knew or should have known its employed and non-employed physician's were performing unnecessary and non-indicated procedures, and failed to prevent or report their actions.

34. At all relevant times, including during the procedure Defendants performed on Robert Huron, the actual and apparent employees or agents of King's Daughters (including cardiac catheterization technicians, radiology technicians, and nurses) were physically present during each of the cardiac catheterizations and other cardiac procedures ordered and performed by its physicians in the catheterization lab. These employees had access to and reviewed the

medical records, images, and charts of each of the patients who underwent cardiac catheterizations and other cardiac procedures in the catheterization lab, conducted and/or should have conducted pre-procedure workups of each of the patients who underwent cardiac catheterizations and other cardiac procedures ordered and performed by Defendants physicians, viewed and monitored the images of the hearts and vascular system of each of the patients who underwent cardiac catheterizations and other cardiac procedures, assisted Defendants in the placement of catheters and other instruments, and provided post-procedure care and treatment to each of the patients.

35. Despite the fact that they knew or should have known that its employees were regularly ordering and performing unnecessary and non-indicated procedures, the Defendants allowed its employees to order, perform, and bill for the procedures.

36. From 2006-2011 Defendants performed or allowed to be performed on Huron multiple unnecessary catheterizations and stenting procedures as well as an intravascular ultrasound.

37. Had Defendants informed Huron of the true condition of his heart, or had they informed him that the risks, benefits, and alternatives to the procedure weighed strongly in favor of not performing PTCA with stenting or IVUS, Huron—like any reasonable patient—would not have consented to the procedures.

38. Huron is allergic to the polymers contained in the drug eluting stents and now and in the future will continue to suffer from allergic reactions to the polymers and is in a constant state of anaphylaxis.

39. As a direct, proximate and foreseeable result of Defendants' misconduct, Plaintiff Huron suffered harm, including by not limited to: unnecessary, painful and dangerous cardiac



procedures, serious, painful and permanent injuries to mind and body, and great physical and mental pain and suffering. As a further result of Defendants' misconduct, Plaintiff is now indefinitely required to take medication that carries life-threatening risks, is subject to life threatening allergic reactions, is now and will always be at risk for future stent thrombosis as well as stent re-stenosis, has suffered a significant impairment in his ability to trust medical providers, continues to live a life of greatly diminished quality, has incurred unnecessary medical expenses and will continue to incur substantial medical costs, has lost wages, and sustained other pecuniary and non-pecuniary losses past, present and future.

**COUNT I**  
**(NEGLIGENCE/GROSS NEGLIGENCE)**

40. Plaintiff Robert Huron hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

41. Defendants had a duty to exercise the degree of care and skill which a reasonably competent healthcare provider, medical group or hospital or billing service, engaged in similar practice and similar circumstances, would use.

42. Defendants breached that duty and were negligent or grossly negligent in their care and treatment of Plaintiff and deviated from the appropriate standard of medical care in one or more of the following particulars:

- a. failed to properly and appropriately interpret and assess angiographic films before performing a stent placement procedure;
- b. failed to recommend alternative medical therapy or another non-surgical course of action instead of performing the cardiac stent placement procedures;
- c. performed unnecessary cardiac procedures;

d. failed to comply with the applicable standards of care in the circumstances presented and was otherwise negligent and careless;

e. failed to accurately document the clinical indications upon the decision to perform a cardiac stent procedure was based;

f. failed to confirm or properly quantify the significance of using well-accepted intra-procedural techniques, such as fractional flow reserve or intravascular ultrasound;

i. implanted a medical device that was not medically indicated or necessary;

j. performed PTCA with stenting that was not medically indicated or necessary; and

43. Plaintiff as suffer harm as set forth above.

**COUNT II**  
**(LACK OF INFORMED CONSENT)**

44. Plaintiff Robert Huron hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

45. Defendants were under a duty to provide Robert Huron with informed consent before subjecting him to PTCA with stenting, including but not limited to disclosure of material information regarding the risks, benefits, and alternatives to the proposed treatment, and disclosure that the risks of such treatment in his particular circumstances exceeded any possible benefit.

46. Defendants failed to provide such informed consent, but rather concealed material facts about the condition of Robert Huron's heart and coronary arteries and about the necessity (or lack thereof) PTCA with stenting procedures.

**COUNT III**  
**(NEGLIGENT MISREPRESENTATION)**

47. Plaintiff Robert Huron hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

48. Defendants, owing a duty of care to Robert Huron, negligently misrepresented and concealed the condition of Robert Huron's heart and coronary arteries and negligently misrepresented that he would benefit PTCA with stenting.

49. Defendants intended that Robert Huron would rely upon and act upon their misrepresentations and concealment by consenting to undergo PTCA with stenting.

50. Defendants knew that Robert Huron would probably rely upon their negligent medical advice, and they knew that Plaintiff Robert Huron would have opted to not undergo the stent procedure if Plaintiff had been provided accurate medical information regarding his condition and the proposed procedures.

51. Robert Huron's reliance on Defendants' misrepresentations and concealment was reasonable and justified, as they are healthcare providers with far greater knowledge of the relevant subject and far superior access of the information underlying the misrepresentations and concealment.

52. As a result of Defendants' misrepresentations, Robert Huron suffered harm as set forth above.

**COUNT IV**  
**(FRAUD AND FRAUDULENT CONCEALMENT)**

53. Plaintiff Robert Huron hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

54. Defendants performed unnecessary and contraindicated catheterizations and PTCA with stent placement on Plaintiff Robert Huron's heart.

55. Likewise, Defendants fraudulently concealed from the patient that his limited degree of coronary artery stenosis rendered the catheterizations and PTCA with stenting improper and unnecessary.

56. Defendants also concealed their pattern and practice of subjecting patients to such unnecessary and medically inappropriate procedures. Defendants concealed these facts despite being under a duty to disclose them.

57. Defendants' false concealment of material information was made knowingly and/or with reckless disregard for their truth.

58. The fraudulent concealing of material information was intended to induce Robert Huron to consent to the performance of the pacemaker implantation surgery, catheterizations and PTCA with stenting and/or to refrain from objecting to those procedures.

59. Defendants' misrepresentations and concealment were material to Plaintiff Robert Huron's consent to the PTCA and stent placement.

60. Plaintiff Robert Huron justifiably and reasonably relied on Defendants' misstatements and concealment—all done in the context of the healthcare provider-patient relationship of trust and confidence—in agreeing to undergo the unnecessary procedure. But for Defendants' misrepresentations and concealment, Plaintiff Robert Huron would not have consented to the PTCA with stent placement.

61. As a direct, proximate and foreseeable result of Defendants' false and fraudulent representations, Plaintiff Robert Huron suffered harm as set forth above.

COUNT V  
NEGLIGENT HIRING, SUPERVISION, CREDENTIALING

62. Plaintiff hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

63. Dr. Paulus and other doctors involved in the unnecessary procedures performed on Huron were the actual agents, ostensible agents, servants or apparent employees of Defendants.

64. Defendants granted hospital privileges to the physicians involved in Huron's care, authorizing them to perform medical procedures including the services, treatment and surgery rendered to Plaintiff Robert Huron.

65. Defendants owed a duty to Plaintiff Robert Huron to train, supervise, credential, and privilege employees who were competent for the position and to supervise those employees in a reasonable manner.

66. Defendants had actual and/or constructive knowledge of its employees' pattern and practice of ordering and performing unnecessary and medically inappropriate procedures, and failure to disclose such information to a patient.

67. Defendants failed to use reasonable care in hiring, supervising, credentialing, privileging, and retaining its employees.

68. Defendants deliberately failed to inquire, probe or examine the competency and conduct of its employees because Defendants profited and were enriched by their misconduct.

69. Defendants had an obligation to properly administer a program of quality control. Proper quality control would have resulted in stricter supervision of its employees and would have prevented Plaintiff—and hundreds of others—from being subjected to medically unnecessary procedures.

70. As a direct, proximate and foreseeable result of the negligence of Defendants in hiring, credentialing, privileging and retaining its employees, Robert Huron suffered harm as set forth above.

**COUNT VI**  
**(CIVIL CONSPIRACY)**

71. Plaintiff hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

72. Defendants, by agreement among themselves, knowingly and unlawfully provided medical facilities and assistance, including billing services, needed to perform and did in fact perform the unnecessary, non-indicated and unlawful procedures on hundreds of patients, including Robert Huron.

73. This agreement or understanding allowed all Defendants to benefit financially from unnecessary and non-indicated procedures, and was likely in violation of state and federal laws regarding kickbacks and referrals.

74. As a direct and proximate result of the agreement or understanding among Defendants, Plaintiff Robert Huron suffered harm as described above.

**COUNT VII**  
**(UNJUST ENRICHMENT)**

75. Plaintiff hereby reasserts and incorporates by reference the allegations contained in this Complaint as if set forth herein.

76. At all times material hereto, the Defendants, received financial benefits for the performance of hundreds of medically unnecessary and harmful cardiac procedures.

77. At all times material hereto, the Defendants represented to Plaintiff that the cardiac procedures were necessary, when in fact the Defendants knew that their representations were medically unnecessary and harmful to Plaintiff.

78. At all times material hereto, the Defendants knew that if they advised Plaintiff of the risks involved with performing these medically unnecessary cardiac procedures, Plaintiff would not have consented to the procedures. Therefore, Plaintiff relied on the false representations of the necessity of these cardiac procedures without knowledge of the risk to his health.

79. At all times material hereto, the Defendants failed to disclose to Plaintiff material facts concerning the harmful effects of the cardiac procedures to Plaintiff.

80. At all times material hereto, the Defendants knew that if they advised Robert Huron of the risks to his health by consenting to and undergoing the unnecessary procedures, he would refuse to consent to the Defendant's performance of these procedures. As a result, the Defendants have been unjustly enriched, through profits, bonuses and incentive payments earned by not properly advising Robert Huron of the risks associated with undergoing unnecessary stenting and IVUS procedures.

**COUNT VIII**  
**(CONSUMER PROTECTION ACT)**

81. Plaintiff adopts, reiterates and incorporates herein by reference all allegations contained in the other paragraphs of this Complaint.

82. Robert Huron obtained services from the Defendants primarily for his personal purposes.

83. The Defendants engaged in unfair, false, misleading and/or deceptive acts or practices in holding themselves out as safe and competent providers of cardiac medical care, all in violation of KRS 367.170.

84. Robert Huron suffered ascertainable losses as a result of the Defendants unfair, false, misleading and/or deceptive acts or practices.

85. Robert Huron is within the class of persons intended to be protected by the Kentucky Consumer Protection Act, KRS 367 *et seq.*

86. Robert Huron has suffered actual damages as alleged in this Complaint as a result of the Defendants violation of KRS 367.170, which he is entitled to recover pursuant to KRS 367.220.

87. Plaintiff is entitled to recover reasonable attorney's fees and costs of litigation pursuant to KRS 367.220(3).

**COUNT IX**  
**(BATTERY)**

88. Plaintiff adopts, reiterates and incorporates herein by reference all allegations contained in the other paragraphs of this Complaint.

89. At all times material hereto, the Defendants represented to Plaintiff that the cardiac procedures were necessary, when in fact the Defendants knew that their representations were medically unnecessary and harmful to Plaintiff.

90. Defendants performed unnecessary and unlawful cardiac medical procedures on the Plaintiff.

91. These unnecessary and unlawful procedures necessarily required the Defendants' to physically touch and operate on the Plaintiff.



92. Had the Defendants represented to the Plaintiff that the cardiac procedures were in fact not necessary, he would not have given consent for the touching necessary for the performance of the procedures.

93. As a result of Defendants' unlawful touching, Robert Huron suffered harm as set forth above.

**COUNT I (Jana Huron)**  
**LOSS OF CONSORTIUM**

94. As a direct and proximate result of the negligence and gross negligence of the Defendants as aforesaid, the Plaintiff, Jana Huron, suffered, and will suffer in the future, the loss of love, society, affection, counsel, companionship and consortium of her husband, Robert Huron.

**WHEREFORE**, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory and punitive damages; interest; trial by jury; for costs herein expended; including but not limited to attorney's fees, loss of power to labor and earn; and for any and all further relief to which the Plaintiff may appear entitled.

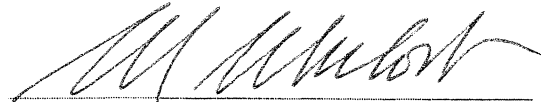
*As to Complaint Huron, et al.  
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Respectfully submitted,



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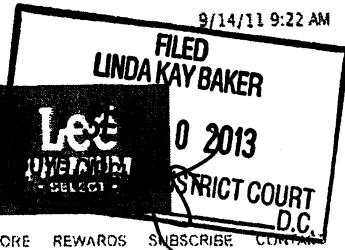
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Counsel for Plaintiffs



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## Cardiologist's license revoked over accusations of placing unneeded stents

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Dr. Mark G. Midei can no longer practice in Maryland

July 13, 2011 | By Tricia Bishop, The Baltimore Sun

The Maryland Board of Physicians revoked the medical license of Dr. Mark G. Midei on Wednesday, finding that the Towson cardiologist falsified patient records in order to justify unnecessary and expensive cardiac stent procedures.

"Dr. Midei's violations were repeated and serious," board members wrote in an 11-page order. "They unnecessarily exposed his patients to the risk of harm. They increased the cost of the patients' medical care."

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The findings cap two years of inquiry into Midei's work at St. Joseph Medical Center. The allegations tarnished Midei's career, pushed the hospital to enter into a multimillion-dollar settlement with the federal government and led the U.S. Senate Finance Committee to open an investigation into the doctor's relationship with stent makers.

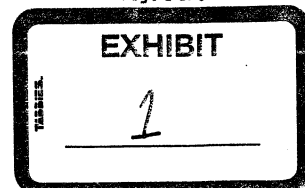
The revocation "validates what we've been saying all along, which is that Dr. Midei was engaged in egregious malpractice and fraud," said Andrew G. Stulkin, a Baltimore attorney who has filed nearly 20 patient lawsuits against Midei.

One of Midei's attorneys, Stephen Snyder, said the "political pressure" to revoke Midei's license was too great for the board to ignore.

The board ruled that Midei violated five provisions of the state's Medical Practice Act while working at St. Joseph through unprofessional conduct, false reports, gross overutilization of health care services, standards of care violations and the failure to keep adequate medical records.

Specifically, the board found that he inserted cardiac stents into arteries that weren't clogged enough to need them — likely because of "pressure to produce."

"Dr. Midei testified that he understood that he was a big generator of business for the hospital, that the hospital



had lost many patients to competition and that its goal was to hold onto the stent business that it saw slipping away," board members wrote, noting that Midei was hired to run St. Joseph's cardiac catheterization lab at a seven-figure salary that was triple his prior earnings.

Snyder said the board's decision was not "supported by the evidence."

"I always believed in Dr. Midei, and I put my heart and soul into [his defense]," Snyder said. "Unfortunately, I think a fine doctor is being put out to pasture and that the community receives a disservice by him not being able to continue to save lives."

Snyder said he will discuss an appeal with Midei. He also provided a statement from Dr. William O'Neill, executive dean of clinical affairs at the University of Miami's Miller School of Medicine. O'Neill was paid more than \$28,000 by Midei's defense team to review the patient case files and testify on Midei's behalf.

He says he found no unwarranted stents.

"I pity any interventional cardiologist practicing in Maryland today," O'Neill said. "If Dr. Midei can lose his license, any of them could."

Midei could not be reached for comment.

Midei filed a lawsuit against St. Joseph, claiming he was made a scapegoat by hospital administrators who were trying to deflect attention from a separate kickback scandal. St. Joseph paid the federal government \$22 million to settle the kickback claims, as well as to repay Medicare funds received for Midei's suspicious stents.

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In a statement Wednesday, the hospital said it respects the board's decision regarding Midei.

He is one of at least three Maryland doctors recently accused of unnecessary medical procedures.

John R. McLean, a cardiologist who practiced on the Eastern Shore, is currently on trial on charges of fraud and false statements in Baltimore's U.S. District Court, accused of implanting unnecessary stents. And the federal government sued a Baltimore eye doctor in March, claiming that he repeatedly performed unnecessary laser eye surgery.

"I think everybody realizes we need to step up here and assure the public" that medical safety is a priority for the state, said Del. Dan K. Morhaim, a physician who introduced legislation this year to strengthen doctor oversight. It passed unanimously.

"Patient care, patient safety, patient comfort" is at stake, he said, "but also the opportunity to find any systemic problems that can be corrected."

Concerns about Midei's work were first raised in the spring of 2009, and he was relieved of hospital duties shortly thereafter. In November of that year, St. Joseph began notifying roughly 600 patients through letters that their stents might have been unnecessary.

A Baltimore Sun article about those letters led to a state investigation and action by the U.S. Senate Finance Committee, which released a report in December calling Midei's work "a clear example of potential fraud, waste and abuse."

The Maryland Board of Physicians, which disciplines and licenses state doctors, filed professional charges against Midei on June 7 of last year. A settlement conference was held in August, and evaluators recommended a lesser penalty than revocation, according to Anthony Leon, a Florida attorney who has represented Midei.

"It was a lot tighter," Leon said.

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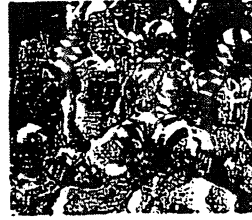
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## JUSTICE NEWS

## Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, November 9, 2010

**St. Joseph Medical Center in Maryland to Pay U.S. \$22 Million to Resolve False Claims Act Allegations***Facility Allegedly Violated Anti-Kickback Act*

BALTIMORE – St. Joseph Medical Center (SJMC) in Towson, Md., has agreed to pay the United States \$22 million to settle allegations under the False Claims Act that it paid unlawful remuneration under the Anti-Kickback Act and violated the Stark Law when it entered into a series of professional services contracts with the Pikesville, Md., based cardiology group, MidAtlantic Cardiovascular Associates (MACVA), the Justice Department announced.

The allegations resolved in the settlement include the payment of kickbacks to MidAtlantic under the guise of professional services agreements, in return for MACVA's referrals to the medical center of lucrative cardiovascular procedures, including cardiac surgery and interventional cardiology procedures, over the period from Jan. 1, 1996, to Jan. 1, 2006. The settlement agreement resolves issues relating to 11 professional services agreements between MidAtlantic and St. Joseph under which MACVA received payments above fair market value, for services not rendered or that were not commercially reasonable and were entered into for the purpose of inducing referrals by MACVA to SJMC.

Under the settlement the hospital also agrees to settle allegations that it received from federal health benefit programs between Jan. 1, 2008, and May 12, 2009, for medically unnecessary stents performed by Mark Midei, M.D., a one time partner in MACVA who was later employed by SJMC.

The settlement was announced by Tony West, Assistant Attorney General of the Justice Department's Civil Division; Rod Rosenstein, U.S. Attorney for the District of Maryland; Nicholas DiGiulio, Special Agent in Charge, Office of Inspector General of the Department of Health and Human Services, Office of Investigations; Roger Craig, Special Agent in Charge of the Defense Criminal Investigative Service - Mid-Atlantic Field Office; and Jill Maroney, Special Agent in Charge of the Office of Personnel Management - Office of Inspector General.

"Kickbacks for medical services undermine the integrity of our health care system," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "When hospitals put their own financial interests ahead of the best interests of patients, we will take action."

The settlement resolves a lawsuit brought by whistleblowers, Stephen D. Lincoln, M.D.; Peter Horneffer, M.D.; and Garth McDonald, M.D., cardiac surgeons who practiced together as members of Cardiac Surgery Associates in Baltimore. The lawsuit, which was filed in the District of Maryland in June 2010, alleges that SJMC violated the Anti-Kickback Act, Stark Law and the False Claims Act by paying various forms of illegal remuneration to MACVA to induce referrals of patients insured by federal health care programs for cardiac procedures.

Drs. Lincoln, Horneffer and McDonald brought their suit under the *qui tam* whistleblower provisions of the False Claims Act, which permit private citizens with knowledge of false claims against the government to bring a lawsuit on behalf of the United States and to share in any recovery. Under the civil settlement announced today, the relators will receive a portion of the federal share of the recovery.

"Kickbacks give doctors an incentive to pursue unnecessary treatments that are costly and sometimes even dangerous to patients," said U.S. Attorney Rosenstein. "Medical care providers are prohibited from giving or receiving kickbacks because of the risk that they will put their own financial interests ahead of their patients' interests."

Saint Joseph's also signed a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). It requires SJMC to engage in activities that will help ensure accurate billing and appropriate relationships with referral sources. The CIA also addresses patient care issues by requiring the hospital to: appoint physician executives to oversee medical staff quality-of-care matters; hire a Peer Review Consultant to evaluate SJMC's peer review practices; and engage an Independent Review Organization to perform a Cardiac Catheterization Procedures Review, evaluating and analyzing the medical necessity and appropriateness of interventional procedures performed at SJMC. The hospital is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for major noncompliance with this CIA and subject to stipulated penalties for less significant noncompliance.

"Payoffs to influence health care decision-making too often result in inappropriate, unnecessary and harmful medical practices," said Daniel R. Levinson, Inspector General of the Federal Department of Health and Human Services. "OIG is committed to protecting patients from needless medical procedures, such as the insertion of unnecessary cardiac stents -- as is alleged in this case."

The settlement announced today was the result of an investigation by the U.S. Attorney's Office for the District of Maryland and the Commercial Litigation Branch of the Justice Department's Civil Division with assistance from the U.S. Department of Health and Human Services, Office of Inspector General; the Department of Defense Office of the Inspector General, Defense Criminal Investigative Service; and the Office of Personnel Management, Office of Inspector General. The case was handled by Maryland Assistant U.S. Attorney Jamie M. Bennett.

10-1271

Civil Division

## **Kentucky doctor admits fraud for unnecessary heart stents**

*Written by Andrew Wolfson The Courier-Journal*

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A Kentucky cardiologist at the center of nearly 400 lawsuits alleging that St. Joseph London hospital performed unnecessary heart procedures has pleaded guilty to criminal charges that he exaggerated the severity of patients' illnesses so he would get paid for treating them.

Dr. Sandesh Patil of London admitted to making false statements regarding the blockage of patients' arteries so he could get reimbursed by Medicaid for inserting stents.

Patil agreed to accept a sentence of 30 to 37 months in prison when he is sentenced in U.S. District Court on Aug. 27. He pleaded guilty Tuesday in Frankfort.

The government said Patil is only the third cardiologist in the United States — and the first in Kentucky — to be prosecuted federally for health care fraud related to the placement of heart stents, the tubes surgically inserted into a patient's arteries to improve blood flow.

"Dr. Patil violated the public's trust in physicians," Kerry Harvey, U.S. attorney for the Eastern District of Kentucky, said in a news release. "Both patients and the entities that pay for medical services trust that our physicians will accurately and honestly assess a patient's medical condition."

Harvey promised to "aggressively pursue any physician or provider that breaches this trust and places their own financial well-being ahead of the well-being of the patients."

Patil's lawyer, Brian Butler, said in an interview that his client "didn't do anything that he didn't think was medically necessary and would benefit the patient." Butler said Patil changed the percentage that one patient's artery was blocked to ensure that the hospital would be reimbursed.

St. Joseph, which is part of Catholic Health Initiatives, has repaid the government \$256,800 for cardiac procedures that Patil submitted for reimbursement in 2009 and 2010.

In lawsuits that are pending, nearly 400 former patients have alleged that Patil and 10 other cardiologists conspired with the hospital and others to perform unnecessary, risky and often painful heart procedures to unjustly enrich themselves.

The suits, which also name Catholic Health Initiatives, allege that two patients died and that the others will be required to take dangerous blood-thinning medications for life and are at risk of other potentially fatal complications.

The hospital and other physicians named as defendants deny the allegations. The hospital's lead counsel, Todd Thompson, said in February that "these were very sick people who needed the interventions, and got them."

David McArthur, a hospital company spokesman, said in an email that Patil has not had privileges or practiced at the London hospital since December 2010. McArthur also said the hospital has cooperated with the U.S. attorney's office throughout the investigation.

But Hans Poppe, lead counsel for the plaintiffs, said the hospital and Catholic Health Initiative “need to accept responsibility for choosing not to monitor doctors like Patil.

“Dr. Patil’s agreement to go to federal prison in recognition of the crimes he committed against patients is merely the first step,” Poppe said. “CHI and St. Joseph-London cannot regain the trust of our community unless and until it agrees to accept financial responsibility for the patients and families who were injured.”

The Kentucky Board of Medical Licensure in January found that Patil provided substandard care to four of five patients whose records it examined, placing stents without justification in three, though it allowed him to continue to practice with additional monitoring and remedial education.

The Centers for Medicare and Medicaid in 2011 cited the hospital for failing to review the medical necessity of 3,367 cardiac catheterizations performed there the year before. In those procedures, a wire is inserted through an artery in the groin into the heart.

The newspaper also reported in February that in research conducted for his Kentucky Health Policy Institute blog, University of Louisville professor emeritus Peter Hasselbacher found that St. Joseph London did more angioplasties with stents in 2008 and 2009 than either of the state’s two major teaching hospitals.

Hasselbacher, an internist, also found that after lawsuits were filed and St. Joseph London came under the spotlight, the number of invasive procedures dropped by one-third, which he called “the most persuasive evidence that too many cardiac catheterizations with placement of stents might have been performed.”

The criminal case was investigated by the FBI, the Kentucky attorney general’s Medicaid fraud abuse and control unit, and the U.S. Department of Health and Human Services.

Patil admitted that he falsely entered into the patient chart of a patient identified only as B.D. that he had a 70 percent blockage in one of his arteries, when it was “substantially less,” according to court records.

Under federal law, physicians can only be reimbursed for medically necessary treatment, and for a stent to qualify, the patient must have a blockage of at least 70 percent.

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