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STAFF REPORT ON CARDIAC STENT USAGE AT ST. JOSEPH MEDICAL CENTER

PREPARED BY THE STAFF OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

MAX BAUCUS, *Chairman*
CHUCK GRASSLEY, *Ranking Member*

DECEMBER 2010

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I. Introduction

The United States Senate Committee on Finance (Committee) has a duty to conduct oversight of the Medicare and Medicaid programs. This duty includes the responsibility to monitor payments made by the Centers for Medicare and Medicaid Services (CMS) for medical devices, drugs, and biologics in order to protect taxpayer dollars from waste, fraud, and abuse.

In February 2010, the Committee initiated an inquiry into reports that cardiologist Dr. Mark Midei (Midei) from the St. Joseph Medical Center in Towson, MD (St. Joseph/the Hospital) may have implanted 585 stents which were medically unnecessary.[1]

The Committee staff reviewed approximately 10,000 documents provided by St. Joseph and Abbott Laboratories (Abbott/the Company), the manufacturer of stents Dr. Midei used most often in the last half of 2008 and first half of 2009. St. Joseph and Abbott were cooperative with the Committee's inquiry.

During the Committee's inquiry, several important facts came to light. The Committee found:

- Despite the ethical and legal questions surrounding Dr. Midei, Abbott hired him as a consultant after he was barred from practicing at St. Joseph. Dr. Midei's duties for Abbot included, among other things, helping the Company market its stents in Japan and working on a safety presentation for Abbott's newest stent, the Xience V. Dr. Midei was paid $30,623 for this consulting work.
- Abbott paid at least $1,925 for social events at Dr. Midei's home, including crab and barbecue dinners. Abbott employees attended the events during the period that Dr. Midei implanted stents without clinical indication and consequently may have been medically unnecessary.
- According to an internal e-mail written by an Abbott sales representative who worked with Dr. Midei, the volume of stent procedures diminished in the entire Baltimore region after the allegations against Dr. Midei were made public.
- In response to *Baltimore Sun (Sun)* columnist Jay Hancock's January 22, 2010 article critical of medical device companies who both manufacture and market, a senior Abbott employee wrote in an e-mail, "Don't you have connections in Balti-

[1] "Stents are inserted into narrowed coronary arteries to help keep them open after balloon angioplasty. The stent then allows the normal flow of blood and oxygen to the heart." See definition at *http://www.MedicineNet.com.* A drug-eluting stent is "a normal metal stent that has been coated with a pharmacologic agent (drug) that is known to interfere with the process of restenosis." Restenosis is when an artery closes after balloon angioplasty. *See* Drug Eluting Stent Overview at Angioplasty.org, *http://www.ptca.org/articles/des1.html.* Similar cases include a Salisbury, MD cardiologist who was recently indicted by a grand jury and could face up to 40 years in prison for allegedly performing more than 200 medically unnecessary stent procedures and a Louisiana doctor who, in 2009, was sentenced to 10 years in prison for implanting medically unnecessary stents. *See* Tricia Bishop, *Salisbury Cardiologist Indicted in Stent Case,* BALT. SUN, Sept. 2, 2010.

more????? Someone needs to take this writer outside and kick his ass! Do I need to send the Philly mob?"

- St. Joseph billed public and private insurers more than $6.6 million for the almost 600 stent procedures in question. Of that amount, Medicare paid more than half—$3.8 million.
- Three patients who received notifications that they may have received a medically unnecessary stent have had medical complications. No deaths were reported to the Committee, but one patient was referred to surgery due to complications.
- After Dr. Midei was stripped of his privileges to practice at St. Joseph, he began work at The Prince Salman Heart Center, a cardiac catheterization lab in Saudi Arabia.

II. Background on Alleged Medically Unnecessary Stent Procedures

St. Joseph told the Committee that it "first became aware of a patient care/quality issue in its Cardiac Catheterization Lab on approximately April 27, 2009."[2] On May 12, 2009, the Hospital barred Dr. Midei from practicing "after it was determined that the complaint had merit."[3] The Maryland Board of Physicians (Board) began receiving complaints about Dr. Midei alleging "medical fraud" on November 11, 2008; about 6 months before St. Joseph barred him from practicing.[4] During this gap, between November 2008 and May 2009, Dr. Midei continued to perform cardiac procedures which may have been unnecessary.[5]

In response to the complaints, St. Joseph hired a panel of experts to review patient records for those who received stents from Dr. Midei during the period of January 2007 through May 12, 2009. The panel reviewed 1,878 cases during three review periods: June 19–21, 2009, October 30–November 1, 2009, and January 22–24, 2010.[6] In all, St. Joseph notified 585 patients that they may have received medically unnecessary cardiac stents. The Hospital's internal Medical Review Committee concluded Dr. Midei's actions "resulted in the substantial likelihood of harm to his patients" as his "placement of stents in patients with no clinical indication for intervention exposes such patients to the potential for serious complications."[7]

On June 12, 2010, the *Sun* reported that the Board formally accused Dr. Midei:

> of "gross overutilization of health care services" and "willfully making a false report or record in the practice of medicine," among other violations of state law. . . . The board's investigation included detailed reviews of five of Midei's cases. In each, Midei wrote in the patient's records

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[2] Update on Federal Investigation and Issues, St. Joseph Medical Center, Feb. 2010, SJMC–SFC 0001. (*See* Appendix II, p. 24.)

[3] *Id.*

[4] Maryland State Board of Physicians Complaint against Dr. Midei at 3. (*See* Appendix II, p. 27.)

[5] St. Joseph Medical Center, Cardiac Notification Patient Encounters, SJMC–SFC 0569. (*See* Appendix II, p. 47.)

[6] St. Joseph Medical Center Catheterization Review Summary, SJMC–SFC0003. (*See* Appendix II, p. 49.)

[7] Report of the Ad Hoc Investigating Committee Regarding Review of Physician, SJMC–SFC 0545. (*See* Appendix II, p. 51.)

> that they suffered from an 80 percent blockage of a coronary artery, which needed to be propped open with a stent. But a subsequent review of X-ray images showed less than 50 percent blockage.[8]

Patients and medical malpractice lawyers have raised concerns that stent procedures performed by Dr. Midei before January 2007 have not undergone clinical review but may have been implanted unnecessarily, according to a May 22, 2010, article in the *Sun.*[9] St. Joseph subsequently explained to the Committee the reason for limiting its review of Midei's procedures to those beginning on January 1, 2007:

> SJMC does not plan to address allegations that Dr. Midei improperly implanted stents in patients prior to the review period of 2007. The review stopped at January 2007 based on very careful discussion and review as to the well-being of the affected patients. That is, SJMC needed to determine the time frame where there was a basis for a "clinical" need to know. The literature and the experts that SJMC consulted in determining the appropriate "Look-Back" period, indicate that the risk of clotting, and perhaps any complication (acute thrombosis or restenosis) is greatly diminished, and is in the realm of 1–2 [percent], after two years. There is even literature that suggests that the risk greatly diminished after one year and hence the need for Plavix for only one year in many cases.[10]

Dr. William Boden, the clinical chief of the University at Buffalo Division of Cardiovascular Medicine and the chief of cardiology at Buffalo General and Millard Fillmore Hospitals, is critical of the decision by St. Joseph to limit its review of Dr. Midei's stent procedures. He said:

> This is not an issue of the likelihood of restenosis or subacute/late stent thrombosis. Yes, these procedural complications are temporally related and decrease after 9–12 months. But, that doesn't explain or exonerate the fact that Dr. Midei may have been stenting normal or minimally narrowed coronary arteries before 2007. It's like the rationale of SJMC is that, since complications were likely to be low prior to 2007, let's not go looking for trouble. It's not sound logic.
>
> If stents were implanted inappropriately, and if I were one of the recipients in 2005 or 2006, I would think those patients likewise have a right to know whether something medically negligent was done to them. This shouldn't be a time-dependent analysis, in my view, with a temporal cutoff in 2007.[11]

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[8] Tricia Bishop, *Towson Cardiologist Faces Professional Charges: Doctor Could Lose License Over Stent Procedures,* BALT. SUN, June 12, 2010.

[9] Robert Little, *Lawyers See St. Joseph's Stent Claims Growing: Hospital Notified 585 Patients of Unnecessary Procedures, but Still More are Coming Forward,* TRIB. BUS. NEWS, May 23, 2010.

[10] St. Joseph Medical Center response to Senate Finance Committee questions received on Sept. 10, 2010. Plavix is drug prescribed to patients who receive stents in order to prevent blood clots. *See* FAQ on the Anticlotting Drug Plavix available from WebMD at *http://www.webmd.com/heart-disease/news/20090403/faq-on-the-anticlotting-drug-plavix.*

[11] Communication between Committee staff and Dr. William Boden on Oct. 9, 2010.

Dr. Boden was the lead investigator of COURAGE, a 2007 Department of Veterans Affairs funded study published in the *New England Journal of Medicine.* According to the *Wall Street Journal,* COURAGE "shook the world of cardiology" when it found that cardiac stent procedures, also referred to as percutaneous coronary interventions (PCIs) "usually yield no additional benefit when used with a cocktail of generic drugs in patients suffering from chronic chest pain." [12]

Despite being barred from employment at St. Joseph, Dr. Midei was able to find work in another cardiac catheterization lab. In an April 20, 2010, e-mail, Dr. Midei confided to Abbott Vascular Chief Medical Officer Dr. Charles Simonton that, "I am back working in the lab at the Prince Salman Heart Center in Saudi Arabia." [13]

Dr. Midei filed a $60 million lawsuit against St. Joseph on October 21, 2010 alleging that the Hospital's letters to Midei's patients informing them that they may not have needed their stent implantations caused "irreparable damage" to his career.[14]

On November 9, 2010, St. Joseph reached a settlement with the federal government agreeing "to pay $22 million to settle federal claims that it engaged in a decade-long kickback scheme with Pikesville cardiology group MidAtlantic Cardiovascular Associates, which was co-founded by Dr. Mark G. Midei." The settlement included "the repayment of federal funds that St. Joseph received for 'medically unnecessary' coronary stents placed by Midei after he had left MidAtlantic to become a full-time St. Joseph employee with a seven-figure salary." [15]

U.S. Attorney Rod J. Rosenstein and HHS Inspector General Daniel R. Levinson both stated that kickback schemes can incentivize doctors to perform medically unnecessary procedures.[16] However, the time period of the alleged kickback scheme between St. Joseph and MidAtlantic Cardiovascular Associates, from 1996 to 2006, does not overlap with the allegations against Dr. Midei for alleged unnecessary medical procedures, from 2007 to mid-2009.

III. The Cost of Dr. Midei's Alleged Medically Unnecessary Cardiac Stent Procedures

The cost to the health care system from the actions of Dr. Midei had substantial cost to taxpayers. St. Joseph billed public and private insurers more than $6.6 million for almost 600 stent procedures in question. Of that amount, Medicare paid $3,817,567, more than half.[17] This sum does not include the cost related to future medical complications that may arise as a result of the stent procedures.

In addition to both private and public insurers paying for allegedly medically unnecessary procedures, Dr. Midei's actions put his patients at serious risk for complications, according to the St. Joseph Ad Hoc Committee. This Committee was appointed by the St.

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[12] Keith J. Winstein, *A Simple Health-Care Fix Fizzles Out,* WALL ST. J., Feb. 11, 2010.

[13] E-mail from Dr. Mark G. Midei to Dr. Charles Simonton, Abbott Vascular Chief Medical Officer, Apr. 20, 2010. (*See* Appendix II, p. 57.)

[14] Tricia Bishop, *Cardiologist Sues Hospital Over Stent Allegations,* BALT. SUN, Oct. 21, 2010.

[15] Tricia Bishop, *Towson Hospital Settles Kickback Claims,* BALT. SUN, Nov. 9, 2010.

[16] *Id.*

[17] St. Joseph Medical Center, Cardiac Settlement—Charges and Payments, Apr. 8, 2010, SJMC–SFC0007. (*See* Appendix II, p. 59.)

Joseph Medical Executive Committee to investigate the alleged unnecessary procedures. The St. Joseph Ad Hoc Committee Report stated:

> Dr. Midei's practice of placing stents in patients where not clinically indicated has resulted in the substantial likelihood of harm to his patients. According to the AMF Review Team, the cardiac catheterization itself carries a 1 percent to 5 percent chance of risk, depending on how one assesses complications. Once the stent is in place, there is a 1 percent chance of stent thrombosis (i.e., where the stent closes off the vessel), which carries a 60 percent chance of mortality. The risk of stent thrombosis increases to 2.4 percent three years following the intervention. Additionally, patients who receive stents must undergo continued therapy with Plavix and aspirin, each of which carry their own side effects. Therefore, Dr. Midei's placement of stents in patients with no clinical indication for intervention exposes such patients to the potential for serious complications.[18]

The Committee asked St. Joseph whether any of the notified patients had experienced medical complications. Prior to responding to the Committee's questions, on September 7, 2010, Ellen Barton, Vice President of Governance and Administrative Services for St. Joseph, disclosed in a *Sun* Op/Ed: "To the best of our knowledge, there have been 'medical' complications in only three patients as a result of the stent procedures."[19] In a subsequent response to the Committee, St. Joseph explained:

> To the best of SJMC's knowledge, there have been three "medical" complications in patients as a result of the stent procedures. The greatest risk of complications is within the first 6 months to a year. However, SJMC does not have access to all these patients' past and current medical records. Without complete medical records, it is impossible to determine with finality the "necessity" of the stent, as the percentage of stenosis only is not the determinant for placing a stent. Likewise, it is not possible to determine with finality if there were complications. SJMC does know that no deaths resulted from these stent procedures and there was only one case where a patient was referred to surgery from the Cardiac Cath lab when it was determined that her condition warranted surgery.[20]

IV. Biased Peer Review Procedures at St. Joseph

According to Professor Katharine Van Tassel, the author of a law review article on hospital peer review, "the term 'peer review' describes several distinct activities which are generally performed by a hospital medical staff committee, all with the goal of maintaining or improving quality of patient care." One of these activities, mandated by CMS as a condition of participation and by The Joint

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[18] Report of the Ad Hoc Investigating Committee, *supra* note 7, at 4. (*See* Appendix II, p. 51.)
[19] Ellen Barton, *Doing the Right Thing; St. Joseph's Medical Center Has Handled Questions About the Use of Stents Appropriately,* BALT. SUN, Sept. 8, 2010.
[20] St. Joseph Medical Center, *supra* note 10.

Commission (a major health care accreditation organization) guidelines, "involves the ongoing collection and evaluation of data regarding the professionalism and competence of each physician who is a current member of the hospital staff."[21]

The Maryland Office of Health Care Quality, the state's licensing and certification organization for hospitals, found that the "hospital's peer review process permitted Dr. Midei, as Chair of the Cardiology Department, to select cardiology cases, including his own, for peer review."[22] St. Joseph has since revised their peer review practices "to include independent, blinded review of interventional providers and has ensured that clinical heads are neither selecting nor reviewing their own cases."[23] The Maryland Department of Health and Mental Hygiene recommended in a recent report that the Maryland Office of Health Care Quality "augment existing standards required of hospital peer review process to include review of volume and medical necessity" to prevent unnecessary procedures in the future.[24]

V. Dr. Midei's Relationship with Abbott

The Committee has been examining financial ties between physicians and the health care industry over the last six years. This oversight effort laid the groundwork for the passage of the Physician Payments Sunshine Act as part of the Patient Protection and Affordable Care Act of 2009 requiring pharmaceutical and medical device companies to report to the government payments to physicians, which are then made publicly available.

A chart provided by St. Joseph shows that Dr. Midei began heavy use of Abbott brand drug eluting stents in the third quarter of 2008.[25] In fact, he was among the physicians targeted by Abbott as a high volume user of stents. A 2007 Abbott document marked "Project Victory" ranks Dr. Midei among the "top volume" doctors in the Northeast.[26]

It is common practice among pharmaceutical companies and medical device companies to collaborate with physicians. Additionally, it is common practice for these same companies to cultivate top volume cardiologists, and this was indeed part of Abbott's marketing strategy regarding stents. An internal Abbott document labeled "Business Plan Q4'08" has a section titled "Action Items." One of the "Action Items" was to "Continue to elevate Mark Midei and the St. Joseph's group within the Abbott Corp (Senior [Management] visits, [Medical Advisory Board], research, VIP trips)."[27]

Abbott documents show that Company officials considered a May 23, 2007, debate between Dr. Midei and Johns Hopkins cardiologist

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[21] Katharine Van Tassel, Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines. *Seton Hall Law Review,* Vol. 36, No. 4, 2006; U. of Pittsburgh Legal Studies Research Paper. Available at SSRN: *http://ssrn.com/abstract=1262898.*

[22] Report of the Maryland Department of Health and Mental Hygiene on Hospital Utilization and Stents, Sept. 21, 2010. (*See* Appendix II, p. 61.)

[23] *Id.* (*See* Appendix II, p. 61.)

[24] *Id.* (*See* Appendix II, p. 61.)

[25] Stent Usage by Dr. Mark Midei, CY2006 Q1 thru CY2009 Q2, SJMC–SFC0046. (*See* Appendix II, p. 71.)

[26] Internal Abbott Chart, Top Volume NE Area MD's in Project Victory Accounts, ABBT0044568. (*See* Appendix II, p. 73.)

[27] Internal Abbott Document, "Business Plan Q4'08", ABBT0028214. (*See* Appendix II, p. 75.)

Dr. Stephen Schulman concerning the COURAGE study at a Ruth's Chris restaurant in Baltimore a "business activity." An internal Abbott document titled "Project Victory Account Strategy" listed: "Point counterpoint Courage, debate with Dr. Midei."[28]

An internal e-mail shows that when Abbott Executive Vice President John Capek learned in August 2008 that Dr. Midei had implanted "30 stents" in a single day, he stated that it "is the biggest day I remember hearing about even when the [Bare Metal Stent] market was the only market."[29]

An Abbott sales representative who marketed stents to Dr. Midei agreed with Capek: "He must be one of the highest implantors [sic] thus far."[30]

Capek wrote to Dr. Midei: "I heard thru the grapevine that you had a truly outstanding day with Xience in the labs on Friday, perhaps settiing [sic] the single day implant record."[31]

An Abbott Regional Sales Manager wrote to an Abbott sales representative who worked with Dr. Midei, lauding the sales representative's success in forming personal relationships with cardiologists. On December 29, 2008, he wrote:

> As you prepare to complete another year in the top 5 in rankings, I want to again congratulate you on this remarkable feat. Moreover, the relationships you have formed at accounts like St. Joe's, Union, and Hopkins are hallmarks of what every rep strives for in their accounts. In my 15 years of being in this business, I have never seen personal relationships as strong as the ones you have developed with Dr.'s Mark Midei, [name redacted], and [name redacted]."[32]

VI. Abbott Reimbursements for Events at Dr. Midei's Home

In response to Committee questions, Abbott disclosed that it reimbursed an Abbott employee $1,235 for a barbecue dinner at Mark Midei's home on August 31, 2008, two days after Dr. Midei's potentially setting the "single day implant record," as expressed by Abbott Executive Vice President of Medical Devices John Capek. Attendees included "Staff from the catheter lab at St Joseph's Medical Center, other healthcare professionals from the Baltimore area, several representatives from Abbott, and representatives from other manufacturers, and their guests."[33] The invoice lists an Abbott sales representative as the "Client/Organization" and describes the event "Theme" as "Appreciation Q/A #3."[34]

In addition to the August 31, 2008, barbecue dinner, Abbott disclosed to the Committee that it reimbursed an employee $690 for a July 21, 2008 crab dinner at Dr. Midei's home attended by Abbott

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[28] Project Victory Account Strategy St. Joseph Medical Center, ABBT0038290, Description of Event, "Controversies in Cardiology: Drug Eluting Stents versus Medical Therapy," ABBT0152209, and Abbott Employee calendar item, ABBT0000346. (*See* Appendix II, p. 84.)

[29] E-mails between Abbott Executive Vice Present of Medical Devices John Capek to an Abbott sales representative, Sept. 4, 2008, ABBT0000250. (*See* Appendix II, p. 93.)

[30] *Id.* (*See* Appendix II, p. 93.)

[31] E-mail from Abbott Executive Vice President of Medical Devices John Capek to Dr. Mark Midei, Sept. 4, 2008, ABBT0000880. (*See* Appendix II, p. 95.)

[32] Letter from an Abbott Regional Sales Manager to an Abbott sales representative, ABBT0028105. (*See* Appendix II, p. 97.)

[33] Abbott Response to Senate Finance Committee Questions received on Sept. 24, 2010.

[34] Andy Nelson's BBQ, Catering Contract, ABBT0028477. (*See* Appendix II, p. 99.)

employees in order to discuss "Abbott Vascular's products and business strategy." [35]

Internal e-mails suggest that Abbott and other medical device companies may have played some role in financing a "staff Christmas party" at Dr. Midei's home on December 20, 2008, based upon a contract in the Committee's possession. More specifically, Dr. Midei forwarded a proposed contract and menu for the party to an Abbott employee. The employee replied, "I have narrowed down the caterers. I am reviewing two proposals tonight and will give you all the information tomorrow morning." In an e-mail dated December 15, 2010, the employee sent Dr. Midei an e-mail with the subject, "Saturday," which reads: "Just to give you the total amount due $9050. So far $4250 has been called in per my last e-mail. Can you please have the girls call; St Jude—Tony and the CRM side", "Boston—Roger and Kevin", and "Medtronic—Kevin." [36]

However, in an e-mail to Committee staff, Abbott stated that it "has found no evidence that any Abbott employee paid for any expenses associated with this event or sought or received reimbursement for any such expenses." [37]

VII. Abbott and Dr. Midei after Allegations of Medically Unnecessary Procedures

After Dr. Midei was barred from practicing at St. Joseph due to a determination that he implanted patients with stents that were "not clinically indicated" [38] and may have been medically unnecessary, he contacted Dr. Charles A. Simonton, the Chief Medical Officer at Abbott Vascular, in July 2009. Dr. Midei wrote: "I'm not sure if you are aware of my situation in Baltimore, but if you've got a few minutes, I would really appreciate your advice." [39]

The Director of the Abbott Vascular Medical Science Group told Dr. Midei on November 11, 2009, that "Chuck Simonton and I are committed to assisting you in any way we can during this transition period. Please do not hesitate to call upon us at any time."

Dr. Midei responded: ". . . I might be interested in working with you if the opportunity arose. I would not rule out a full time position as my practice has been mortally wounded in Baltimore due to a toxic political environment." [40]

In December 2009, Abbott Senior Vice President Robert "Chip" Hance wrote to another Abbott employee:

> Mark talked to me about possibly doing some work for us. I'm very open to doing some consulting work with him to see how it might go—either getting the word out in China/

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[35] Abbott Response to Senate Finance Committee Questions, *supra* note 33. E-mail from an Abbott Regional Sales Manager, July 2, 2008, ABBT0001069. (*See* Appendix II, p. 103.)

[36] E-mails between Dr. Midei and Abbott employee, Nov. 24–25, 2009, and Dec. 15, 2010, ABBT0000866, ABBT0000867, ABBT0000889, ABBT0000891, and ABBT0001670. (*See* Appendix II, p. 105.)

[37] Abbott Response to Senate Finance Committee Questions, *supra* note 33.

[38] Report of the Ad Hoc Investigating Committee, *supra* note 7, at 4.

[39] E-mail from Dr. Midei to Charles Simonton, July 1, 2009, ABBT0001101. (*See* Appendix II, p. 114.)

[40] E-mails between the Director of the Abbott Vascular Medical Science Group employee and Dr. Midei, ABBT0052040. (*See* Appendix II, p. 116.)

> Japan, medical or safety work. I suggested he talk to all three of us and then we'd regroup after the meeting.[41]

Abbott paid Dr. Midei $30,623 in consulting fees after he was forced to resign from St. Joseph. This was ten times the amount of money he was previously paid by Abbott. In 2008 and 2009, Abbott paid Midei $3,400 and $3,000, respectively, for his work on the Medical Advisory Board.[42]

The serious allegations lodged against Dr. Midei regarding the medically unnecessary implantation of cardiac stents did not appear to deter Abbott's interest in assisting him. One Abbott employee wrote that employing Dr. Midei was "the right thing to do because he helped us so many times over the years."[43]

On January 12, 2010, Dr. Simonton wrote an e-mail outlining the work that Dr. Midei would do for Abbott. He wrote, "You are aware of the sensitivities in Baltimore, so would clearly avoid that region, but please find key physicians or cath labs you'd like him to get in front of with our data."[44]

However, due to the negative press Dr. Midei was receiving in Baltimore, Abbott decided it was a better strategy not to use Dr. Midei to market stents in the United States. Abbott Divisional Vice President Lance Scott wrote to Dr. Simonton and said:

> "[Abbott staff] and I discussed this morning and we recommend that we not use Dr. Midei in the US at this time (the press is just too hot). We recommend that we use Dr. Midei in the field in Japan/China as well as home office activities (including slide development, etc.)"[45]

Abbott also used Dr. Midei to work on a presentation called, "Lets [sic] talk about [Xience V] Safety." An Abbott Vascular Sales Trainer wrote in an e-mail to Abbott Vascular Chief Medical Officer: "I wanted to follow-up after my meeting with Dr Midei yesterday in Baltimore. As you know our primary goal was to review the 'Lets [sic] talk about XV Safety' deck that our team has been working on for the upcoming STAR meeting."[46]

According to the Abbott Vascular Clinical and Sales Integration Manager: "The purpose of this deck is to tell our best Xience V safety story."[47]

Bad publicity caused Dr. Midei's trip to Japan on behalf of Abbott to help market the Xience V stent to be cut short. Chief Medical Officer Dr. Simonton wrote to Abbott Vascular President Chip Hance on January 25, 2010 that "Dr. Midei understands the sensitivities and is returning to Baltimore today."[48]

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[41] E-mail from Senior Vice President Robert Hance, Dec. 4, 2009, ABBT0000669. (*See* Appendix II, p. 118.)

[42] Chart of Abbott Payments to Dr. Midei, St. Joseph's provided by Abbott. (*See* Appendix II, p. 120.)

[43] E-mail from an Abbott employee, Jan. 7, 2007, ABBT001054. (*See* Appendix II, p. 124.)

[44] E-mail from Abbott Vascular Chief Medical Officer Dr. Charles Simonton, Jan. 12, 2010, ABBT0000452. (*See* Appendix II, p. 126.)

[45] E-mail from Abbott Divisional Vice President Lance Scott, Jan. 15, 2010, ABBT0000220. (*See* Appendix II, p. 128.)

[46] E-mail from Abbott employee to Abbott Vascular Chief Medical Officer Dr. Charles Simonton, Jan. 16, 2010, ABBT0000760. (*See* Appendix II, p. 134.)

[47] E-mail from an Abbott employee, Feb. 1, 2010, ABBT0000218. (*See* Appendix II, p. 137.)

[48] E-mail from Abbott Vascular Chief Medical Officer Dr. Charles Simonton, Jan. 25, 2010, ABBT0052488. (*See* Appendix II, p. 139.)

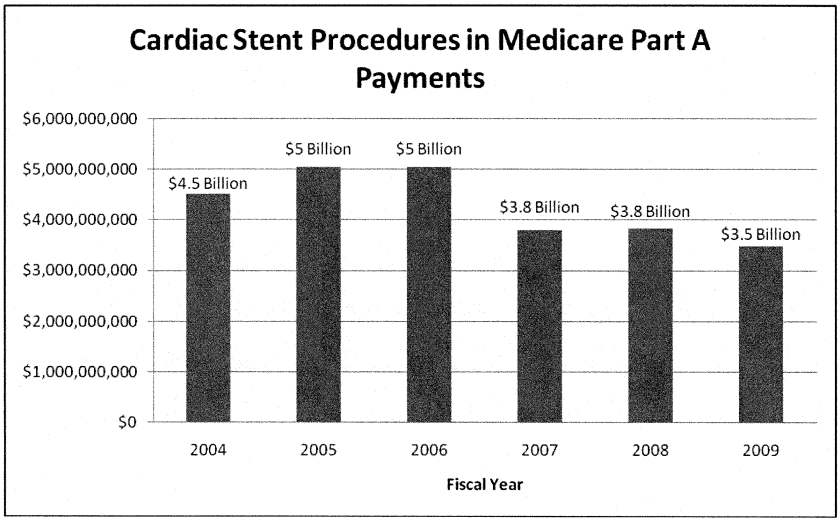
However, his work for Abbott Labs did not stop immediately. Dr. Simonton instructed an Abbott employee that "I would continue to work with him, behind the scenes, at this point. We've just decided not to have him doing any public type work in the U.S. right now." [49]

VIII. Cardiac Stent Usage in the U.S.

Stents as devices for coronary use were introduced into clinical practice in the mid 1980s. "By the end of 2002, in the United States, balloon-expandable stents were being implanted in more than 90 percent of all interventional coronary procedures, attesting to the generalized acceptance of this breakthrough technology." [50]

According to data provided to the Committee from the Centers for Medicare and Medicaid Services (CMS), Medicare Part A paid an estimated $25.7 billion for 1,863,823 inpatient stays where the patient's principal diagnosis was heart-related and the patient received a cardiac stent from FY2004 to FY2009.[51] Medicare Part B paid approximately $1.3 billion from CY2005–2009 for 248,116 procedures.[52]

Set forth below is a chart showing the cost of cardiac stent procedures paid for by Medicare Part A per year from 2004 through 2009.



[49] E-mail from Abbott Vascular Chief Medical Officer Dr. Charles Simonton, Feb. 2, 2010, ABBT0001107. (*See* Appendix II, p. 141.)

[50] Fuster, Topol, and Natel, *Atherothrombosis and Coronary Artery Disease,* at 1446. (Lipincott Williams and Wilkins, 2005).

[51] For FY2004 and FY2005, this included inpatient stays in diagnosis-related groups 517, 526, and 527. For FY2006 and FY2007, this included inpatient stays in diagnosis-related groups 556, 557, and 558. For FY2008 and FY2009, this included inpatient stays in Medicare-severity diagnosis-related groups 246, 247, 248, and 249. (*See* Appendix I, p. 17.)

[52] CMS Medical Device Data for the Senate Finance Committee. (*See* Appendix I, p. 17.)

IX. Studies Analyzing Stent Usage

A February 11, 2010, *Wall Street Journal* article reported that in the wake of the COURAGE study, "U.S. stent implants declined 13 percent in the month after the study's release. But as the headlines about [COURAGE] faded, stentings soon began to rise again, and are now back at peak levels of about one million a year, according to hospital surveyor Millennium Research Group."[53]

An internal Abbott report summarizing an Abbott Labs Medical Advisory Board meeting which took place October 13–14, 2007, mentioned the national drop in stent procedures following the COURAGE study. One of the "key takeaways" of the Medical Advisory Board meeting was that panelists "revealed candidly that they're [sic] profession has done a better job promoting PCI than policing it and that some of these practices have alienated their fellow cardiologists." In addition, Abbott noted,

> The [Medical Advisory Board] members were evenly split, with half thinking the drop in [drug eluding stent] usage and PCI volume represents a swing in the pendulum and the other half thinking it represents a new plateau (i.e., this was a necessary correction). Many cited the need to improve relationships with the cardiology community in order to help turn this around.[54]

In her recent book on health care, journalist Shannon Brownlee cites a joint Harvard University and Brown University study of stent usage from 2003 which notes that "more than two million Americans a year find themselves lying on a catheterization table" and roughly "eight hundred thousand of those catheterizations are considered absolutely necessary. Of the remaining "1.2 million elective cardiac procedures, at least 160,000 are 'inappropriate,' meaning they should not have been done, according to cardiologists' own rules for when to put in a stent or do an angioplasty."[55]

In January 2009, the Associated Press reported that a *New England Journal of Medicine* study "gives fresh evidence that many people with clogged heart arteries are being treated too often with stents, and that a simple blood-flow test might help prevent unnecessary care."[56] In addition, Reuters recently reported that a study published in *Circulation,* a medical journal published by the American Heart Association, found that, "U.S. heart patients are more likely to undergo stenting procedures to clear blocked coronary arteries than Canadians."[57]

If it is the case that potentially millions of procedures conducted in the United States are medically unnecessary, the situation at St. Joseph may very well be emblematic of a larger problem. *Sun* columnist Jay Hancock wrote on January 22, 2010:

> Thanks to extraordinary promotion and advertising, stents have become a multibillion-dollar business, substantially

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[53] Keith J. Winstein, *supra* note 12.

[54] Abbott Medical Advisory Board Meeting October 13–14, 2007, Summary Report, January 2008, ABBT0161927. (*See* Appendix II, p. 143.)

[55] Shannon Brownlee, *Overtreated: Why Too Much Medicine Is Making Us Sicker and Poorer,* 99 (Bloomsbury, 2007).

[56] Marilynn Marchione, *Stents Overused in Heart Patients, Study Says,* AP, Jan. 15, 2009.

[57] Anne Harding, *Heart Stents Used Twice as Often in U.S. vs. Canada,* Reuters, June 15, 2010.

> contributing to soaring medical-insurance costs and federal deficits. They're a perfect illustration of why American health care costs more but delivers less. [58]

In response to the *Sun* column, Vice President of Global Marketing for Abbott Vascular David C. Pacitti wrote to Abbott Divisional Vice President for Sales Sam L. Conaway: "Don't you have connections in Baltimore????? Someone needs to take this writer outside and kick his ass! Do I need to send the Philly mob?" [59]

Similar to the aftermath of the COURAGE trial, the publicity surrounding Dr. Midei may have prompted other cardiologists in the Baltimore region to reduce their procedure volume. According to an Abbott sales representative who marketed stents to Dr. Midei, the increased scrutiny after the revelations of alleged medically unnecessary stent procedures at St. Joseph led to a decline in the volume of stent procedures in the entire Baltimore area. The sales representative wrote in an e-mail:

> I did look at a Year on Year comparison through the end of February (per your request Chal to try to capture true trends) and the overall decline in numbers were ugly . . . Although the decline was first noted at the time Dr. Midei was dismissed of his duties at St. Josephs in May, the most devastating impact occurred in November into December when the media, [HHS Office of Inspector General] and lawyers became involved in a very aggressive manner.[60]

X. Medicare Spending for Medical Device Procedures

CMS provided the following figures for total spending for 2005 to 2009 for diagnosis-related groups (DRGs) related to medical devices generally. The Medicare DRG system "pays hospitals a set fee for each diagnosis, regardless of how much the individual patient actually costs the hospital." [61]

The following table shows Medicare Part A payments for medical device related DRGs.

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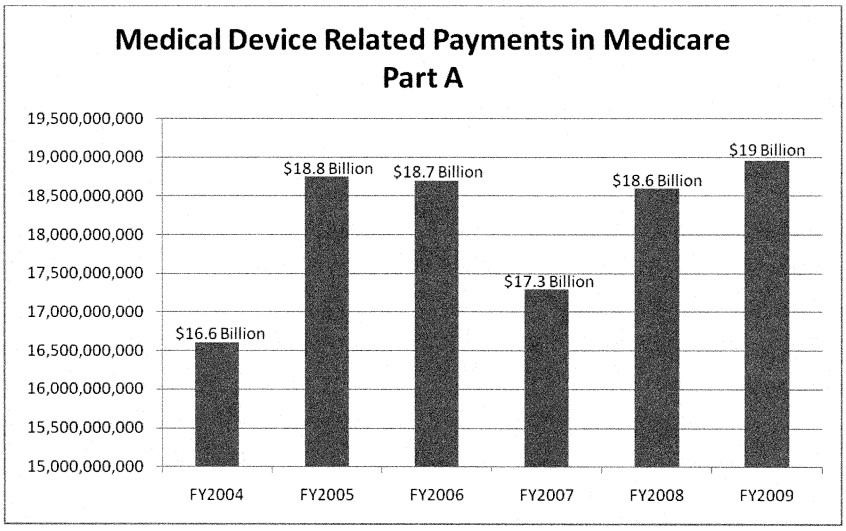
[58] Jay Hancock, *Heart-stent Popularity is Costly in Many Ways,* BALT. SUN, Jan. 22, 2010.

[59] E-mail from Abbott Vascular Vice President of Global Marketing David Pacitti to Abbott Divisional Vice President for Sales Sam Conaway, ABBT000237. (*See* Appendix II, p. 160.)

[60] E-mail from an Abbott sales representative, Mar. 9, 2010, ABBT0225906. (*See* Appendix II, p. 163.)

[61] Shannon Brownlee, *supra* note 49.



Medicare Part A paid an estimated $108.9 billion for 6.9 million procedures related to medical devices from FY2004 to FY2009.[62]

According to an analysis prepared for the Advanced Medical Technology Association (AdvaMed), total medical device spending was $131.6 billion in 2006.[63]

The following table from CMS shows the year by year increases or decreases in the DRGs associated with medical devices compared with all DRGs.

DRG Category	% Change 2005	% Change 2006	% Change 2007	% Change 2008	% Change 2009
ALL DEVICE DRG TOTALS	12.94%	-0.34%	-7.48%	7.57%	1.90%
ALL NON DEVICE TOTALS	4.75%	0.11%	2.53%	2.12%	4.67%

CMS believes the swings in payment between FY2006 and FY2008 reflect the significant changes in the inpatient Prospective Payment System (PPS) that were occurring during that time; that is, the transition to cost-based relative weights and to MS-DRGs, respectively. The increase of 1.90 percent from FY2008 to FY2009 reflects the beginning of more stable payment trends.

[62] CMS Medical Device Data for the Senate Finance Committee. (*See* Appendix I, p. 17.)

[63] Gerald Donahoe and Guy King, Estimates of Medical Device Spending in the US, May 2009, at 2 available at *http://www.advamed.org/NR/rdonlyres/6ADAAA5B-BA37-469E-817B-3D61DEC4E7C8/0/King2009FINALREPORT52909.pdf.*

The following table reflects changes in average payment per case for device dependent DRGs and all other DRGs in the aggregate.

DRG Category	% Change 2005	% Change 2006	% Change 2007	% Change 2008	% Change 2009
ALL DEVICE DRG TOTALS	5.97%	1.92%	-9.91%	-3.37%	2.16%
ALL NON DEVICE TOTALS	5.26%	4.07%	-5.97%	1.28%	3.54%

XI. Conclusion

Medical devices are miracles of modern medicine that help save and improve lives. Cardiac stents are among the medical miracles that can greatly improve someone's life but can be damaging if they are used inappropriately and unnecessarily. Equally important, the Medicare and Medicaid programs are intended to provide medical devices, like cardiac stents, only to those who need them. In the case of St. Joseph, Dr. Midei often implanted cardiac stents without clinical indication and many may have been medically unnecessary, potentially putting at least 585 patients in harm's way.

Due to a failure of its peer review process, St. Joseph was unaware of any problems in its catheterization lab until receiving a complaint from a patient concerned about the treatment received. Concerns remain about whether St. Joseph acted appropriately by limiting the scope of its review of patient records to exclude those implanted with stents before 2007. Patients may have received medically unnecessary cardiac stents from Dr. Midei without ever having been informed by the hospital.

With health care costs soaring at a rate well above other sectors of the U.S. economy, it is important to examine each element of the health care sector to identify ways to either moderate cost increases or to reduce costs. The impact on the federal budget of health care costs also demands that each health care dollar is spent on necessary medical care only.

This joint staff report explores two practices that put upward pressure on health care costs. The St. Joseph's panel of experts finding that the 585 stents implanted were without clinical indication and probably medically unnecessary is a clear example of potential fraud, waste, and abuse. Fraud, waste, and abuse is estimated to cost the medical sector at least $60 billion a year, or about 3 percent of health care spending;[64] this report describes an element of that cost.

The second practice—efforts by medical device and other health companies to encourage the increased utilization of medical products—is harder to quantify. Accordingly, there is a question that remains as to whether or not Abbott Laboratories indirectly encouraged Dr. Midei to intensify his use of stents, with unfortunate results.

[64] The cost estimate for health care waste, fraud, and abuse is from the National Health Care Anti-Fraud Association. *See http://www.nhcaa.org.*

In addition, one of the deficiencies at St. Joseph discovered by the Maryland Office of Health Quality officials was that Dr. Midei, as head of the cardiology department, was allowed to select which cases were peer reviewed. This raises concerns about peer review processes in place at hospitals and may require that state governments and medical societies review best practices to strengthen peer review and ensure that doctors performing procedures are not in a position to select which cases undergo peer review.

The allegations of medically unnecessary cardiac stent procedures at St. Joseph Medical Center have put the spotlight on potentially improper use of stents by physicians and hospitals. In response to concerns raised by the events at St. Joseph, the Maryland Health Services Cost Review Commission, a state agency responsible for setting Medicare rates in Maryland, is determining which hospitals have higher than average cardiac stent procedures.[65] This effort may be a model to ensure hospitals focus on the issue of possible cardiac stent overutilization, ensuring that patients are protected from medically unnecessary surgery and tax dollars are not wasted.

Given that $25.7 billion was spent by Medicare Part A from FY2004–FY2009 on cardiac stent procedures and $108.9 billion was spent on medical device related procedures during the same period, the Committee will continue to monitor issues relevant to improper use of cardiac stents and medical device procedures and perhaps most importantly the mechanisms in place to identity such situations at the earliest possible time.

[65] Tricia Bishop and Robert Little, *St. Joseph, Two Others, Had Highest Stent Rates: Hospitals in Towson, Baltimore and Takoma Park Lead Maryland in Costly Procedure,* BALT. SUN, July 4, 2010.

APPENDIX I

MEDICAL DEVICE AND CARDIAC STENT
PAYMENT DATA FROM THE CENTERS
FOR MEDICARE AND MEDICAID SERVICES

Medical Device Data for Senate Finance Committee
Percent Change in Payment Per Case
FY 2004 - FY 2008

DRG Category	% Change 2005	% Change 2006	% Change 2007	% Change 2008	% Change 2009
ALL DEVICE DRG TOTALS	5.97%	1.92%	-9.91%	-3.37%	2.16%
ALL NON DEVICE TOTALS	5.26%	4.07%	-5.97%	1.28%	3.54%

		FY 2004			FY 2005			FY 2006			FY 2007		
CMS DRG	DRG TITLES - 2004-2007	Payments	Cases	Payment Per Case	Payments	Cases	Payment Per Case	Payments	Cases	Payment Per Case	Payments	Cases	Payment Per Case
103	HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM	93,798,396	575	$163,128	153,368,568	878	$174,679	174,958,300	980	$178,529	174,377,014	1,073	$162,514
104	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W CARD CATH	1,057,484,071	21,030	$ 50,285	1,058,323,176	20,020	$ 52,863	1,014,802,535	19,207	$ 52,835	1,019,627,831	21,172	$ 48,159
105	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W/O CARD CATH	1,143,553,769	31,547	$ 36,249	1,253,226,878	32,317	$ 38,779	1,260,236,723	31,707	$ 39,746	1,296,351,685	36,096	$ 35,914
115	PRM CARD PACEM IMPL W AMI/HR/SHOCK OR AICD LEAD OR GNRTR	456,365,571	22,034	$ 20,712	476,264,276	21,540	$ 22,111			N/A			N/A
116	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT	1,561,029,492	117,785	$ 13,253	1,563,122,263	113,068	$ 13,825			N/A			N/A
118	CARDIAC PACEMAKER DEVICE REPLACEMENT	71,728,212	7,608	$ 9,428	77,627,565	7,612	$ 10,198	80,873,227	7,901	$ 10,236	86,025,729	8,851	$ 9,719
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY	5,119,109,993	457,387	$ 11,192	5,702,730,954	485,110	$ 11,756			N/A			N/A
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY	277,033,376	15,588	$ 17,772	311,473,147	16,631	$ 18,728	361,424,282	18,648	$ 19,381	279,517,514	15,591	$ 17,928
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	881,286,673	27,315	$ 32,264	1,538,868,852	43,882	$ 35,068	1,995,748,420	56,982	$ 35,024	1,731,615,683	56,312	$ 30,750
517	PERC CARDIO PROC W NON-DRUG ELUTING STENT W/O AMI	798,645,520	66,042	$ 12,093	308,361,635	24,941	$ 12,364			N/A			N/A
525	HEART ASSIST SYSTEM IMPLANT	45,131,130	356	$126,773	20,466,484	209	$ 97,926	15,037,658	150	$100,251	14,052,810	159	$ 88,382
526	PERCUTNEOUS CARDIOVASULAR PROC W DRUG ELUTING STENT W AMI	977,754,491	55,511	$ 17,614	1,383,994,789	75,938	$ 18,225			N/A			N/A
527	PERCUTNEOUS CARDIOVASULAR PROC W DRUG ELUTING STENT W/O AMI	2,736,313,109	191,695	$ 14,274	3,358,498,935	237,177	$ 14,160			N/A			N/A
535	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK	641,682,395	13,052	$ 49,164	722,849,831	14,706	$ 49,153	443,098,510	8,514	$ 52,044	393,592,851	8,844	$ 44,504
536	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK	744,908,651	19,682	$ 37,847	660,433,254	16,505	$ 40,014	348,642,854	7,716	$ 45,184	316,133,346	7,884	$ 40,098
543	CRANIOTOMY W MAJOR DEVICE IMPLANT OR ACUTE COMPLEX CNS PRINCIPAL DIAGNOSIS			N/A	164,685,076	5,493	$ 29,981	168,223,549	5,457	$ 30,827	188,200,629	6,685	$ 28,153
544	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY			N/A			N/A	5,190,320,310	437,761	N/A	5,381,905,537	483,960	$ 11,121
545	REVISION OF HIP OR KNEE REPLACEMENT			N/A			N/A	623,399,147	40,197	N/A	710,959,422	48,637	$ 14,618
551	PERMANENT CARDIAC PACEMAKER IMPL W MAJ CV DX OR AICD LEAD OR GNRTR			N/A			N/A	981,403,033	50,750	N/A	932,331,344	53,143	$ 17,544
552	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT W/O MAJOR CV DX			N/A			N/A	983,918,226	77,734	N/A	966,195,443	83,140	$ 11,621
556	PERCUTANEOUS CARDIOVASC PROC W NON-DRUG-ELUTING STENT W/O MAJ CV DX			N/A			N/A	205,735,330	17,756	N/A	463,931,413	45,415	$ 10,215
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX			N/A			N/A	2,320,644,556	127,452	N/A	1,609,206,972	100,251	$ 16,052
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX			N/A			N/A	2,521,772,928	182,326	N/A	1,727,538,004	143,467	$ 12,041
	total device	**16,605,824,849**	**1,047,207**	**15,857**	**18,754,295,683**	**1,116,027**	**16,805**	**18,690,239,588**	**1,091,238**	**17,128**	**17,291,563,227**	**1,120,680**	**15,430**
	ALL OTHER DRG TOTALS	**88,585,108,813**	**10,994,842**	**8,057**	**92,795,934,530**	**10,942,398**	**8,480**	**92,899,154,366**	**10,525,750**	**8,826**	**95,245,300,451**	**11,477,252**	**8,299**
	TOTAL ALL	**105,190,933,662**	**12,042,049**	**8,735**	**111,550,230,213**	**12,058,425**	**9,251**	**111,589,393,954**	**11,616,988**	**9,606**	**112,536,863,678**	**12,597,932**	**8,933**

MS-DRG	MS-DRG Title FY 2008	FY 2008 Payments	FY 2008 Cases	FY 2008 Payment Per Case	FY 2009 Payments	FY 2009 Cases	FY 2009 Payment Per Case
1	Heart transplant or implant of heart assist system w MCC	206,652,652	1,000	$206,653	246,279,517	1,159	$212,493
2	Heart transplant or implant of heart assist system w/o MCC	30,573,778	249	$122,786	32,775,997	279	$117,477
23	Cranio w major dev impl/acute complex CNS PDX w MCC or chemo implant	162,833,980	5,078	$ 32,067	185,581,330	5,449	$ 34,058
24	Cranio w major dev impl/acute complex CNS PDX w/o MCC	58,373,696	2,477	$ 23,566	47,043,977	2,097	$ 22,434
29	Spinal procedures w CC or spinal neurostimulators	69,177,052	3,847	$ 17,982	74,321,073	4,024	$ 18,469
34	Carotid artery stent procedure w MCC	16,296,935	1,003	$ 16,248	23,075,197	1,152	$ 20,031
35	Carotid artery stent procedure w CC	30,107,160	2,697	$ 11,163	30,372,814	2,641	$ 11,500
36	Carotid artery stent procedure w/o CC/MCC	65,158,060	6,772	$ 9,622	61,101,399	6,972	$ 8,764
129	Major head & neck procedures w CC/MCC or major device	22,897,706	1,829	$ 12,519	27,559,062	1,864	$ 14,785
215	Other heart assist system implant	13,779,192	165	$ 83,510	18,748,031	213	$ 88,019
216	Cardiac valve & oth maj cardiothoracic proc w card cath w MCC	660,979,673	11,717	$ 56,412	760,053,249	12,772	$ 59,509
217	Cardiac valve & oth maj cardiothoracic proc w card cath w CC	313,514,616	7,487	$ 41,875	287,123,461	7,385	$ 38,879
218	Cardiac valve & oth maj cardiothoracic proc w card cath w/o CC/MCC	63,673,245	1,694	$ 37,588	47,407,573	1,563	$ 30,331
219	Cardiac valve & oth maj cardiothoracic proc w/o card cath w MCC	677,767,743	14,816	$ 45,746	852,357,469	17,197	$ 49,564
220	Cardiac valve & oth maj cardiothoracic proc w/o card cath w CC	551,118,684	16,700	$ 33,001	588,292,615	19,005	$ 30,955
221	Cardiac valve & oth maj cardiothoracic proc w/o card cath w/o CC/MCC	172,712,138	5,970	$ 28,930	138,950,240	5,646	$ 24,610
222	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK W MCC	192,283,231	3,821	$ 50,323	209,342,533	3,978	$ 52,625
223	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK W/O MCC	203,892,556	5,206	$ 39,165	147,477,698	4,043	$ 36,477
224	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK W MCC	156,973,046	3,453	$ 45,460	171,761,910	3,638	$ 47,213
225	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK W/O MCC	202,873,683	5,575	$ 36,390	176,812,966	5,198	$ 34,016
226	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH W MCC	343,546,089	9,515	$ 36,106	431,233,622	10,719	$ 40,231
227	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH W/O MCC	1,137,379,747	38,670	$ 29,412	1,000,660,191	34,787	$ 28,765
242	PERMANENT CARDIAC PACEMAKER IMPLANT W MCC	450,145,909	24,580	$ 18,314	576,753,141	28,042	$ 20,567
243	PERMANENT CARDIAC PACEMAKER IMPLANT W CC	609,988,277	43,464	$ 14,034	604,181,615	42,568	$ 14,193
244	PERMANENT CARDIAC PACEMAKER IMPLANT W/O CC/MCC	681,340,518	58,651	$ 11,617	592,327,878	54,390	$ 10,890
245	AICD GENERATOR PROCEDURES	135,409,297	7,237	$ 18,711	116,692,376	4,842	$ 24,100
246	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W MCC OR 4+ VESSELS/STENTS	608,037,683	35,083	$ 17,331	789,457,353	42,020	$ 18,788
247	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W/O MCC	2,068,532,898	172,820	$ 11,969	1,855,246,910	171,746	$ 10,802
248	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W MCC OR 4+ VES/STENTS	348,742,571	22,544	$ 15,469	330,186,792	19,507	$ 16,927
249	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W/O MCC	803,967,258	78,130	$ 10,290	504,724,801	54,002	$ 9,346
250	Perc cardiovasc proc w/o coronary artery stent or AMI w MCC	151,114,859	9,348	$ 16,165	203,609,879	10,621	$ 19,170
251	Perc cardiovasc proc w/o coronary artery stent or AMI w/o MCC	461,872,021	44,040	$ 10,488	416,166,409	42,133	$ 9,877
258	CARDIAC PACEMAKER DEVICE REPLACEMENT W MCC	13,899,484	997	$ 13,941	20,059,445	1,166	$ 17,204
259	Cardiac pacemaker device replacement w/o MCC	67,317,648	7,088	$ 9,497	56,375,067	5,810	$ 9,703
461	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY W MCC	27,519,704	1,166	$ 23,602	26,987,190	1,009	$ 26,746
462	Bilateral or multiple major joint procs of lower extremity w/o MCC	250,526,029	13,840	$ 18,102	242,954,300	13,118	$ 18,521
466	REVISION OF HIP OR KNEE REPLACEMENT W MCC	108,373,327	5,225	$ 20,741	138,617,901	5,485	$ 25,272
467	REVISION OF HIP OR KNEE REPLACEMENT W CC	303,679,464	19,784	$ 15,350	383,541,390	22,878	$ 16,765
468	REVISION OF HIP OR KNEE REPLACEMENT W/O CC/MCC	274,525,725	19,777	$ 13,881	266,738,413	19,154	$ 13,926
469	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY W MCC	577,571,351	40,589	$ 14,230	685,672,389	40,083	$ 17,106
470	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY W/O MCC	5,061,216,668	466,370	$ 10,852	5,304,673,083	486,821	$ 10,897
490	BACK & NECK PROC EXC SPINAL FUSION W CC/MCC OR DISC DEVICE/NEUROSTIM	243,959,961	27,053	$ 9,018	280,748,488	27,170	$ 10,333
	total device	**18,600,305,314**	**1,247,527**	**14,910**	**18,954,046,744**	**1,244,346**	**15,232**
ALL OTHE	**ALL OTHER DRG TOTALS**	**97,262,539,071**	**11,572,593**	**8,405**	**101,808,699,094**	**11,698,927**	**8,702**
	TOTAL ALL	**115,862,844,385**	**12,820,120**	**9,038**	**120,762,745,838**	**12,943,273**	**9,330**

Total Stent Procedures FY2004-FY2009

Medicare Part B Spending on Cardiac Stent Procedures by Region

Stent Study - Payment and Units by Region (2005 - 2009 claims)

APC 104: Transcatheter Placement of Intracoronary Stents

APC 656: Transcatheter Placement of Intracoronary Drug-Eluting Stents

	2011 Proposed Rule Data (partial year CY 2009 claims, inflated by 10% to estimate full year data)											
	Non-Drug Eluting				Drug Eluting				Total			
Region	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year
East North Central	3,859	11.7%	$16,471,991	9.9%	10,922	57.4%	$67,422,967	58.4%	14,781	42.2%	$83,894,958	45.8%
East South Central	2,303	20.6%	$9,037,539	19.7%	7,341	49.2%	$41,676,250	50.3%	9,645	41.2%	$50,713,789	43.7%
Middle Atlantic	1,379	40.5%	$6,326,066	37.8%	4,278	76.6%	$29,019,350	80.1%	5,657	66.1%	$35,345,416	70.7%
Mountain	948	0.9%	$4,046,724	0.4%	3,720	39.6%	$23,191,883	42.7%	4,668	29.5%	$27,238,608	34.3%
New England	593	113.3%	$2,829,343	112.7%	1,178	115.0%	$7,972,198	119.1%	1,771	114.4%	$10,801,541	117.4%
Pacific	1,577	14.7%	$8,049,420	13.2%	5,469	51.0%	$39,333,511	54.3%	7,047	41.0%	$47,382,931	45.3%
South Atlantic	4,304	4.8%	$17,863,164	3.1%	15,268	41.1%	$91,670,905	42.1%	19,572	31.1%	$109,534,069	33.8%
West North Central	1,892	41.0%	$7,800,651	39.8%	6,303	70.3%	$37,421,433	72.8%	8,195	62.5%	$45,222,084	66.1%
West South Central	3,934	27.2%	$15,835,815	24.4%	13,136	50.1%	$76,919,375	51.0%	17,070	44.1%	$92,755,190	45.7%
Total	20,790	18.9%	$88,260,713	17.3%	67,616	52.3%	$414,627,873	54.2%	88,406	42.9%	$502,888,586	46.1%

	2010 Final Rule Data (CY 2008 claims)											
	Non-Drug Eluting				Drug Eluting				Total			
Region	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year
East North Central	3,454	79.4%	$14,981,981	90.1%	6,941	92.7%	$42,577,128	124.4%	10,395	88.1%	$57,559,109	114.4%
East South Central	1,910	27.7%	$7,551,663	33.6%	4,921	132.0%	$27,732,262	164.5%	6,831	88.9%	$35,283,925	118.7%
Middle Atlantic	982	27.0%	$4,590,729	35.6%	2,423	53.1%	$16,116,379	81.5%	3,405	44.5%	$20,707,108	68.8%
Mountain	940	66.7%	$4,031,153	73.3%	2,665	113.4%	$16,251,570	142.7%	3,605	98.8%	$20,282,723	124.8%
New England	278	89.1%	$1,330,231	107.4%	548	133.2%	$3,639,229	162.1%	826	116.2%	$4,969,461	144.8%
Pacific	1,375	33.8%	$7,111,835	44.9%	3,623	85.5%	$25,495,301	116.6%	4,998	67.7%	$32,607,136	95.5%
South Atlantic	4,106	61.5%	$17,328,868	70.2%	10,818	98.6%	$64,515,790	126.9%	14,924	86.8%	$81,844,658	111.9%
West North Central	1,342	53.0%	$5,581,285	61.7%	3,702	129.4%	$21,652,438	162.4%	5,044	102.5%	$27,233,723	132.7%
West South Central	3,093	47.6%	$12,725,133	57.5%	8,752	99.1%	$50,949,519	130.3%	11,845	82.5%	$63,674,652	110.8%
Total	17,480	52.7%	$75,232,879	61.8%	44,393	100.0%	$268,929,616	129.9%	61,873	83.9%	$344,162,495	110.5%

Region	2009 Final Rule Data (CY 2007 claims)											
	Non-Drug Eluting				Drug Eluting				Total			
	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year
East North Central	1,925	145.2%	$7,882,094	187.4%	3,602	-19.8%	$18,970,268	-16.5%	5,527	4.7%	$26,852,362	5.5%
East South Central	1,496	87.5%	$5,653,397	111.1%	2,121	-35.9%	$10,483,444	-33.5%	3,617	-11.9%	$16,136,842	-12.5%
Middle Atlantic	773	109.5%	$3,385,183	134.0%	1,583	-5.6%	$8,879,292	0.4%	2,356	15.2%	$12,264,474	19.2%
Mountain	564	99.3%	$2,326,725	140.6%	1,249	-17.3%	$6,695,545	-14.2%	1,813	1.1%	$9,022,270	2.8%
New England	147	137.1%	$641,431	156.2%	235	-25.6%	$1,388,384	-22.3%	382	1.1%	$2,029,815	-0.4%
Pacific	1,028	35.4%	$4,908,257	59.5%	1,953	-30.5%	$11,771,578	-25.7%	2,981	-16.5%	$16,679,835	-11.8%
South Atlantic	2,542	116.3%	$10,180,609	151.8%	5,448	-11.6%	$28,439,615	-7.3%	7,990	8.9%	$38,620,223	11.2%
West North Central	877	155.7%	$3,451,338	201.4%	1,614	-8.4%	$8,251,704	-5.1%	2,491	18.3%	$11,703,042	18.9%
West South Central	2,096	127.1%	$8,081,631	161.3%	4,396	-8.4%	$22,119,057	-6.1%	6,492	13.5%	$30,200,689	13.3%
Total	11,448	108.3%	$46,510,665	139.2%	22,201	-17.3%	$116,998,886	-13.8%	33,649	4.1%	$163,509,551	5.4%

Region	2008 Final Rule Data (CY 2006 claims)											
	Non-Drug Eluting				Drug Eluting				Total			
	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year
East North Central	785	8.7%	$2,742,100	12.0%	4,492	1.6%	$22,708,125	9.5%	5,277	2.6%	$25,450,224	9.7%
East South Central	798	-9.1%	$2,677,817	4.4%	3,307	-15.3%	$15,766,341	-8.4%	4,105	-14.2%	$18,444,158	-6.8%
Middle Atlantic	369	5.1%	$1,446,369	14.0%	1,677	-10.3%	$8,839,573	-5.3%	2,046	-7.8%	$10,285,942	-3.0%
Mountain	283	4.0%	$966,977	5.7%	1,511	6.6%	$7,808,210	17.8%	1,794	6.2%	$8,775,188	16.3%
New England	62	-31.9%	$250,385	-20.6%	316	-37.5%	$1,787,047	-33.6%	378	-36.7%	$2,037,432	-32.2%
Pacific	759	-1.9%	$3,077,263	3.3%	2,810	6.4%	$15,833,283	15.0%	3,569	4.5%	$18,910,545	13.0%
South Atlantic	1,175	40.7%	$4,042,649	47.6%	6,162	28.1%	$30,689,332	36.8%	7,337	30.0%	$34,731,981	38.0%
West North Central	343	59.5%	$1,145,265	63.2%	1,762	11.8%	$8,697,913	22.7%	2,105	17.5%	$9,843,178	26.4%
West South Central	923	-15.4%	$3,092,972	-13.6%	4,798	-12.5%	$23,556,811	-4.8%	5,721	-13.0%	$26,649,782	-5.9%
Total	5,497	5.1%	$19,441,796	11.0%	26,835	0.8%	$135,686,634	8.9%	32,332	1.5%	$155,128,430	9.1%

Region	2007 Final Rule Data (CY 2005 claims)											
	Non-Drug Eluting				Drug Eluting				Total			
	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year	Units	% Change from Prior Year	Payment	% Change from Prior Year
East North Central	722	n/a	$2,448,922	n/a	4,421	n/a	$20,746,733	n/a	5,143	n/a	$23,195,654	n/a
East South Central	878	n/a	$2,564,022	n/a	3,904	n/a	$17,219,896	n/a	4,782	n/a	$19,783,918	n/a
Middle Atlantic	351	n/a	$1,268,288	n/a	1,869	n/a	$9,337,797	n/a	2,220	n/a	$10,606,085	n/a
Mountain	272	n/a	$914,498	n/a	1,418	n/a	$6,627,705	n/a	1,690	n/a	$7,542,204	n/a
New England	91	n/a	$315,482	n/a	506	n/a	$2,690,037	n/a	597	n/a	$3,005,518	n/a
Pacific	774	n/a	$2,978,824	n/a	2,642	n/a	$13,763,025	n/a	3,416	n/a	$16,741,849	n/a
South Atlantic	835	n/a	$2,739,700	n/a	4,809	n/a	$22,428,654	n/a	5,644	n/a	$25,168,354	n/a
West North Central	215	n/a	$701,915	n/a	1,576	n/a	$7,087,377	n/a	1,791	n/a	$7,789,292	n/a
West South Central	1,091	n/a	$3,581,474	n/a	5,482	n/a	$24,735,234	n/a	6,573	n/a	$28,316,707	n/a
Total	5,229	n/a	$17,513,126	n/a	26,627	n/a	$124,636,457	n/a	31,856	n/a	$142,149,583	n/a

APPENDIX II

SELECT DOCUMENTS CITED IN THIS REPORT

FOOTNOTE 2, 3

St. Joseph Medical Center
Update on Federal Investigation and Issues
February 2010

Cooperating with Federal Investigation

- St. Joseph Medical Center (SJMC) was served with a subpoena on June 3, 2008 in connection with a civil investigation conducted by the U.S. Department of Justice (DOJ) and the Office of Inspector General of the U.S. Department of Health and Human Services (OIG)
    - Subpoena focused on the financial relationship between Midatlantic Cardiovascular Associates (MACVA) and SJMC
- SJMC has cooperated fully with DOJ and OIG beginning very early in the investigation
- In July 2009, an agreement in principle was reached with the DOJ to resolve all potential liability to federal health care programs and the Maryland Medicaid program, the terms of which include:
    - A financial penalty to the federal and state government; and
    - A Corporate Integrity Agreement (CIA), which will require SJMC to strengthen its corporate responsibility program, peer review process and oversight.
- SJMC anticipates that the DOJ will approve the final agreement in the coming months and has already implemented many of the changes called for in the Corporate Integrity Agreement

Cardiac Catheterization – Fully Informing Patients and Their Physicians

- SJMC first became aware of a patient care/quality issue in its Cardiac Catheterization Lab on approximately April 27, 2009, when a patient, who was then an employee of SJMC, indicated concerns with the treatment he had received by a certain physician. At about the same time, the federal government inquired about the same physician's utilization data.
- SJMC acted immediately to investigate the matter and on May 12, 2009, relieved this physician of all patient care responsibilities after it was determined that the complaint had merit
- SJMC immediately engaged a panel of experts to review additional patient records and determined a quality problem existed with this physician
- SJMC began an intensive effort to look-back and review all cases that involved this physician for two years and required the gathering of experts and the review of thousands of cases
- SJMC acted in the best interests of its patients by putting patient safety first, performing individual reviews and notifying affected patients and physicians
    - In total, 585 Patients (and their treating/referring physicians) were notified of the subsequent clinical review of their stent procedures performed by the physician

Moving Forward: Strengthen Oversight Systems

SJMC has already begun to implement changes throughout the hospital to strengthen oversight. These include, but are not limited to:

- Strengthening SJMC's Corporate Responsibility Program, including a disclosure program
- Continuing extensive training and education of governance, management, and staff
- Revising a detailed physician contract review process
- Updating an appropriate and effective peer review mechanism for the Cardiac Catheterization Lab
- Reviewing and revising policies and procedures for corporate responsibility, quality, peer review, credentialing, oversight & management of Cardiac Catheterization Lab
- Engaging a peer review consultant to assist with assessment and development of peer review program
- Engaging an Independent Review Organization (IRO) to conduct perform a review of program implementation and effectiveness

FOOTNOTE 4

IN THE MATTER OF	*	**BEFORE THE MARYLAND STATE**
MARK G. MIDEI, M.D.	*	**BOARD OF PHYSICIANS**
Respondent	*	**Case Numbers: 2009-0364**
		2009-0803
License Number: D30042	*	**2010-0036**

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

CHARGES UNDER THE MARYLAND MEDICAL PRACTICE ACT

The Maryland State Board of Physicians (the "Board") hereby charges Mark G. Midei, M.D. (the "Respondent") (D.O.B. 06/24/1957), License Number D30042, under the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 14-401 *et seq.* (2009 Repl.Vol.).

The pertinent provisions of the Act under H.O. § 14-404(a) provide as follows:

§ 14-404. Denials, reprimands, probations, suspensions, and revocations – Grounds.

(a) *In general.* Subject to the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of the quorum, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:

(3) Is guilty of:

...

(ii) Unprofessional conduct in the practice of medicine;

(11) Willfully makes or files a false report or record in the practice of medicine;

(19) Grossly overutilizes health care services;

(22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State; and

(40) Fails to keep adequate medical records as determined by appropriate peer review.

GENERAL ALLEGATIONS OF FACT[1]

The Board bases its charges on the following facts that the Board has reason to believe are true:

1. At all times relevant hereto, the Respondent, who is board-certified in cardiology, was and is licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on October 18, 1983. His license will expire on September 30, 2011.
2. At all times relevant hereto, the Respondent was the Director of the Cardiac Catheterization Laboratory at St. Joseph Medical Center ("SJMC") in Towson, Maryland, a position he had held as of January 1, 1995. While functioning in that capacity, the Respondent was a member of Mid-Atlantic Cardiologist Associates until January 21, 2008, when he was hired by SJMC.
3. In November 2008, the Board received the first of several complaints that the Respondent was performing cardiac stent procedures in the absence of medical necessity and sufficient clinical indications.
4. A stent is a cylindrical metal mesh tube or scaffolding that is placed in a coronary artery or arteries where there is a severe blockage or "lesion," the purpose of which is to keep the artery open and relieve symptoms or ischemia in the treatment of severe coronary artery disease. The physician places a stent during a percutaneous coronary intervention ("PCI") procedure, typically after having performed a diagnostic coronary angiogram to assess

[1]The statements of the Respondent's conduct with respect to the patients identified herein are intended to provide the Respondent with notice of the alleged charges. They are not intended as, and do not necessarily represent, a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent.

the coronary arterial circulation.

5. At all times relevant to the complaints, the 2005 American College of Cardiology/American Heart Association ("ACC/AHA") Guidelines were in effect. The Guidelines provided that PCI was indicated in patients with significant coronary stenosis (narrowing of the artery), which the Guidelines defined as greater than 50% diameter stenosis. PCI was not recommended for patients with less than 50% stenosis.[2]

6. PCI and the placement of coronary stents is not risk-free. The cardiac catheterization itself carries a 1% - 5% risk of complications that ranges from bleeding to a stroke or heart attack. Once a stent is placed, there is additional risk of stent thrombosis, which happens rarely (1%) but carries a 40-50 % chance of mortality. Accordingly, patients in whom stents are placed must undergo continued anti-platelet therapy with Plavix (clopidogrel) and aspirin to protect them against this. Placement of coronary stents in patients in whom sufficient clinical indications are not present exposes them to needless risk of harm.

Procedural History

7. On November 10, 2008, the Board received the first of 2 anonymous complaints regarding the Respondent from an individual ("Complainant") who identified him/herself as an SJMC employee. The Complainant alleged that the Respondent was committing "medical fraud" by placing stents in coronary arteries with insignificant blockages. The Complainant provided a list of

[2] The 2009 ACC/AHA Guidelines are more stringent; PCI is not indicated unless the stenosis is greater than 70%.

medical record numbers and dates of 36 stent procedures performed by the Respondent from July 2008 through early November 2008 for which the Complainant alleged there were insufficient blockages to justify the procedure. The complaint was designated as Board Case Number 2009-0364.

8. On April 24, 2009, the Board received a second letter from the Complainant regarding the Respondent's continued performance of medically unnecessary stent procedures. The Complainant listed 41 such procedures performed by the Respondent from mid-November 2008 through mid-February 2009. This complaint was designated as Board Case Number 2009-0803.

9. On July 21, 2009, the Board received an Adverse Action Report from SJMC notifying the Board that the Respondent's privileges had been summarily suspended based on the findings of an SJMC investigation that had revealed, *inter alia*, that the Respondent "displayed a repeated pattern of placing stents in patients based on [the Respondent's] overestimation of the degree of stenosis in the cardiac catheterization reports, and without clinical indication of the need for percutaneous intervention." This matter was designated as Board Case Number 2010-0036.

10. Thereafter, the Board initiated an investigation of the Respondent's performance of stent procedures at SJMC. The Board's investigation included obtaining from the Respondent a response regarding his placement of stents in specified patients under his care. The patient records and the Respondent's response were then referred to a peer review entity for review

of the Respondent's practice. The results of the peer review are set forth below:

Patient-Specific Allegations

Patient A[3]

11. Patient A, a female born in 1946, was referred to the Respondent by her cardiologist on August 22, 2008 for elective cardiac catheterization.

12. Patient A's past medical history included a strong family history of premature coronary artery disease ("CAD"). Patient A had a 10-year history of chest pain occurring with exertion and relieved with rest.

13. Prior to her referral to the Respondent, on May 14, 2008, Patient A had undergone a nuclear stress test which revealed no myocardial ischemia.[4] On August 12, 2008, Patient A's treating cardiologist had ordered her to undergo a computed tomography ("CT") angiogram. The CT angiogram revealed, *inter alia*, a mildly elevated coronary calcium score (277) and 80% calcified stenosis of the left anterior descending coronary artery ("LAD"). Patient A also underwent an electrocardiography ("EKG"), the results of which were normal.

14. Patient A's medical therapy at the time included aspirin, Nexium and sublingual nitroglycerin ("SL NTG").

15. Patient A's cardiologist noted in his referral that Patient A had "no further symptoms" at the time of the referral.

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[3] Patient names are confidential. The Respondent may obtain the names from the Administrative Prosecutor.

[4] Patient A performed at 91% maximum age-related heart rate ("MAPHR"), with 10.1 metabolic equivalents ("METS"). These results generally indicate the physiologic adequacy of the stress test .

16. On August 29, 2008, the Respondent performed a coronary angiogram. In his procedure note, the Respondent listed "unstable angina" and "positive exercise test in the anterior distribution" among the procedural indications.

17. In the Respondent's catheterization report ("cath report"), the Respondent documented that the angiogram revealed a normal left main coronary artery, a calcified mid-LAD with 80% stenosis and insignificant disease of the left circumflex and right coronary artery ("RCA").

18. Based on the Respondent's findings, he performed PCI on Patient A's LAD with direct stenting[5] using a drug-eluting stent ("DES")[6] The Respondent administered intra-arterial heparin for procedural anticoagulation.

19. Review of the coronary angiogram performed by the Respondent reveals at most a 40% – 50% calcified mid-LAD stenosis, not 80% as reported by the Respondent. The angiogram did not reveal any evidence of a flow-limited lesion or plaque rupture in the LAD or any other of the coronary arteries that may have resulted in unstable angina, as had been documented by the Respondent.

20. To perform PCI safely, a patient's blood must first be anti-coagulated, or "thinned" before introducing a device into the coronary artery to avoid thrombosis or clotting of the artery. In this case, as in all the cases reviewed, the Respondent failed to document the effect of anti-coagulation when using unfractionated heparin; specifically, he failed to obtain and document Patient

[5] In "direct stenting" the stent is threaded through the lesion over a guidewire and expanded without having first pre-dilated the lesion with a balloon.
[6] A drug-eluting stent is a coronary stent which is coated with an anti-proliferative medication that is released into the surrounding tissues to prevent re-blockage of the stented segment from neointima formation and restenosis.

A's activated clotting time ("ACT") prior to performing PCI with unfractionated heparin.

21. The Respondent violated the Act for reasons including, but not limited to the following:

    a. The Respondent failed to accurately document the clinical indications, including Patient A's symptoms, upon which he based his decision to perform PCI and place a stent;

    b. The Respondent exaggerated the degree of mid-LAD stenosis and used this as clinical justification for placement of the stent;

    c. The Respondent placed a coronary stent in Patient A and needlessly exposed her to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications;

    d. The Respondent failed to consider that a trial of more optimal medication therapy would be a more appropriate form of treatment for Patient A rather than placement of the stent; and

    e. The Respondent failed to obtain and document Patient A's ACT prior to the start of the PCI procedure after administering intra-arterial unfractionated heparin.

Patient B

22. Patient B, a male born in 1930, developed profound weakness and shortness of breath on September 10, 2008 after moving some boxes. Patient B's medical history included rheumatoid arthritis, bladder cancer, gastroesophageal reflux disease ("GERD"), hypertension and dyslipidemia.

23. On October 6, 2008, while still experiencing weakness and shortness of breath, Patient B presented to his cardiologist who transferred him to Carroll Hospital Center ("CHC") based upon Patient B's abnormal EKG results (poor R wave progression), a mildly elevated troponin[7] level (0.117), a creatinine level that ranged from normal to mildly elevated (1.1) and a negative CPK.[8] Patient B's cardiologist, suspecting that Patient B had had a cardiac event, started him on a medication regimen of aspirin and Coreg.[9] Patient B had no reported chest pain.

24. While at CHC, Patient B was started on a statin, a beta-blocker, lisinopril[10] and was intravenously administered a full dose of low molecular weight heparin (Lovenox; dose80 mg.), an anti-coagulant used for the treatment of an acute coronary syndrome.

25. On October 7, 2008, Patient B was transferred to SJMC for cardiac catheterization by the Respondent. Patient B's last dose of Lovanox was administered prior to his discharge from CHC, at 10:23 a.m.

26. On October 7, 2008, the Respondent performed a coronary angiography. In his procedure note, the Respondent noted "unstable angina" and "elevated enzymes" among the indications for the procedure. He also noted that Patient B had chest pain, although this complaint was not noted elsewhere in the record.

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[7] Troponin is a diagnostic biochemical enzyme marker of necrosis (death) of cardiac muscle cells or heart muscle damage..
[8] CPK is the abbreviation for creatine phosphokinase, another enzyme found in the heart. An elevated level indicates heart muscle damage.
[9] Coreg is a beta-blocker used to treat hypertension and heart failure.
[10] Lisinopril is an ACE inhibitor used to treat hypertension and congestive heart failure.

27. In his cath report, the Respondent noted, *inter alia*, a normal left main coronary artery, 30% proximal and 80% mid LAD obstruction.

28. Based on his finding of 80% mid-LAD obstruction, the Respondent performed PCI with direct stenting using a drug-eluting stent (DES) and placed a second stent distal to the first stent for what may have been an edge dissection. The Respondent used 6000 units of intra-arterial heparin for procedural anticoagulation, which was administered to Patient B at 1:34 p.m.

29. Review of the angiogram performed by the Respondent revealed a "wrap around" LAD[11] with no more than a 50% mid-LAD calcified stenosis with TIMI III[12] flow present and no stigmata of plaque rupture, thrombus, flow-limiting stenosis or spontaneous dissection. Patient B's left ventricle ("LV") demonstrated preserved hyperdynamic function, suggesting that no prior or ongoing transmural infarction had had any permanent adverse effect on LV function.

30. The Respondent violated the Act for reasons including but not limited to the following:

    a. The Respondent documented an exaggerated degree of stenosis and used this as clinical justification for placement of the stent;

    b. The Respondent documented symptoms that were not present elsewhere in Patient B's chart as clinical indications for stent placement;

[11] A "wrap around" LAD reaches not only the cardiac apex, but also a portion of the inferior wall of the heart.

[12] TIMI is the abbreviation for Thrombolysis In Myocardial Infarction (the dissolution of abnormal blood clots that damage blood vessels). The TIMI Grade Flow is a scoring system (from 0 to III) of the levels of coronary blood flow. TIMI III indicates complete perfusion/normal flow.

c. The Respondent failed to recognize that Patient B's angiogram was reassuring with a 50% stenosis or less in the LAD and did not support his placement of the stent;

d. The Respondent placed a coronary stent in Patient B and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications;

e. The Respondent failed to document Patient B's ACT.

f. Using two anti-coagulants simultaneously with both unfractionated heparin and low molecular weight heparin (Lovanox). Patient B had received essentially a double dosage of anti-coagulation on the same day: a full dose of Lovanox at CHC prior to discharge and 6000 units of inter-arterial heparin at 1:34 p.m. for the procedure prior to the PCI. The Respondent's administration of unfractionated heparin prior to performing PCI after he had already been fully anti-coagulated with low molecular weight heparin (Lovanox) put Patient B at a much higher risk for bleeding complications.

Patient C

31. Patient C, a male born in 1945, presented to SJMC Emergency Department ("ED") on September 10, 2008, complaining of chest pain. Patient C had previously undergone PCI in March 2007, at which time LAD and RCA stents had been placed; he reported that his chest pain felt "just like the pain before his stents."

32. Patient C underwent an EKG and laboratory studies while in the ED. His

EKG results were unremarkable and his cardiac enzymes were negative. Patient C did not complain of chest pain while in the ED.

33. Patient C's treating physician referred him to the Respondent for a coronary angiogram, noting Patient C's history of unstable angina.

34. On September 10, 2008, the Respondent performed a coronary angiography on Patient C. In his cath report, the Respondent documented a normal left main coronary artery, an 80% obstruction past the previously stented site on the LAD with a widely patent stent, insignificant disease of the left circumflex artery and a dominant RCA with an 80% obstruction at the proximal stent margin with a widely patent stent.

35. Based on his findings, the Respondent performed a mid-LAD PCI and placed a DES. The Respondent also performed RCA PCI and placed two additional drug-eluting stents proximal to the original stent.

36. Review of the coronary angiogram performed by the Respondent failed to reveal an 80% obstruction to either the mid-LAD or RCA, as the Respondent had reported. Instead, review determined the LAD stenosis to be no more than 40%, and in the RCA at most a 50% stenosis proximal to the previously placed RCA stent. Notably, upon review, the previously placed stents were widely patent with no filling defect. There was no clear evidence of a flow-limiting lesion, thrombus or plaque rupture either within the LAD or the RCA or in any of the other coronary arteries that otherwise would have justified the Respondent's placement of stents.

37. The Respondent failed to document Patient C's ACT after administering

unfractionated heparin for procedural anti-coagulation.

38. The Respondent violated the Act for reasons including but not limited to the following:

a. The Respondent exaggerated the degree of stenosis and used this as clinical justification for placement of the stents;

b. The Respondent failed to consider alternate causes of Patient C's symptoms;

c. The Respondent failed to recognize that aggressive medical therapy was the appropriate course of treatment in this case;

d. The Respondent placed a total of 3 coronary stents in 2 of Patient C's coronary arteries and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications;

e. The Respondent failed to document Patient C's ACT after administering unfractionated heparin.

Patient D

39. Patient D, a male born in 1941, had a past medical history that included: CAD; a strong family history of CAD; hypertension; hyperlipidemia and atypical chest pain for the prior 30 years. Patient D reported that his chest pain was resolved completely in a few minutes after taking Mylanta, an antacid. His medication regimen included aspirin, metoprolol, Lipitor, protonix and lorazepam.

40. In March 2007, Patient D had undergone cardiac catheterization at another

facility (performed by a physician other than the Respondent) that revealed mild LAD irregularities and a normal left circumflex artery and RCA.

41. On October 13, 2008, Patient D underwent an exercise myoview nuclear stress test[13] the results of which revealed "minimal mild ischemia noted in the RCA distribution." Patient D attained a workload of 81 % MAPHR and 8 METS during the stress test; he reported dizziness, but no chest pain at his peak exercise level. The results of an echocardiogram performed on that date were unremarkable.

42. On October 16, 2008, Patient D's cardiologist referred him to the Respondent for cardiac catheterization.

43. The Respondent listed "unstable angina" as one of the indications for the coronary angiography. In his clinical summary, the Respondent documented that Patient D had borderline disease with symptoms dating back 2 years who presented with recurrence of symptoms and anteroseptal ischemia upon stress testing.

44. The Respondent documented that the angiogram revealed a normal left main artery, 80% proximal obstruction of the LAD with a 50% obstruction at the junction of the mid and distal vessel.

45. Based on his findings, the Respondent performed PCI of Patient D's proximal LAD with direct stenting using a DES.

46. The Respondent administered 6000 units of intra-arterial unfractionated heparin during the procedure; he failed to document the ACT.

[13] This test uses a radioactive isotope to examine blood flow to the heart while the patient is at rest and exercising.

47. The Respondent obtained only 1 image of the intervention in which the stent was already deployed.

48. The Respondent violated the Act for reasons including but not limited to the following:

    a. The Respondent incorrectly reported that Patient D had unstable angina and anteroseptal ischemia. Patient D in fact had 30 years of atypical chest pain with a small zone of ischemia referable to the RCA (which was not the artery that was stented);

    b. The Respondent exaggerated the degree of proximal LAD stenosis and used this as clinical justification to place the stent; there is no 80% stenosis in any coronary artery;

    c. The Respondent failed to recognize that aggressive medical therapy was the appropriate course of treatment in this case;

    d. The Respondent placed a stent in Patient D and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications;

    e. The Respondent failed to obtain sufficient visual documentation of the PCI; the Respondent obtained only one cine image which shows the stent as already deployed and the wire down the LAD. The Respondent failed to obtain images of his positioning and inflation of the stent or a final image of the treated vessel with the wire removed;

    f. The Respondent failed to document Patient D's ACT after administering unfractionated heparin for procedural anti-coagulation.

Patient E

49. Patient E, a female born in 1938, presented to her cardiologist on July 7, 2008 with atypical chest pain and an abnormal EKG. Her past medical history included hypertension, GERD, hyperlipidemia and a family history of CAD.

50. On July 7, 2008, Patient E underwent a myoview nuclear stress test, attaining a workload of 90% and 7 METS. Patient E had no ischemic ST segment changes and a small mild reversible area of anterior ischemia with normal left ventricular ("LV") function. Her EKG revealed non-specific T wave changes. Patient E's cardiologist added aspirin and a beta-blocker to her medication regimen and referred her to the Respondent for cardiac catheterization.

51. On July 16, 2008, the Respondent performed coronary angiography. He noted "unstable angina" and "positive stress test" as the indications for the procedure.

52. The Respondent reported that the angiogram revealed, *inter alia*, a normal left main artery, insignificant disease of the LAD, a 40% circumflex marginal branch obstruction and an 80% proximal RCA obstruction.

53. Based on his findings, the Respondent performed PCI on Patient E's RCA with direct stenting using a DES.

54. The Respondent administered 6000 units of intra-arterial heparin for procedural anti-coagulation for the PCI. He failed to document Patient E's ACT.

55. Review of the angiogram revealed a 30 – 40% stenosis at the proximal bend

of the RCA; not 80% as reported by the Respondent. The lesion would not be expected to cause LAD territory ischemia or "unstable angina" as there was no evidence of plaque rupture or thrombus.

56. The Respondent violated the Act for reasons including but not limited to the following:

a. The Respondent exaggerated the degree of stenosis and used this as clinical justification for placement of the stent;

b. The Respondent failed to recognize that aggressive medical therapy was the appropriate course of treatment in this case;

c. The Respondent placed a coronary stent in Patient E and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications. Moreover, the stent was placed in the RCA without any evidence of inferior ischemia noted on the nuclear stress test (which showed a small mild area of anterior ischemia which would be more likely referable to the LAD, which in this case was undiseased).

d. The Respondent failed to document ACT after administering unfractionated heparin for procedural anti-coagulation.

SJMC's Independent Review of the Respondent's Practice

57. As stated above, SJMC had conducted its own investigation of the Respondent's placement of stents. The findings of SJMC's investigation (which were not provided to the Board's peer reviewers) are consistent with those of the peer reviewers.

58. During the course of the SJMC investigation, a committee met with the Respondent to review his stent procedure cases. According to the report of the committee, the Respondent acknowledged that it was his practice to use the percentages of 70%, 80% and 90% as "surrogates" or "defaults" in all cases to designate a mild, moderate or significant level of stenosis, respectively. He expressed "a little bit of surprise" that he had an established pattern of overestimating the degree of stenosis by consistently using the default percentages. Indeed, when asked to review the cases reviewed by the SJMC committee, the Respondent found significantly lower percentages of stenosis than he had initially dictated at the time of the procedure. The Respondent asserted that he considered the patients' clinical symptoms when determining whether to place a stent. The committee reported however, that the Respondent repeatedly performed interventions based on his overestimation of stenosis and in the absence of sufficient clinical indications to support the need for PCI. These findings are consistent with those of the Board's peer reviewers.

59. By letter dated July 10, 2009, SJMC notified the Respondent that he was summarily suspended. In the letter, the following practice deficiencies were noted:

    a. Systematic failure to document in the pre-procedure evaluation objective findings of ischemia to justify an intervention;

    b. Failure to include clinical descriptions of the patients' symptoms sufficient to explain [the Respondent's] decision to intervene;

c. Decisions to treat a less significant lesion, instead of the likely culprit lesion;

d. Failure to confirm or qualitate lesion significance using well-accepted intra-procedural techniques, such as fractional flow reserve or intravascular ultrasound;

e. Failure to document the effect of anti-coagulation, and failure to obtain ACT prior to the start of the intervention;

f. Decision to perform "non-culprit" coronary interventions in the setting of an Acute Myocardial Infarction without clinical indications; and

g. Failure to obtain adequate angiographic views to properly assess lesion severity.

CONCLUSION

60. The Respondent's treatment of Patients A, B, C, D and E in whole or in part, unprofessional conduct in the practice of medicine, in violation of H.O. § 140404(a)(3)(ii), willfully making a false report or record in the practice of medicine, in violation of H.O. § 14-404(11), gross overutilization of health care services, in violation of H.O. § 14-404(a)(19), violations of the standard of quality care, in violation of H.O. § 14-404(a)(22) and failure to maintain adequate medical records, in violation of H.O. § 14-404(a)(40).

NOTICE OF POSSIBLE SANCTIONS

If, after a hearing, the Board finds that there are grounds for action under H.O. § 14-404(a)(3)(ii), (11), (19), (22) and/or (40), the Board may impose disciplinary sanctions against the Respondent's license, revocation, suspension, or reprimand and

may place the Respondent on probation, and/or may impose a monetary fine.

NOTICE OF CASE RESOLUTION CONFERENCE

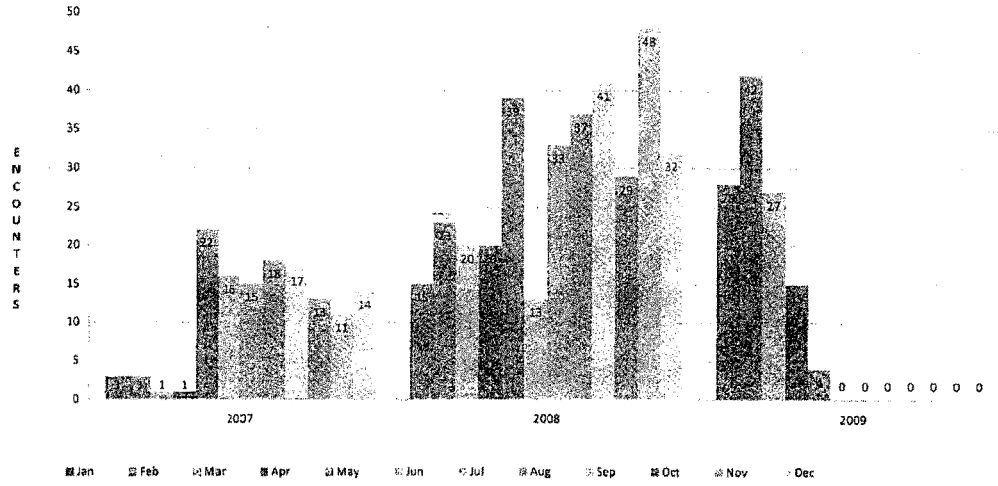
A Case Resolution Conference has been scheduled for **Wednesday, August 4, 2010 at 10:00 a.m.** at the offices of the Board, 4201 Patterson Avenue, Baltimore, Maryland, 21215. The nature and purpose of the Case Resolution Conference and Pre-Hearing Conference are described in the attached letter to the Respondent. If this case is not resolved at the Case Resolution Conference, an evidentiary hearing will be scheduled.

6/7/10
Date

C. Irving Pinder, Jr.,
Executive Director
Maryland State Board of Physicians

FOOTNOTE 5

St. Joseph Medical Center
Cardiac Notification Patient Encounters*
For the Period 01/01/07-05/12/09



Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2007	3	3	1	1	22	16	15	18	17	13	11	14	134
2008	15	23	20	20	39	13	33	37	41	29	48	32	350
2009	28	42	27	15	4								116
Total	46	68	48	36	65	29	48	55	58	42	59	46	600

* Note: These volumes represent patient encounters and not stents as patients may have had multiple stents in a single encounter. For purposes of presenting this data, an encounter is defined as a single inpatient stay. If a patient was admitted a second time, it is counted here as a separate encounter.

The information contained in this report is as of April 6, 2010.

FOOTNOTE 6

Catheterization Review Summary

1st Review - 6/19/09 - 6/21/09

	Total	Class 1	Class 2	Class 3	Class 4
Number of Cases Reviewed	156	76	33	12	35

Class 1: Meets reasonable standard of care
Class 2: Care was suboptimal, but met the standard of care
Class 3: Does not meet reasonable standard of care
Class 4: Does not meet reasonable standard of care and merits special review

2nd Review - 10/30/09 - 11/1/09

	Total	< 50% Stenosis Insignificant	>50% Stenosis Significant
Number of Cases Reviewed	1113	378	735

3rd Review - 1/22/10 - 1/24/10

	Total	< 50% Stenosis Insignificant	>50% Stenosis Significant
Number of Cases Reviewed	609	165	444

FOOTNOTE 7, 18, 38

Report of the Ad Hoc Investigating Committee Regarding Review of Physician

Introduction

This Report will summarize the findings and recommendations of the Ad Hoc Committee appointed by the Medical Executive Committee ("MEC") of St. Joseph Medical Center ("SJMC" or "Hospital") on May 27, 2009 relating to a detailed review of Dr. Mark Midei's cases at SJMC.

Background

Dr. Midei is the Director of the Cardiac Catheterization Laboratory ("Cath Lab") at SJMC, a position he has held since January 1, 1995. Dr. Midei was previously a member of Mid-Atlantic Cardiovascular Associates, and became an employee of SJMC on January 21, 2008.

An inquiry of Dr. Midei's clinical practice was initiated in late-April 2009 following a sentinel case in which a prior SJMC employee complained that Dr. Midei inserted an unnecessary stent without clinical indication. Following discovery of the sentinel case, Harry Brandt, M.D., President of the Medical Staff, and Beth O'Brien, Interim President of SJMC, recommended that Dr. Midei voluntarily agree to cease all activity in the Cath Lab and utilize paid time off ("PTO") while the issues were being investigated further. Dr. Midei elected that option on May 12, 2009 and is currently on PTO.

Additionally, the Hospital learned of six (6) other cases that were the subject of subpoenas to the Hospital from the Maryland Board of Physicians (the "Board") dated December 29, 2008 and May 12, 2009. At the request of Hospital administration, a consulting angiographer, [redacted], reviewed the six (6) cases subpoenaed by the Board,[1] eight (8) other single vessel cases selected at random, and the sentinel case (the [redacted] Review"). The cases reviewed were performed during the period from July 2008 through April 2009. [redacted] reached the following conclusions:

- Seven (7) cases were not within acceptable standards with respect to at least one lesion
- Four (4) cases may be within acceptable standards
- Five (5) cases were within acceptable standards

[redacted] noted concerns about the significant overestimation by Dr. Midei of the degree of stenosis justifying cardiac intervention and inconsistencies in the documentation in the Cath Lab reports when compared to the films. Dr. Midei promptly reviewed and responded to the findings of the [redacted] Review.

[1] One case subpoenaed by the Board involved two patient charts, so seven (7) charts were reviewed total.

On May 26, 2009, the Credentials Committee recommended that the MEC initiate an investigation of Dr. Midei by appointing an ad hoc committee pursuant to Section 11.2.3.5 of the Medical Staff Bylaws. This is required when a physician's conduct may be detrimental to the health or welfare of any patient or below accepted standards of care. The Credentials Committee also recommended that the investigation include a review by the American Medical Foundation for Peer Review and Education ("AMF") and include a more in-depth evaluation of a larger, random sampling of cases. On May 27, 2009, the MEC authorized the initiation of an investigation under the parameters recommended by the Credentials Committee. The MEC appointed an ad hoc committee (the "Ad Hoc Committee" or "Committee") to review the matter, and named the following Medical Staff members to the committee: [redacted] M.D., [redacted] M.D., Chair; [redacted] M.D.; [redacted] M.D.; and [redacted] M.D.

Ad Hoc Committee and AMF Review

The Ad Hoc Committee held meetings on the following dates: June 1, June 4, June 8, June 17, June 22, June 29, and July 8, 2009. Over the course of these meetings, the Ad Hoc Committee interviewed a number of key personnel in the Cath Lab, including [redacted] R.N., scrub nurse; [redacted] Registered Cardiac Interventional Specialist ("RCIS"); [redacted] RCIS; and [redacted] M.D., Division Chief of Cardiology. Additionally, the Ad Hoc Committee interviewed the AMF physicians involved in the review and interviewed Dr. Midei on two separate occasions (June 29, 2009 and July 8, 2009).[2]

Pursuant to authorization by the MEC, the Hospital retained AMF to conduct an in-depth evaluation of a large, random sampling of Dr. Midei's cases. The AMF Review Team conducted an on-site review at SJMC from June 19, 2009 through June 21, 2009. The AMF Review Team consisted of the following interventional cardiologists:

- [redacted]

The AMF Review Team reviewed 157 cases in which Dr. Midei placed a stent, of which 125 involved Federal payors ("Federal Cases") and 32 involved non-Federal payors ("Non-Federal

[2] Dr. Midei was interviewed on June 29, 2009, and the Committee had also reserved July 1, 2009 for additional time, if needed. The July 1st interview date was then switched to July 8th to give Dr. Midei more time to review the AMF Preliminary Draft Report, which was issued on July 3rd. Dr. Midei cancelled the interview for July 8th on July 6th on the basis that he preferred to retain an expert and submit a report to the Ad Hoc Committee. Therefore, the Ad Hoc Committee cancelled its meeting on July 8th. Dr. Midei then requested another interview with the Ad Hoc Committee on July 7th. The Committee accommodated this request and met with Dr. Midei on July 8th.

Cases"). Every fifteenth (15th) Federal Case and every fifty-third (53rd) Non-Federal Case performed by Dr. Midei from January 1, 2006 through March 31, 2009 were selected for review. The Federal Cases represented a statistically significant sample. The AMF Review Team assigned each case to one of four categories: (i) Level 1: meets reasonable standard of care; (ii) Level 2: care was suboptimal; (iii) Level 3: does not meet the standard of care; or (iv) Level 4: does not meet the standard of care and merits special review.

AMF submitted a Preliminary Draft Report to the Ad Hoc Committee on July 6, 2009. See **Attachment A** – Excerpt from AMF Preliminary Draft Report. The following chart depicts the AMF Review Team's preliminary conclusions:

	Level 1 (meets reasonable standard of care)	**Level 2 (care was suboptimal)**	**Level 3 (does not meet standard of care)**	**Level 4 (does not meet standard of care and merits special review)**	**TOTAL**
Federal Cases	56 (44.8%)	27 (21.6%)	10 (8%)	32 (25.6%)	125 (79.6%)
Non-Federal Cases	20 (62.5%)	3 (9.4%)	4 (12.5%)	5 (15.6%)	32 (20.4%)
TOTAL	76 (48.4%)	30 (19.1%)	14 (8.9%)	37 (23.6%)	157

The AMF Review Team determined that Dr. Midei's interpretation of lesion severity and the performance of coronary angiography did not meet the standard of care in a significant number of cases reviewed (Levels 3 and 4). The AMF Review Team found that Dr. Midei repeatedly overestimated the severity of lesions visualized during cardiac catheterizations, which resulted in percutaneous interventions that were not clinically indicated and, thus, potentially harmful to the patients.

The AMF Review Team also found a number of additional quality of care and other deficiencies in Dr. Midei's clinical practice, including, but not limited to:

- There was a systematic failure to document in the pre-procedure evaluation objective findings of ischemia to justify an intervention
- There were often no clinical descriptions of the patients' symptoms sufficient to explain Dr. Midei's decision to intervene
- Dr. Midei will treat a less significant lesion, instead of the likely culprit lesion, thereby worsening the clinical situation for the patient
- Dr. Midei made no attempt to confirm or measure lesion significance using well-accepted intra-procedural techniques, such as fractional flow reserve or intravascular ultrasound
- During the procedures, there were not attempts to document the effect of anti-coagulation by Dr. Midei, and there was no ACT obtained prior to the start of the intervention: this is worrisome because the failure to administer heparin or inadequate heparin effect are

recognized risks for intracoronary thrombosis, which would be preventable if ACTs were routinely checked

- There are several occasions where Dr. Midei performed "non-culprit" coronary interventions in the setting of an Acute Myocardial Infarction without clinical indication such as cardiogenic shock or ongoing ischemia
- Dr. Midei frequently failed to obtain adequate angiographic views to properly assess lesion severity

In summary, the AMF Review Team reached an opinion which is critical of Dr. Midei's invasive and interventional practice.

Conclusions of the Ad Hoc Committee

The Ad Hoc Committee finds that Dr. Midei has frequently inserted stents where there is no clinical indication for doing so and where he has exaggerated the patient's degree of stenosis in the cardiac catheterization report.

Particularly troubling is Dr. Midei's practice of repeatedly overestimating the severity of lesions visualized during numerous cardiac catheterizations. This practice has resulted in Dr. Midei performing percutaneous interventions that were not clinically indicated and, thus, potentially harmful to Dr. Midei's patients. For example, the AMF Review Team indicated in the Preliminary Draft Report that it was common for Dr. Midei to report an 80-90% lesion which was less than 50% in the opinion of all four physician reviewers. See **Attachment B** – Comparison of Documented Levels of Stenosis in Level 3 and 4 Cases Between Dr. Midei and AMF Review Team. This trend was also apparent from the [redacted] Review and Dr. Midei's responses to the review. See **Attachment C** – Comparison of Documented Levels of Stenosis Between Dr. Midei and Dr. [redacted]

Dr. Midei's practice of placing stents in patients where not clinically indicated has resulted in the substantial likelihood of harm to his patients. According to the AMF Review Team, the cardiac catheterization itself carries a 1% to 5% chance of risk, depending on how one assesses complications. Once the stent is in place, there is a 1% chance of stent thrombosis (*i.e.*, where the stent closes off the vessel), which carries a 60% chance of mortality. The risk of stent thrombosis increases to 2.4% three years following the intervention. Additionally, patients who receive stents must undergo continued therapy with Plavix and aspirin, each of which carry their own side effects. Therefore, Dr. Midei's placement of stents in patients with no clinical indication for intervention exposes such patients to the potential for serious complications.

When interviewed by the Committee on June 29, 2009, Dr. Midei stated that he used the percentages of 70%, 80% and 90% as "surrogates" or "defaults" in all cases to designate a mild, moderate or significant level of stenosis, respectively, in order to get through the dictations. Dr. Midei indicated to the Committee that it came as a "little bit of a surprise" to him in looking back at the cases in the [redacted] Review that he had an established pattern of overestimating the degree of stenosis by consistently using these default figures. In fact, when he reviewed these cases following the [redacted] Review, Dr. Midei found significantly lower percentages of stenosis than he initially dictated in the patient's medical record at the time of the procedure. See **Attachment C**.

He expressed surprise and disappointment in discovering his practice of exaggerating degrees of stenosis to the Committee.

Dr. Midei also explained that he considers the patients' clinical symptoms in conjunction with the lesion when determining whether to place a stent. However, the AMF Review Team concluded that Dr. Midei repeatedly performed interventions that were not clinically indicated either by the level of stenosis or the lack of clinical indicators. Consequently, Dr. Midei has displayed a repeated pattern of placing stents in patients based on his overestimation of the degree of stenosis in the cardiac catheterization reports, and without clinical indications of the need for percutaneous intervention.

The Committee interviewed Dr. Midei for a second time on July 8, 2009. Dr. Midei presented four of the Level 4 Federal Cases where he disagreed with the findings of the AMF Review Team in the Preliminary Draft Report. The Committee had the opportunity to ask Dr. Midei questions about the four cases and the other conclusions reached by the AMF Review Team. At the conclusion of the meeting, the Committee members reached consensus that the information provided by Dr. Midei at this meeting did not change their fundamental view that he has displayed repeated patterns of placing stents in patients that were not in accordance with the standard of care.

Recommendation

Dr. Midei's practice of inserting stents without clinical indication, of repeatedly exaggerating the patient's degree of stenosis in the cardiac catheterization report, and the other deficiencies noted above constitute a clear and present danger that requires prompt action to protect the life of patients and to reduce the substantial likelihood of injury to the health or safety of patients at SJMC. Therefore, the Ad Hoc Committee recommends that the MEC authorize a summary suspension of Dr. Midei's medical staff privileges as required by Section 11.3.1 of the Medical Staff Bylaws.

[redacted]

07/08/09
Date

[redacted]
Chairman, Ad Hoc Committee

Attachments:

A. Excerpt from Preliminary Draft Report of American Medical Foundation for Peer Review and Education (peer review findings and summary);
B. Comparison of Documented Levels of Stenosis in Level 3 and 4 Cases Between Dr. Midei and AMF Review Team; and
C. Comparison of Documented Levels of Stenosis Between Dr. Midei and [redacted]

FOOTNOTE 13

From: Simonton, Charles A
Sent: Tuesday, April 20, 2010 06:04 AM
To: 'mmidei@K[redacted]
Subject: Re: Research

Hey, glad you've landed square on your feet. Will stay in touch about all you've asked. Best of luck!
Chuck
Chuck Simonton MD, FACC, FSCAI
Chief Medical Officer
Abbott Vascular
Santa Clara, CA
[redacted] office
[redacted] cell

From: Mark G. Midei [redacted]
To: Simonton, Charles A
Sent: Tue Apr 20 05:27:50 2010
Subject: Research

Hi Chuck:

I hope you can keep this confidential for the time being. I spoke with[redacted] and told her she could share some of this with you so you already may have some knowledge.

I am back working in the lab at The Prince Salman Heart Center in Saudi Arabia. It is one of the hospital specialty centers in the kingdom and is part of the King Fahad Medical City. It is a large facility with one of the busiest cath labs in the middle east. There is an enormous amount of coronary disease in young people, and a staggering amount of rheumatic disease.

At some time in the near future we are interested in pursuing research opportunities, especially the left main protocol, and the short clopidogrel protocol if these are being considered OUS. They already have RN followup available.

I am also trying to convince the Ministry of Health to consider Mitra-Clip as there is a tremendous amount of MR that is functional in nature for whom surgery is not a good option. I am wondering if you have the resources to provide field support for this endeavor.

I know this all sounds a little unbelievable, but events in Baltimore forced me to take action. I am happy to be back in the lab and busy. Hopefully, the truth will someday prevail.

Thanks again for your support earlier this year. Please feel free to share this information with Chip if you see fit.

Mark

FOOTNOTE 17

St. Joseph Medical Center
Cardiac Settlement - Charges and Payments

Total Charges	$	7,152,863
Total Payments	$	6,634,344
% Collected		92.8%

Payment Detail:

Federal:			
	Aetna Medicare	$	43,454
	Amerigroup		12,537
	BC Federal Employee Program		143,585
	Care Improvement Plus		9,140
	Evercare		20,165
	Mailhandlers		1,024
	Maryland Physicians Care		47,978
	Medicare		3,507,259
	Other Medicare Replacement		16,259
	Tricare		6,503
	Tricare for Life		2,092
	United Healthcare MCO		7,571
	Total Federal	$	**3,817,567**
Medicaid:	Total Medicaid	$	**75,066**
Other:			
	AARP	$	30,940
	Aetna		175,237
	Alliance		15,344
	Blue Cross		1,547,440
	CIGNA		71,093
	Kaiser		11,602
	MDIPA		43,795
	Other		548,504
	Self Pay		78,544
	United		219,212
	Total Other	$	**2,741,711**
Total Payments		$	**6,634,344**

Date Prepared: 04/08/10

FOOTNOTE 22, 23, 24

STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

September 21, 2010

The Honorable Peter A. Hammen, Chair
House Health & Government Operations Committee
Lowe House Office Building, Room 240
Annapolis, MD 21401-1991

Re: Hospital Utilization and Stents

Dear Chairman Hammen:

In a letter dated February 16, 2010, you directed a two-fold written response to questions about oversight of utilization of procedures and services in hospitals. This inquiry arose from specific concerns about allegedly unnecessary coronary stent procedures performed by Dr. Mark Midei at St. Joseph's Hospital in Baltimore County, which occurred prior to Dr. Midei's suspension from the hospital in July 2009. On March 15 of this year, I provided an interim response outlining actions taken by State agencies to date in response to the concerns at St. Joseph's hospital. The letter also presented a chronology of events from the perspective of the State agencies. This letter updates that information and responds to your other requests, specifically that the Department:

> *Using the tools available to the Department, the Maryland Health Care Commission, and the Health Services Cost Review Commission, determine whether:*
>
> > *Patients at other hospitals may have received unnecessary coronary stents or may continue to be at risk for receiving unnecessary coronary stents; or patients may have received or may be at risk of receiving other unnecessary invasive procedures that could jeopardize their health;*

Undertake a comprehensive review of patient safety and physician practice measures established in recent years, analyze how these measures failed to prevent or quickly detect the unnecessary procedures at St. Joseph, and develop recommendations for actions, including any legislation, needed to remedy those failures; and

Provide a report on the Department's determination with regard to unnecessary stents at other hospitals and its review, analysis, and recommendations with regard to patient safety and physician practice pattern measures.

This letter addresses these requests and concludes that, while the State agencies have used the tools available to them to ensure that unnecessary coronary stent placement does not continue at St. Joseph's, State regulatory agencies alone are not currently equipped, either with sufficient resources or with sufficient scope of authority, to prevent this type of problem from recurring at other hospitals. This response includes suggested legislative and programmatic changes if the Department and General Assembly were to enhance State regulatory measures to coordinate responses among agencies when there is a potentially cross-cutting concern. However, prevention of overutilization on any systemic basis will require coordinated effort among hospitals, payors, policymakers, law enforcement authorities, State regulatory agencies, health care professionals, and other stakeholders.

I. Update on State's Regulatory Response, St. Joseph's Hospital.[1] As outlined in the March 15 response and updated here, there has been significant and comprehensive regulatory response to the concerns identified at St. Joseph's.[2]

A. OHCQ on-site review of peer review processes under federal regulation. While peer review processes have been traditionally focused upon adverse patient outcomes and not concerns related to volume or necessity of services, a hospital with strong internal quality and peer review system will be more likely to detect its own utilization problems. Using its authority under State and federal law as licensing and certification agency, the Office of Health Care Quality (OHCQ) conducted an on-site survey of St. Joseph's concluding in March 2010. The investigation included review of medical records, policies procedures and other pertinent documentation, and interviews with staff. OHCQ identified deficiencies, or violations of federal regulations which are attached to this letter with the hospital's plan of correction. Of note, OHCQ found that the hospital's peer review process permitted Dr. Midei, as chair of the cardiology department to

[1] This letter does not address the activities of federal and State law enforcement authorities, as these agencies are not a part of the Department. However, it should be noted that it is within the jurisdiction of the U.S. Attorneys office and the State's Medicaid Fraud Control Unit to investigate and prosecute cases of suspected fraud. Even if regulatory agencies are granted more resources and authority, law enforcement agencies will remain better equipped to detect and deter cases of purposeful fraud, where efforts are made to hide fraudulent activity. The Department's Office of Inspector General investigates fraud claims and makes referrals for prosecution, but the OIG's jurisdiction is limited to review of payments by Medicaid and other State programs.

[2] While this letter focuses on the response of the State regulatory agencies, St. Joseph's Hospital's response should also be noted, including investigating and suspending the physician, coordinating extensive outside review of patient records, and notifying patients, as well as notifying the regulatory agencies.

select cardiology cases, including his own, for peer review. St. Joseph's has now revised its practices to include independent, blinded review of interventional providers and has ensured that clinical heads are neither selecting nor reviewing their own cases.

Additionally, OHCQ through its Patient Safety Program reviewed reported adverse events for evidence of inadequate systems of physician quality review. The Patient Safety Program has issued a Clinical Alert, "Assessing Physician Quality: More Than Peer Review," to leadership in all hospitals. The Clinical Alert underscores the need to include review of physician practice as a part of hospital quality review. The OHCQ also suggests that reviews include: assessment of medical necessity for invasive procedures: compliance with hospital policies and bylaws and evidence-based guidelines; and an appraisal of team dynamic measured by outcomes associated with poor communication.

B. Board of Physicians investigation. On June 7, 2010, the Maryland Board of Physicians charged Dr. Midei with violations of the Maryland Medical Practice Act including unprofessional conduct in the practice of medicine, willfully making a false report or record, gross overutilization of health care services, violations of the standard of quality care, and failure to maintain adequate medical records. Possible sanctions listed in the charging document include revocation, suspension, or reprimand, probation, or a monetary fine. The Board held a Case Resolution Conference with Dr. Midei on August 4, 2010. If a public consent order is not agreed upon by the physician and the Board, the matter will proceed to a hearing before an Administrative Law Judge at the Office of Administrative Hearings.

C. Joint Commission review. Because of Maryland's laws permitting deemed status, routine hospital inspections are conducted at least every three years by The Joint Commission and not by the State regulatory agencies. A Joint Commission team, including a cardiologist, conducted an unannounced review of St. Joseph's over a four-day period in July. An OHCQ representative participated in the survey and attended the exit conference, as permitted under Maryland law and facilitated by the Joint Commission. The Joint Commission concluded that the hospital should retain its full accreditation.

II. Plan for Coordinated Utilization Review of Additional Hospitals

The regulatory agencies (OHCQ, the Health Services Cost Review Commission (HSCRC), the MHCC, Office of the Inspector General, and Physicians' Board) have met multiple times over the summer and have developed a plan for on-site review of hospitals when data indicates that there may be overutilization of procedures or services. It was agreed that available data may suggest trends but that the data is not conclusive and onsite clinical investigation is necessary to confirm whether procedures are inappropriate or unnecessary. The agencies do not have the resources to conduct systemic onsite clinical review of hospital records[3], but could conduct

[3] The OHCQ employs 6 nurse surveyors in its hospital unit, who investigate over 400 complaints per year, in addition to surveying residential treatment centers, HMO's, transplant centers, and a percentage of hospitals

periodic "spot check" reviews to investigate outlier trends revealed in data analysis. These spot checks would encourage hospitals to engage in their own review of utilization practices and have a broad deterrent effect.

The HSCRC has stated that it is able to refine its payment data to refer to OHCQ outlier ratios of stents to catheterizations.[4] OHCQ would conduct on-site investigation of the HSCRC-referred hospitals, to include hospital's peer review and quality improvement processes, credentialing files, and utilization review activity, applying standards of Joint Commission as well as federal and State law. Nurse-surveyors would also review a directed sample of patient records for information. Using the information gathered from review, OHCQ's Medical Director would, with assistance of other regulatory agency staff, interview physicians and hospital staff. The focus of the interviews would be deviations from standard data, evidence to support hospital's rationale for deviation, whether hospital has taken steps to resolve deviation, and whether the hospital evaluation process includes medical necessity or other utilization standards. Hospital responses and survey results would be reviewed to determine if further survey activities are required. If a deficient practice is identified, deficiencies would be issued. Plans of correction to be submitted by the hospitals may be directed to include extrinsic peer review by other professionals, as appropriate to remedy identified deficient practices. Referrals would be made, if appropriate, to other investigative bodies, including OIG, law enforcement authorities, and the Physicians' Board. The HSCRC retains its independent authority to adjust hospital rates in response to utilization concerns.[5]

The Department had hoped to begin on-site reviews this summer. However, because HSCRC has experienced unanticipated difficulties in producing the refined analysis of its data to launch the investigations, the data-driven reviews have not yet begun.[6] This delay and the untested nature of the data underscores the challenges to the State regulatory agencies of conducting even these periodic checks of hospitals to review utilization practices. However, the regulatory agencies believe that even such limited checks will have a deterrent effect and will protect

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annually. Because all Maryland hospitals are accredited by The Joint Commission and have deemed status according to Maryland law, the Department does not have jurisdiction to routinely conduct full surveys of hospitals. Hospital surveys are complex and require a team of trained staff with a variety of experience and educational backgrounds. While OHCQ employs a board certified physician Medical Director, expert review of the full array of practices will require the availability of contractual consultant specialists in a number of medical fields.

[4] The Department has been referred by medical practitioners to other potential sources of data that are not exclusively payment-based. We will not know, without initiating a review process and comparing data to patient records, which data source is the most indicative of overutilization concerns. In either event, current data analysis is not conclusive but may suggest that more detailed clinical investigation is warranted.

[5] This coordinated response would not take the place of any other law enforcement or regulatory activity permitted under federal or State law.

[6] Based upon other available facts and information, OHCQ has initiated an on-site survey of a Maryland hospital to review utilization and peer review practices, applying the federal conditions of participation. This review is not yet complete; although any deficiencies which result from the review will be publically available information.

consumers and ultimately save costs. If successful, this process could and should be extended to non-hospital settings where costly procedures take place.

III. Ongoing State efforts to improve quality and outcomes through voluntary and mandatory reporting

Since 2006, the Maryland Health Care Commission (MHCC, the Commission) has administered a waiver program for community hospitals without on-site cardiac surgery that provide emergency or primary PCI services. As part of this program, 13 community hospitals have been required to report process and outcome data to the MHCC for on-going quality assessment. The Commission has recently expanded this data reporting requirement to encompass all Maryland acute general hospitals with a PCI program, including community hospitals with primary PCI programs and hospitals with a Certificate of Need issued by the MHCC for a cardiac surgery and PCI program offering both emergency or primary PCI and elective PCI services. Effective July 1, 2010, all hospitals offering PCI services are required to enroll in and report quarterly data to the Commission from the: American College of Cardiology (ACC) Foundation's National Cardiovascular Data Registry (NCDR) ACTION Registry-GWTG; and, ACC Foundation's NCDR CathPCI Registry. The Commission published formal notice regarding these reporting requirements in the *Maryland Register* on April 23, 2010.

On June 29, 2010, the MHCC held an ACTION Registry-GWTG Training Session to assist hospitals in preparing for the new requirements. Representatives from the NCDR provided an in depth review of the system data requirements, reporting features and quality metrics. Over thirty participants representing eighteen hospitals participated in the workshop. Maryland is the only state that has adopted both of these NCDR Registries. The Commission will use this data to:

- Support the development of a STEMI system for Maryland by providing timely data on all components of the system;
- Monitor clinical, process, and outcome data for hospitals without on-site cardiac surgery providing primary PCI services as required under the Commission's waiver program;
- Establish and report on a common set of process and risk-adjusted outcome measures (taking into consideration hospital and patient characteristics) for PCI services as part of the publically reported Maryland Hospital Performance Evaluation System: and,
- Support statewide planning for specialized cardiac care services, including cardiac surgery and PCI services.

The data from the ACTION Registry-GWTG will be shared with the Maryland Institute for Emergency Medical Services Systems (MIEMSS) to support their work in Designation of Cardiac Interventional Centers.

The Commission is also in the process of organizing a standing Maryland State Cardiac Data Advisory Committee to assist in implementing the percutaneous coronary intervention (PCI) data

reporting requirements. All meetings of the Advisory Committee will be open to the public. A webpage has been added to the Commission's website to post materials related to the Maryland State Cardiac Data Advisory Committee and may be accessed at:

http://mhcc.maryland.gov/cardiac_advisory/index.html.

IV. Other strategies for identifying overutilization or fraudulent practices

Ultimately, it is important to distinguish between behaviors that represent overutilization that arises from a lack of awareness of clinical guidelines, a disagreement with the guidelines, or subtle incentives, on one hand, and behaviors that represent illegal behavior, including fraud and deliberate falsification, on the other.

The first category of overutilization is most appropriately identified through one of several avenues:

- Departures from clinical guidelines that can be identified either through electronic decision support in electronic health records or carriers' automated claims review engines or from the initial screening of HSCRC data described above;
- Inappropriate utilization detected through carrier review processes conducted either prospectively through prior authorization, contemporaneously through utilization review, or retrospectively through claims analyses;
- Inappropriate utilization identified through professional peer review processes; or
- Mandatory reporting to procedure registries, verified by audits, and followed by analysis, feedback, and public reporting of hospital or practitioner quality and outcomes.

The first is promising but not yet widely implemented. The second raises the question of the level of documentation which carriers require in determining medical necessity for certain procedures that may be particularly prone to overutilization, although in the case of elective angioplasty, review of the actual angiography films would be necessary to detect outright data falsification. The third is the object of one of our specific recommendations. The fourth is the MHCC process.

Outright fraud and falsification present a different challenge. Even labor-intensive record reviews may not suffice to detect this pattern of behavior. Unfortunately, whistle-blower activity is often the means by which these illegal behaviors are unearthed. In this regard, both appropriate whistle-blower protections and rewards may provide the best available option for detection, unsatisfactory as that may be. These were important elements of the State's False Health Claims Act, enacted during the 2010 Session.

V. Recommendations for Legislative and Policy Changes.

As summarized in this letter, the State agencies have investigated and issued public findings as to St. Joseph's and Dr. Midei. The State has planned coordinated investigations for additional hospitals, to the extent resources permit. Additional data on cardiac procedures is now collected by MHCC. However, in addition to limitation of resources previously discussed, the regulatory agencies have encountered regulatory or statutory constraints that limit our ability to coordinate an investigation among regulatory agencies. We have also identified areas where laws could be changed or strengthened to enhance the State's ability to respond and we will work with legislators and stakeholders to discuss, refine, and effect these changes.

A. ***Strengthen and change the focus of hospital peer review standards.*** Traditional hospital peer review practices, regulations and Joint Commission standards have focused upon errors causing injury to patients and other such adverse events. Using existing law, the OHCQ should augment existing standards required of hospital peer review process to include review of volume and medical necessity. These standards should require hospitals to implement clear and consistent standards for peer review, and there should be records maintained to track and audit the peer review processes. Since procedures are not limited to hospitals, the same type of requirement should be considered in ambulatory surgical or other settings. **We are initiating a process for public consideration of these regulatory changes.**

B. ***Broaden the reporting requirements under the Maryland Patient Safety regulations.*** The definition of a Level 1 Patient Safety event, which must be reported to OHCQ, requires that to be reportable an event must cause death or serious injury. (COMAR 10.07.06) There is often uncertainty as to when a procedure which is unnecessary causes serious injury. The definition of a Level 1 event should be broadened to include such events as: 1) retained foreign bodies detected and removed before discharge; and 2) all wrong-site, unnecessary or wrong patient surgeries or procedures regardless of whether harm in the traditional sense has occurred. Additionally, the current regulation requiring notice to patients "whenever the final outcome of care differs significantly from an anticipated outcome" should be reconsidered in discussions among stakeholders about the extent of required disclosure to patients. In the interim, caregivers should be encouraged to inform patients of adverse events and potential consequences even when adverse events do not meet the language of the current regulations. **We are initiating a process for public consideration of these regulatory changes.**

C. ***Increase permissible sharing of information among investigatory agencies.*** State agencies possess a variety of tools to combat fraud and to remediate quality of care concerns. There is also value in sharing information so that the agencies may work in concert and not duplicate efforts. Current law may be outdated in limiting communications among agencies. Under current law, Maryland hospitals are required to report financial information to the Health Services Cost Review Commission including physician information sufficient to identify practice patterns of individual physicians across facilities. However, the names of the individual

physicians are considered confidential and not discoverable or admissible in a civil or criminal proceeding. Current law, however, permits the names of physician to be disclosed by HSCRC to:

(1) The utilization review committee of a Maryland hospital;
(2) Med Chi; and
(3) The State Board of Physicians.

This language should be expanded to reflect additional investigatory bodies, including OHCQ and MHCC, under State and federal law. **This would require legislative action.**

Similarly, HG §14-411 limits the Board of Physicians' ability to disclose "any information contained in a record." There are a number of specific exceptions to this general rule, including the Board's discretion to share information with a hospital, HMO or health care facility where a physician is employed or has privileges. The Board under some circumstances may disclose information to "a health occupational regulatory board" and to law enforcement officials. There is, however, no provision permitting the Board to disclose information to the Secretary of DHMH (aside from an audit) or to the HSCRC. There is some uncertainty regarding the authority to disclose to OHCQ. It would be useful for the Board to be able to discuss concerns about providers prior to there being a public charge or finding. That would facilitate a coordinated investigation and information sharing among the agencies. **This would likely require legislative change. The Board and its legal counsel are examining the issue.**

D. ***The regulatory agencies should be granted Medical Review Committee status in shared investigations.*** While we advocate transparency and availability to the public of government findings and decisions, regulatory agencies must also be able to discuss complaints that cross agency jurisdictions. Making unverified allegations publicly available potentially inhibits discussions and could foil the investigation. Medical review committee status protects the integrity of investigations and assures that only valid and fully vetted findings are released. Each of the regulatory agencies is individually granted Medical Review Committee (MRC) status under State law; however, there is no assurance that there is protection when information is shared among a number of agencies. Health Occupations Article 1-401 should be amended to include not only individual regulatory agencies, but a meeting of multiple regulatory agencies and the Secretary or the Secretary's designee. **This would require legislative change.**

Conclusion

It is challenging to craft a thoughtful strategy for oversight of quality and utilization in an environment shaped by a dramatic case that, if the allegations are proved, represents a range of behaviors and systems failures. It will be important to distinguish among the range of problem presented by the instant case, since the oversight required to identify potentially illegal behavior (including fraud, abuse, and falsification of records) is different from the oversight to measure, report and act on meaningful differences in quality and utilization. Moreover, even when there is

no criminal intent on the part of providers, our country's health care reimbursement systems are typically structured to reward the frequency and numbers of procedures rather than patient outcomes.[7]

The Department and regulatory agencies have benefitted by convening to discuss the coordinated response to this case. Particularly when resources are limited, it is important to coordinate responses when there is shared jurisdiction among the agencies. Coordinated communication and referrals will also assist State and federal law enforcement authorities in their review and prosecution of criminal matters. Existing State data sources must be bolstered, refined, and tested before they are accepted as proxies for evaluation of health care quality and utilization. Pending assurance that data alone is sufficient confirmation of overuse, the Department cannot look over the shoulders of all practitioners in all hospitals at all times. We share your concerns that unnecessary procedures not only cost us scarce fiscal resources, but expose patients to unnecessary harm and risk of harm. The regulatory activities and suggestions for change outlined in this letter present a diligent yet realistic response.

Sincerely,

John M. Colmers
Secretary

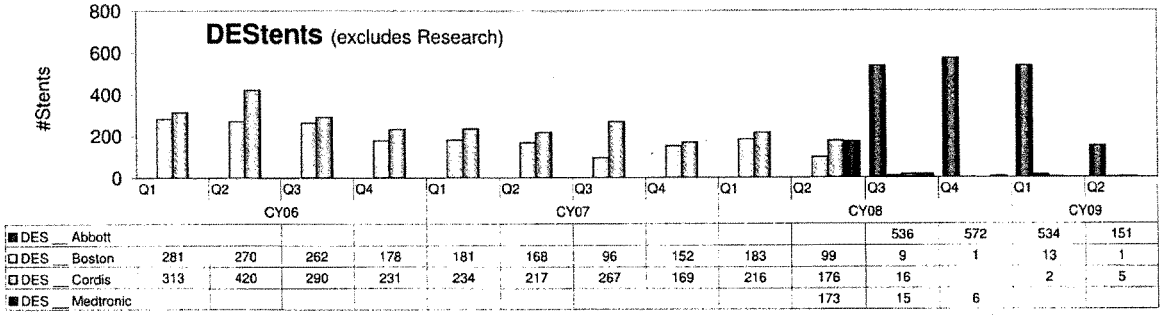
cc: Patrick Chaulk
Rex Cowdry
Nancy Grimm
Robert Murray
Irving Pinder

[7] Changing delivery systems is one of the goals of national and State health care reform. As you know, the Health Care Delivery Systems workgroup of the Health Care Reform Coordinating Council is charged with reviewing key drivers of health care costs as it works to also improve quality and safety of health care systems.

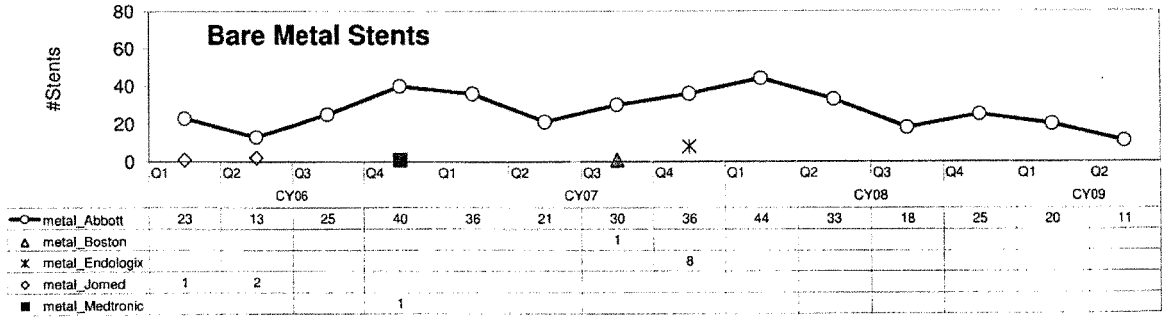
FOOTNOTE 25

Stent Usage by Dr. Mark Midei

CY 2006 Q1 thru CY2009 Q2



	CY06				CY07				CY08				CY09	
DES_Abbott										536	572	534	151	
DES_Boston	281	270	262	178	181	168	96	152	183	99	9	1	13	1
DES_Cordis	313	420	290	231	234	217	267	169	216	176	16		2	5
DES_Medtronic										173	15	6		



	CY06				CY07				CY08				CY09	
metal_Abbott	23	13	25	40	36	21	30	36	44	33	18	25	20	11
metal_Boston							1							
metal_Endologix								8						
metal_Jomed	1	2												
metal_Medtronic				1										

FOOTNOTE 26

	A	B	C	D	E	F	G	H
1	Top Volume NE Area MD's in Project Victory Accounts							
2								
3		MD Name	Project Victory Account Name	#	City	State	PTCI Cases/Year	Rep Name
4	1	[redacted]	Mt. Sinai Hospital	27375	NY	NY	1,000 Plus	[redacted]
5	2	[redacted]	NY Presbyterian Hospital	27236	NY	NJ	1,000	
6	3	[redacted]	Washington Hospital Center	30145	DC	DC	1000	
7	4	[redacted]	Washington Hospital Center	30145	DC	DC	1000	
8	5	[redacted]	PinnacleHealth	27497	Harrisburg	PA	1000	
9	6	Mark Midei	St. Joseph Hospital	27286	Baltimore	MD	1000	
10	7	[redacted]	Union Memorial Hospital	27287	Baltimore	MD	1000	
11	8	[redacted]	Lenox Hill Hospital	27239	NY	NY	900	
12	9	[redacted]	Rochester General	27381	Rochester	NY	900	
13	19	[redacted]	NY Presbyterian Hospital	27236	NY	NY	850	
14	11	[redacted]	Our Lady of Lourdes	28438	Camden	NJ	850	
15	12	[redacted]	Hackensack Medical Center	28568	Hackensack	NJ	800	
16	13	[redacted]	Mt. Sinai Hospital	27375	NY	NY	800	
17	14	[redacted]	St.Francis Heart Hosp.	27384	Roslyn	NY	775	
18	15	[redacted]	Umass	27278	Worchester	Ma	700	
19	16	[redacted]	St. Vincents	28232	Worchester	Ma	500	
20	17	[redacted]	Cape Cod	28557	Hyannis	Ma	500	

FOOTNOTE 27

Business Plan

Q4 '08

Territory overview

- Coronary Revenue
  - QTD $[redacted] YTD [redacted]

DES
QTD $[redacted] YTD [redacted]

Xience Launch

- St.Jospeh
- Union
- Johns Hopkins
- Sinai
- University of Maryland
- C-Port Accounts
  - St. Agnes
  - Howard Co.
  - Franklin

- Pending Q4 launch
  - Johns Hopkins Bayveiw
  - Upper Chesapeake
  - Carroll Co.

St.Joseph's Medical center

- 2800 intervention
- 90% DES/ 10% BMS
- 85% OTW/ 15% RX
- Product Penetration
  - DES 84% ABT, 7% MDT, 7% J&J, 2% BSX
  - Core Products
    - BMS 100% ABT
    - BDC 75% ABT, 25% BSX
    - Wires 95% ABT, 5% BSX

cont. of St. Joseph Medical Center

- All Coronary Revenue
  - QTD $[redacted]
  - YTD $[redacted]
- Core Product Revenue
  - BMS
    - QTD $[redacted]
    - YTD $[redacted]
  - Non-Stent
    - QTD $[redacted]
    - YTD $[redacted]
- DES Revenue
  - QTD $[redacted]
  - YTD $[redacted]

Cont. St.Joseph Medical Center

- Status
  - **Volume Penetration**
    - 65% St.Joseph (i.e. Mark Midei), 35% MACVA
  - Strongly supporting HPG contracts
  - Xience well received by all, MACVA supporting competitors, as well, due to research commitment
  - Xience V USA imminent , St.Joseph's,Mark Midei, invited to participate in SV/LL
  - Atom and Libertie not launched due to HPG pricing

Cont. St.Joseph Medical Center

- Competitive Activity
  - BSX promus push, apex intro
  - All competitors pushing research opportunity

Action Items

- Continue to elevate Mark Midei and the St.Joseph group within the Abbott Corp(Senior Mngt visits, MAB,research,VIP trips)
- Present to St.Joseph Hos.(administration) and St.Joseph's Cardiology group the Abbott Vision Presentation
- Present Q3 Business review to Administration and Mark Midei
- Implement Indigent Care and Co-pay program
- Involve [redacted] in local educational symposiums
- Attend St.Joseph Cardiovascular Assoc.'s Open House
- Cont. to educate staff on the Clinical Benefit of
  - Everolimus
  - Xience
  - Vision
  - BDC and family of wires

FOOTNOTE 28

Project Victory
Account Strategy
St Joseph Hospital
Account Number 27286

Regional Manager: [redacted]

Territory Manager: [redacted]

Region: Capitol

Abbott
A Promise for Life

St. Joseph Hospital

RM: [redacted]

TM: [redacted]

	OPPORTUNITY	STRONG
C	[redacted]	
Mix	[redacted]	4389
T	[redacted]	
Lab days	[redacted]	4x/mo
# of lab days before launch	[redacted]	1-16
IDN Name: If Applicable CHI-(Consorta/HPG)		
Status	CHOOSE [redacted]	[redacted]

NOTE: XIENCE™ V is an investigational device in the U.S. You may not market XIENCE™ V until approval.

Competitive activity in account:

B.S.:*Sr. Mgt Field Visits*

JNJ: *Sr. Mgt Field Visits*

MDT: *None*

[redacted]

[redacted]

CT activities in account: Point counterpoint Courage, debate with Dr. Midei, Local TM dinners with, CCL Dir., Off and on site in-services with CCL staff, on going conversations with CCL Administration.

Keeping Dr. Midei informed on progression of pipeline and most importantly Xience V.

Given that XIENCE™ V is currently an investigational device in the U.S, please describe your plans for strengthening your current position and increasing your understanding of this account with currently available market products and marketing materials, and that you may not promote XIENCE™ V until approval.

Abbott Vascular

Planning for XIENCE™ V

NOTE: XIENCE™ V is an investigational device in the U.S. You may not market XIENCE™ V until approval.

	XIENCE™ V			PROMUS™
	Key steps in process	**Decision maker**	**Time to complete**	**Time to complete**
CHOOSE	1. Pricing Structure in Place, Competitive	• [redacted] Mark Midei	day	N/A
BUY	1. Ready to implant			
STOCK	1. [redacted]	Dr. Mark Midei	Day	N/A
TOTAL TIME TO GET PRODUCT ON THE SHELF:			**Days**	**# weeks**

Given that XIENCE™ V is currently an investigational device in the U.S, please describe your plans for strengthening your current position and increasing your understanding of this account with currently available market products and marketing materials, and that you may not promote XIENCE™ V until approval.

Abbott Vascular

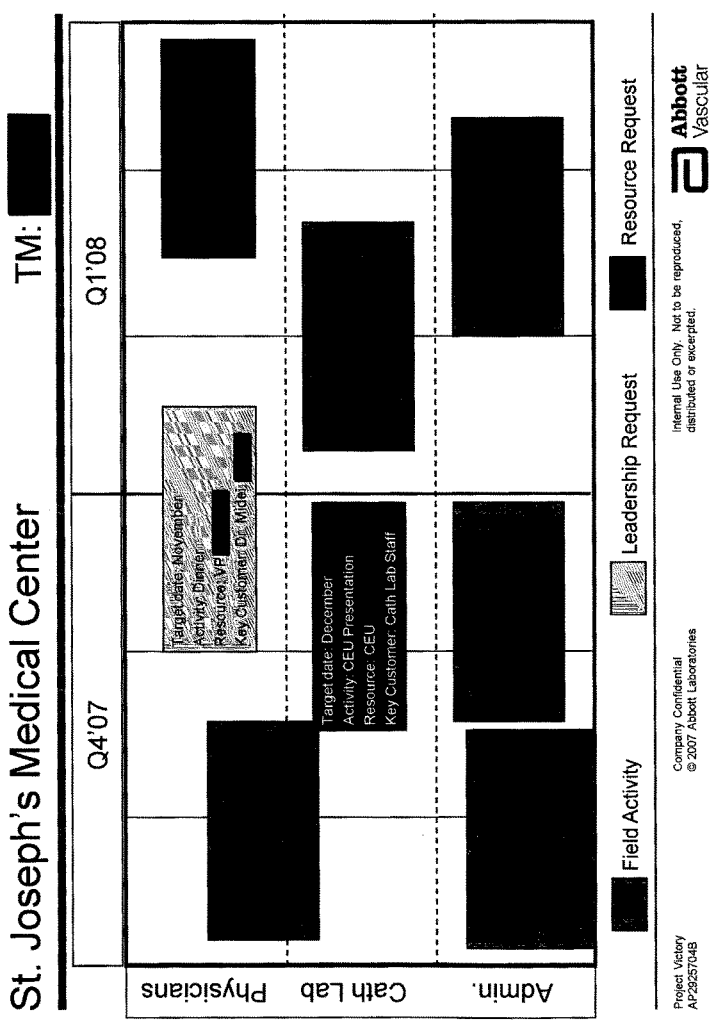
Account Strategy

Account strategy:

[redacted]

Top two activities that will make the difference:

1. *Meet with Administration, Dir of Mat Mgt. AV Presentation by Local Management*
2. *Q4 dinner with* [redacted], [redacted], *Dr. Midei, reinforce strategy around AV and St. Joe's*



ABBT 0038294

Title: Controversies in Cardiology: Drug Eluting Stents versus Medical Therapy
Speaker: Mark Midei, MD and Stephen Schulman, MD
Date: May 23rd, 2007
Location: Ruth's Chris, Baltimore, MD

Objectives: At the completion of the symposium, the participants will be able to:

1. Describe the appropriate use of drug-eluting stents in high and low-risk patients.
2. Discuss the clinical decision making process for patients with obstructive coronary artery disease.
3. Utilize evidence-based medicine from clinical trials to aid in the real-world management of patients with coronary artery disease.

Agenda:

6:00-6:30 PM Registration/Reception
6:30-6:35 PM Welcome and Introductions
6:35-7:35 PM Program/Speakers
7:35-7:45 PM Discussion/ Questions
7:45-8:00 PM Concluding Remarks & Evaluation
8:00-9:00 PM Dinner

From: [redacted] </O=ONEABBOTT/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=[redacted]
Sent: 4/17/2007 9:11:24 AM
Subject: Courage Debate - Mark Midei
Location: Baltimore
Start: Wed 5/23/2007 3:00:00 PM
End: Wed 5/23/2007 6:00:00 PM
Recurrence: (none)

FOOTNOTE 29, 30

From: [redacted]
Sent: Tuesday, September 02, 2008 05:21 AM
To: Capek, John M
Subject: RE: Mark Midei

John,
I hope all is going well.
Thank you for reaching out to Mark. I know that always means a lot to him
His email is [redacted] and his cell is [redacted].
He must be one of the highest implantors thus far.
Again, thank you
[redacted]

From: Capek, John M
Sent: Saturday, August 30, 2008 9:04 AM
To: [redacted]
Subject: Mark Midei
[redacted] .... I was going to send Mark an email to congrat him on a "30 stent day", which is the biggest day I remember hearing about even when the BMS market was the only market.
I only have his work information ... no email or cell phone... can you help me out.
[redacted], a great day, congrats !!!
jmc
John M. Capek, Ph.D
Executive Vice President, Medical Devices
Abbott
100 Abbott Park Road
[redacted]
Abbott Park, IL 60064
Tel [redacted]
Fax [redacted]
[redacted]
www.abbott.com

FOOTNOTE 31

From: Capek, John M
Sent: Thursday, September 04, 2008 01:33 PM
To: [redacted]
Subject: FW: Congrats

fyi from Mark.
jmc

From: markgmidei[redacted] [mailto:markgmidei[redacted]
Sent: Thursday, September 04, 2008 1:06 PM
To: Capek, John M
Subject: Re: Congrats

thanks John,

Mark

Mark G. Midei, MD, FACC
[redacted]
(h) [redacted]
(c) [redacted]
(p) [redacted]

-----Original Message-----
From: Capek, John M <[redacted]>
To: markgmidei[redacted]
Sent: Thu, 4 Sep 2008 2:03 pm
Subject: Congrats

Mark,
Thought I would send a quick note. I heard thru the grapevine that you had a truly outstanding day with Xience in the labs on Friday, perhaps settiing the single day implant record. I'm glad the product is living up to both your and our expectations.
Stay in touch, and thanks for your support.
jmc
John M. Capek, Ph.D
Executive Vice President, Medical Devices
Abbott
100 Abbott Park Road
[redacted]
Abbott Park, IL 60064
Tel [redacted]
Fax [redacted]
[redacted]
www.abbott.com

FOOTNOTE 32

December 29th, 2008

[redacted]
TM – Baltimore

Dear [redacted],

I am writing a long overdue congratulations letter on the launch and continued success of XIENCE V in your territory. You have exceeded my expectations on your Xience MS achievement in such a short amount of time.

Your preparation and conditioning with your customers has enabled you to have an immediate impact with Xience. Your ability to secure the business in three accounts the first week of launch is another testament of your competitive knowledge of your accounts. You continually showed your customers who Abbott Vascular is, what we could do, and how we could win. You turned the phrase, "if we can see it and believe it, we can achieve it," into reality as the launch began.

As you prepare to complete another year in the top 5 in rankings, I want to again congratulate you on this remarkable feat. Moreover, the relationships you have formed at accounts like St. Joe's, Union, and Hopkins are hallmarks of what every rep strives for in their accounts. In my 15 years of being in this business, I have never seen personal relationships as strong as the ones you have developed with Dr's Mark Midei, [redacted] and [redacted]. Through your hard work and dedication, you have truly differentiated yourself from all your competitors in the Baltimore area. **Outstanding job!**

[redacted] I am extremely pleased with your performance in 2008, and more specifically with the Xience launch. It's not too often in sales that you have an opportunity to launch a technology like Xience. However, it's how you take advantage of this opportunity that will define you as a sales representative. I recommend you take some time over the holidays to reflect on your accomplishments. You earned it!

In closing, I want to thank you again for your hard work and dedication. It must have felt good the other day when we were presenting to U of M, and they were thanking you for all that you do for them. It's been a pleasure working with you over this last year, and watching you take on a leadership role in the Philadelphia region. I know this is not a role you often like to take on, but you have stepped-up to the challenge and have lead by example. However, as we move forward into 2009 our job will get tougher. BS wants the business back. We will have to work as hard in maintaining and looking for growth as we ever did in the preparation for the XIENCE V launch. The expectations will not decline but only grow. But you are the person for the job. I am proud to have you on my team.

Thanks again,

[redacted]

FOOTNOTE 34

Andy Nelson's BBQ [redacted]
Cockeysville, MD 21030
(P) [redacted]
(F) [redacted]

Catering Contract

Client/Organization	Event Date	Booking Tel	Booking Fax	Event #
[redacted]	8/31/2008 (Sun)	[redacted]	[redacted]	E09382
Address		**Booking Contact**	**Site Contact**	**Guests**
[redacted]		[redacted]	Dr. Mark Midei	60/0 (Act)

Theme	Party Name	Sales Rep	Category
Appreciation Q/A#3	[redacted]	Paul Nelson	Mobile Pit with Crew

Adults: 60 **Children:** **Time of Event:** 4:00 pm - 7:00 pm **Time of Food Service:** 4:00 pm - 7:00 pm

EVENT LOCATION

Site Name	Site Address
Dr. Mark Midei	[redacted]

Directions

Phone # [redacted]

FOOD/SERVICE ITEMS

Food/Service Items	Total
The Alabama Pig Pickin' (Mobile Pit)	1,407.00
A Whole Pig (slow smoked for 15 hours) Smokehouse Dixie Chicken Grandma's Cole Slaw Redskin Potato Salad Andy's Famous BBQ Beans Fresh Kaiser Rolls	
Extra Fixin's	
Regular Hotdogs (All Beef) (for 30 guest)	58.50
Memphis Style Ribs (Wet for 40 guest)	140.00
DESSERTS	
Peach Cobbler (whole pan) 38-39 pieces (2 total)	120.00
Gratuity	330.00
(Includes: Assorted Sodas, Sweet Tea, All Plastic & Paper Goods and Condiments)	

EVENT NOTES

St. Joe Medical Center Cardiac Cath Lab - Barbecue

E09382 - [redacted]

Subtotal	2,055.50	Paid	250.00
Tax	103.53	Balance	1,909.03
Total Value	2,159.03		

PAYMENTS MADE

Payment	Date	Method
250.00	7/29/2008	Credit Card

DEPOSIT DUE TO HOLD YOUR EVENT DATE IS:
GRATUITY IS NOT ALWAYS INCLUDED, BUT IS APPRECIATED.
Andy Nelson's BBQ Catering Policies

1. Catering dates are reserved on a first come, first serve basis with a 30% deposit. The deposit is only refundable if the event is cancelled within 10 days or the event. The balance is due the day of the event.

2. It is Andy Nelson's policy to bring more than enough food to feed your guests. This policy allows your guests to eat as much as they like only for the service time booked. Any remaining food stays with us.

3. Our pricing is listed for any event within a 25 mile radius from Andy Nelson's BBQ. Additional charges are $3.50 a mile after 25 miles.

4. A full service event is a 2 hour serve and a mobile pit event is a 3 hour serve. Any extra hours added are $1 extra per person, per hour.

5. We set-up, serve and clean up the serving line. We provide the tables from which we serve and all the necessary tableclothes and plastic ware for the menu we are serving. If you plan to serve a food or beverage item not from our menu, please provide the necessary paper and plastic ware.

6. Our serving lines require some heavy equipment. Therefore, the distance between where we can unload our vehicles and where we set up the serving line must be reasonable. If this is not the case an extra charge will be added. Extra charges also apply if a caterer is needed for any extra service or cleanup.

7. In case of inclement weather, we request that you provide a covered area in which to serve for full service events. We have info. about tent rentals.

8. For our serving lines, we use black heavy duty plastic ware and red and white tableclothes. If you would rather use white, please let us know when booking your event. Additional fees apply for extra tableclothes needed.

9. Our menus are flexible. If you have questions concerning food items or menus, please ask and we will try to work with you and your circumstances.

10. Gratuity of 15%-20% will be added to full service and mobile pit events booked for 100 or

more people. Please note that having an event with less than 100 people with extra labor involved, a whole pig event, extra serving hrs., extra fixings, a Mobile Pit, school, business or Sunday event, a tip will be added into the contract.

11. The guest count & menu should be finalized one week prior to the event and should not be changed after that.

Customer Signature_____ Date_____

FOOTNOTE 35

From: [redacted]
Sent: Wednesday, July 02, 2008 07:24 AM
To: [redacted]
Subject: Re: Chip Visit

That is outstanding.

Sent using BlackBerry

From: [redacted]
To: [redacted]
Sent: Wed Jul 02 07:14:08 2008
Subject: Chip Visit

[redacted]
We are good for dinner with Dr.. Midei on the night of Monday the 21st. We will have dinner at his house. "Beers and Crabs".
Still working on accounts for that day.
Regards,
[redacted]
Regional Sales Manager
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA, 95054
Cell: [redacted]
Fax: [redacted]
[redacted]
www.abbott.com

FOOTNOTE 36

From: [redacted]
Sent: Monday, November 24, 2008 05:33 PM
To: [redacted]
Subject: FW: Fwd: Christmas Party
Attachments: 1220MideiContract.doc; 1220Midei.doc

>From: markgmidei[redacted]
>To: [redacted]
>Subject: Fwd: Christmas Party
>Date: Mon, 24 Nov 2008 14:46:36 -0500
>
>
>
>
>Mark G. Midei, MD, FACC
>[redacted]
>[redacted]
>(h) [redacted]
>(c) [redacted]
>(p) [redacted]
>
>
>-----Original Message-----
>From: [redacted]chefsexpressions.com>
>To: markgmidei[redacted]
>Sent: Fri, 21 Nov 2008 11:36 am
>Subject: RE: Christmas Party
>
>
>
>
>Hi Mark,
>
>Attached is a menu and contract.? Please review the menu and let me know
>What you think.? This is just the beginning, I am happy to revise it if you
>like.
>
>?
>
>Feel free to call me with any questions.
>
>?
>
>
>[redacted]
>
>Chef's Expressions
>
>[redacted]
>
>www.chefsexpressions.com
>
>?
>
>
>
>
>
>From: markgmidei[redacted] [mailto:markgmidei[redacted]
>Sent: Friday, October 31, 2008 3:40 PM
>To: [redacted]@chefsexpressions.com
>Subject: Christmas Party

>
>
>?
>
>Hi [redacted]:
>
>I was given your name by [redacted] at [redacted].
>
>I am planning a staff Christmas party for the last Saturday before
>Christmas.? It will be at my house [redacted]
[redacted].? Aproximately 80 adults usually attend.? I would like to have a bar
>service, circulating starters, and a buffet style dinner.
>
>I am interested in your availability, and a price quotation.
>
>Mark
>
>
>Mark G. Midei
>[redacted]
>[redacted]
>(h) [redacted]
>(c) [redacted]
>(p) [redacted]
>
>
>
>?
>
>
>
>McCain or Obama? Stay up to date on the latest from the campaign trail with
>AOL News.
>

From: [redacted]
Sent: Tuesday, November 25, 2008 07:54 PM
To: 'markgmidei[redacted]
CC: [redacted]
Subject: RE: Christmas Party

Mark - I have narrowed down the caterers. I am reviewing two proposals tonight and will give you all of the information tomorrow morning. Sorry for the delay. [redacted]

[redacted]
Territory Manager
Endovascular/Vessel Closure
Abbott Vascular
[redacted]
Finksburg, MD, 21048
Tel [redacted]
Fax [redacted]
[redacted]
www.abbottvascular.com

From: markgmidei[redacted] [mailto:markgmidei[redacted]
Sent: Monday, November 24, 2008 1:58 PM
To: [redacted]
Subject: Fwd: Christmas Party

Mark G. Midei, MD, FACC
[redacted]
(h) [redacted]
(c) [redacted]
(p) [redacted]

-----Original Message-----
From: [redacted]@chefsexpressions.com>
To: markgmidei[redacted]
Sent: Fri, 21 Nov 2008 11:36 am
Subject: RE: Christmas Party

Hi Mark,
Attached is a menu and contract. Please review the menu and let me know what you think. This is just the beginning, I am happy to revise it if you like.

Feel free to call me with any questions.

[redacted]
Chef's Expressions
[redacted]
www.chefsexpressions.com

From: markgmidei[redacted] [mailto:markgmidei[redacted]
Sent: Friday, October 31, 2008 3:40 PM
To: [redacted]@chefsexpressions.com
Subject: Christmas Party

Hi [redacted]:

I was given your name by [redacted] at [redacted].

I am planning a staff Christmas party for the last Saturday before Christmas. It will be at my house [redacted]. Aproximately 80 adults usually attend. I would like to have a bar service, circulating starters, and a buffet style dinner.

I am interested in your availability, and a price quotation.

Mark
Mark G. Midei
[redacted]
(h) [redacted]
(c) [redacted]
(p) [redacted]

From: [redacted]
Sent: Monday, December 15, 2008 01:08 PM
To: mark midei; [redacted]
Subject: Saturday

Mark - Just a follow up from the last email. Just to give you the total amount due $9050. So far $4250 has been called in per my last email.
Can you please have the girls call;
St Jude - Tony and the CRM side
Boston - Roger and Kevin
Medtronic - Kevin
Thank you very much,
[redacted]

Chef's Expressions

Mark Midei
[redacted]
Home

Date	*Saturday, December 20, 2008*
Event	*# 4989 Midei Holiday Party*
Location	*[redacted]*
Time	
Guest Count	*80*

STAFFING

1 Supervisor
2 Servers
1 Bartender
1 Action Chefs
1 Kitchen Chef

BAR

Chef's Traditional Bar

Smirnoff Vodka, Gordon's Gin, J & B Scotch, Virginia Gentlemen's Bourbon, Bacardi White Rum, Seagrams 7, Quarra Merlot, Terre de Monte Pinot Grigio and Five Roses Rosato, Budweiser, Coors Light and O'Doul's Coke, Diet Coke, Sprite, Ginger ale, Juices and Mixes, Bottled Spring Water, Sparkling Water, Lemons, Limes, Cherries, Olives & Ice.

THIS INCLUDES BAR SERVICE ONLY. SPECIALTY DRINKS OR TABLE SERVICE IS NOT INCLUDED AND WILL BE AN ADDITIONAL CHARGE.

TERMS & CONDITIONS

PRICING: The price for this event is based on the estimated guest count listed on the contract. This price also includes all cooking equipment necessary to carry out this event If the guest count decreases your price per person will increase to cover fixed costs associated with the event.

STAFFING: In addition to the serving time stated on your proposal, we will provide ample set-up and clean-up time. Any additional service time, however, will be billed at a rate of $37.00 per hour per server.

PERSONAL ITEMS: From time to time, Chef's Expressions will be asked to deliver, setup and / or return a personal item provided by the client. Chef's Expressions will take no responsibility if this item is broken, stolen or misplaced.

TABLE & CHAIR RENTALS: If tables and chairs are rented by the caterer, an additional fee for delivery and pickup will apply. Each location has its own policy regarding delivery and pickup times. This fee can vary from $50.00 - $400.00 depending upon rental company, date of event and times of delivery / pickup.

GRATUITY: No gratuity will be placed on your bill. It is completely up to your discretion whether a gratuity is left for the servers, bartenders and kitchen staff.

BAR: A bar price list may be provided upon request. Under Maryland State Law you may only purchase your alcoholic beverages from a liquor licensed caterer when holding the event outside of your residence. Chef's Expressions number is #CG-00844. Please be aware that many off-premise locations require us to close the bar 15-30 minutes prior to the contracted event conclusion.

CANCELLATION: In the event of a cancellation is 120 days or more before the event date 50% of your deposit or $500.00 whichever is less will be returned. If cancellation is less than 120 days, but more than 21 days before the event we will retain the entire deposit. If cancellation is 30 days or less before the party time, we will retain the deposit or you will be responsible for the agreed upon deposit not yet submitted with the signed contract. You will have no further responsibility under the terms of this agreement. If cancellation is less than 21 days before the party, you will be responsible for the entire cost of the party. If a deposit has been rendered and the contract has not been signed, that deposit will be under the same stipulations.

The caterer is in no way responsible for failure to provide services due to strikes, floods, fires, severe snow storms, power failure, location unavailability, contract negotiations or acts of God.

INCREASES: For a party scheduled 90 days in advance, we reserve the right to increase food costs should our costs increase due to market fluctuations.

GUARANTEE: We request that you notify Chef's Expressions with a guaranteed head count ten days before the event. This guarantee will be the basis for your final billing charges. No reduction in guest count reported after this date can be made after that time. _____ (initial)

FIRST DEPOSIT: A deposit of $2,041.00 is due by 11/28/2008 to secure your date .

SECOND DEPOSIT: A second deposit is due 90 days after initial deposit is received.

DEPOSIT RECEIVED: A deposit of $0.00 was received on

UPDATED BALANCE (including Maryland State Sales Tax): The current balance of your event is $8,167.52 which is DUE FIVE BUSINESS DAYS PRIOR to the Event Date. _____ (initial)

There will be a 5% service charge for any payments over $500.00 made on a credit card. All credit card purchases must be pre-approved and receive proper authorization prior to the event. _____ (initial)

SUMMARY OF ESTIMATED COST

Menu:	*3,674.40*
Liquor :	*1,360.00*
Service :	*2,034.00*
Rentals :	*642.19*
Sub Total :	*$7,778.59*
Sales Tax :	*$466.72*

Please return a signed copy of this contract with your deposit in order to secure your date selection. Sales Tax will be added to all non tax-exempt bills. A Tax Exempt Certificate must be returned with this signed contract or you will be charged Sales Tax.

Accepted By : _____ **Date :**_____ **Billing Address**

Client

Mark Midei

[redacted]

Accepted By :_____ **Date :**_____

Chef's Expressions

FOOTNOTE 39

From: Simonton, Charles A
Sent: Wednesday, July 01, 2009 04:01 AM
To: 'Markgmidei[redacted]
Subject: Re: current events

Mark,

Would be happy to talk. I'm at our facility in Ireland today and traveling back to NY tomorrow. Can you send me your cell # or beeper?

Chuck

Sent using BlackBerry

From: Markgmidei[redacted] <Markgmidei[redacted]
To: Simonton, Charles A
Sent: Wed Jul 01 03:56:05 2009
Subject: current events

Hi Chuck:

I'm not sure if you are aware of my situation in Baltimore, but if you've got a few minutes, I would really appreciate your advice.

Mark Midei

FOOTNOTE 40

From: [redacted]
Sent: Wednesday, November 11, 2009 09:06 AM
To: Markgmidei[redacted]
Subject: RE: An Update from Abbott Vascular

Hi Mark, would you be available to talk tomorrow or Friday? I am open most of the day on each day...scheduling catch up time! . Let me know if you have some time. I look forward to speaking live.

[redacted]

From: Markgmidei[redacted] [mailto:Markgmidei[redacted]
Sent: Wednesday, November 11, 2009 8:38 AM
To: [redacted]
Subject: Re: An Update from Abbott Vascular

[redacted]:

Thanks for reaching out. Chuck called me earlier today with the same information. I told him I might be interested in working with you if the opportunity arose. I would not rule out a full time position as my practice has been mortally wounded in Baltimore due to a toxic political environment.

Mark

In a message dated 11/10/2009 6:28:37 P.M. Eastern Standard Time, [redacted]av.abbott.com writes:
Dear Dr. Midei,

[redacted], former medical science manager in the northeast, is no longer with Abbott Vascular. We are actively seeking a replacement for this very important role. In the interim, Chuck Simonton and I are committed to assisting you in any way we can during this transition period. Please do not hesitate to call upon us at any time. My contact information is listed below.

I look forward to speaking with you soon. Thank you very much.

Sincerely,
[redacted]
Director, Medical Science Group
Abbott Vascular
3200 Lakeside Drive | Santa Clara, CA 95054
[redacted] | MB[redacted]
Email: [redacted]
www.abbottvascular.com

FOOTNOTE 41

From: Hance, Chip B
Sent: Friday, December 04, 2009 10:44 AM
To: Johnson, Gary (Divisional Vice President) C; Simonton, Charles A
Subject: Dr. Midei

Mark talked to me about possibly doing some work for us. I'm very open to doing some consulting work with him to see how it might go - either getting the word out in China/Japan, medical or safety work. I suggested he talk to all three of us and then we'd regroup after the meeting. Chip

---

Sent using BlackBerry

FOOTNOTE 42

Mark Midei

Name	Date	Purpose	Study	Payment Amount
			2007 Total	**$0.00**
MARK MIDEI	12/22/2008	Advisory Board Consulting and/or Expense Reimbursement	n/a	$3,000.00
			2008 Total	**$3,000.00**
MARK MIDEI	01/14/2009	Advisory Board Consulting and/or Expense Reimbursement	n/a	$60.00
MARK MIDEI	12/18/2009	Advisory Board Consulting and/or Expense Reimbursement	n/a	$3,400.00
			2009 Total	**$3,460.00**
MARK MIDEI	03/24/2010	Consulting Fees and/or Expense Reimbursement	n/a	$2,473.85
MARK MIDEI	03/24/2010	Consulting Fees and/or Expense Reimbursement	n/a	$26,162.29
MARK MIDEI	04/27/2010	Consulting Fees and/or Expense Reimbursement	n/a	$2,000.00
			2010 Total	**$30,636.14**
			Grand Total	**$37,096.14**

St Joseph Medical Center

Name	Date	Purpose	Study	Payment Amount
			2007 Total	**$0.00**
			2008 Total	**$0.00**
SAINT JOSEPH MEDICAL CENTER	03/30/2009	Clinical Trials Execution and Analysis	Spirit SV	$14,150.00
SAINT JOSEPH MEDICAL CENTER	05/11/2009	Clinical Trials Execution and Analysis	Spirit SV	$8,100.00
SAINT JOSEPH MEDICAL CENTER	05/11/2009	Clinical Trials Execution and Analysis	Spirit SV	$825.00
SAINT JOSEPH MEDICAL CENTER	05/11/2009	Clinical Trials Execution and Analysis	Spirit SV	$2,500.00
SAINT JOSEPH MEDICAL CENTER	06/09/2009	Clinical Trials Execution and Analysis	Spirit SV	$650.00
SAINT JOSEPH MEDICAL CENTER	10/27/2009	Clinical Trials Execution and Analysis	Spirit SV	$7,125.00
SAINT JOSEPH MEDICAL CENTER	11/17/2009	Clinical Trials Execution and Analysis	Spirit SV	$1,175.00
SAINT JOSEPH MEDICAL CENTER	11/17/2009	Clinical Trials Execution and Analysis	Spirit SV	$80.60
SAINT JOSEPH MEDICAL CENTER	12/09/2009	Clinical Trials Execution and Analysis	Spirit SV	$2,500.00
			2009 Total	**$37,105.60**
SAINT JOSEPH MEDICAL CENTER	01/25/2010	Clinical Trials Execution and Analysis	Spirit SV	$4,350.00
SAINT JOSEPH MEDICAL CENTER	03/12/2010	Clinical Trials Execution and Analysis	Spirit SV	$1,150.00
			2010 Total	**$5,500.00**
			Grand Total	**$42,605.60**

SJMC Foundation

Name	Date	Purpose	Study	Payment Amount
			2007 Total	**$0.00**
SAINT JOSEPHS MEDICAL CENTER FOUNDATION	05/23/2008	Charitable Contribution	n/a	$5,000.00
			2008 Total	**$5,000.00**
			2009 Total	**$0.00**
			2010 Total	**$0.00**
			Grand Total	**$5,000.00**

FOOTNOTE 43

From: [redacted]
Sent: Thursday, January 07, 2010 03:11 AM
To: [redacted]
Subject: Re: Dr. Midei

[redacted],

Thanks for the heads up on Mark Midei. We are taking some hits in Baltimore right now from his old partners because we have retained him for this work. It's the right thing to do because he helped us so many times over the years. I will fill you in sometime.

It would have been a nice perk for you and [redacted] to have gone together.

As you said... Maybe next time.
Hope all is well.

[redacted]

Sent using BlackBerry

From: [redacted]
To: [redacted]
Sent: Wed Jan 06 23:06:44 2010
Subject: Dr. Midei

Just an FYI that Chuck asked me to meet with him to provide an overview of the US DES market from a field based perspective and learnings from XV launch. I just had an informal talk w/ him.
He said he will most likely be focusing on supporting the Japan and China launches and some slide deck for [redacted].
PS. I'm going to Japan this week to share the XV launch learnings w/ the Japanese sales team at their launch meeting. The "dream" was for [redacted] and I to do it together, but they ended up allowing just me because we have STAR planning+ going on. :-(Hopefully we'll find another reason to go to Japan together as this trip is turning out to be a get there and get back event.

[redacted]
Clinical & Sales Integration Manager
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054-2807
Cell [redacted]
[redacted]
www.abbottvascular.com

FOOTNOTE 44

From: Simonton, Charles A
Sent: Tuesday, January 12, 2010 12:40 PM
To: [redacted]
Subject: ATTENTION: DR MARK MIDEI's Schedule Outline: PLEASE NOTE AND PLAN FOR HIS TIME
Attachments: Midei_Calendar.doc

Dear ALL,
Attached is a general schedule outline for us to make best use of having Dr Mark Midei on board for the next 2 1/2 months, which can move around as needed between the groups. As you review his calendar, PLEASE NOTE WHERE YOU HAVE SPECIFIC ASSIGNMENT TO FILL HIS SCHEDULE.
After he met with each of you last week here in Santa Clara and you gave me your feedback, the following major areas have risen to the top for his time with us:
(1) APJ: He will be going to Japan a few days before CCT and bridging to China the next week (1st week of Feb). He can also return to Japan and China, or go to Australia or other targets, for another 2 weeks later in Feb or March as needed. [redacted], please look at late Feb and March for him to return. I have just blocked out 2 weeks arbitrarily which can be moved.
(2) CLINICAL: Per [redacted] and [redacted], please see the weeks he's scheduled to be in Santa Clara and plan time for him to work with your groups on clinical trial enrollment "best practices", reimbursement needs such as even calls or visits with targeted Medicare regional medical directors or working on preparation for upcoming trials, or help with abstracts/publications development/review.
(3) PRODUCT TESTING: [redacted], although you did not get to specifically meet with Mark, his greatest skill is his hands-on in the lab, and he would be great to help me with product testing in the fluoro or side lab (like I've been doing to finalize the TREK testing). Can you or [redacted] speak with the appropriate persons [redacted] etc) to set this up?
(4) FIELD SALES SUPPORT: [redacted], please look strategically at what's happening in the next 2 1/2 months and look at the attached rough breakdown of Mark's calendar, and please use his weeks with you effectively. You are aware of the sensitivities in Baltimore, so would clearly avoid that region, but please find key physicians or cath labs you'd like him to get in front of with our data. He's been through Speaker Training and spent time with me and [redacted] last week. [redacted], please follow-up on your suggestion to have him help review the new fluoro copolymer slide decks with you.
(5) MEDICAL SCIENCE GROUP: Work on disease-state slide material, beginning with Structural Heart and specifically valvular heart disease. Consider accompanying [redacted] or [redacted] with specific physicians around development of scientific material.
In order to maximize our investment in Mark over the next 2 1/2 months, we'll need everyone's help, as directed by Chip.
Thanks!
Chuck <<...>>

Chuck Simonton, M.D., FACC, FCAI
Chief Medical Officer
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA, 95054, USA
Tel [redacted]
Fax [redacted]
[redacted]
www.abbottvascular.com

FOOTNOTE 45

From: Simonton, Charles A
Sent: Sunday, January 17, 2010 06:50 PM
To: Conaway, Sam L
Subject: RE: Baltimore Sun: Patients learn they might have unneeded stents

Sam,

Thanks. I have sent a message to Chip to give me some guidance here. I still think he would be helpful to the teams in APJ and don't want to unecessarily "pollute" the waters over there by discussing with Dan's team unless necessary.

Let's see what Chip thinks.

Chuck

Chuck Simonton, M.D., FACC, FCAI
Chief Medical Officer
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA, 95054, USA
Tel [redacted]
Fax [redacted]
[redacted]
www.abbottvascular.com

From: Conaway, Sam L
Sent: Sunday, January 17, 2010 5:58 PM
To: Simonton, Charles A; Scott, Lance C
Cc: Pacitti, David C; Hance, Chip B
Subject: Re: Baltimore Sun: Patients learn they might have unneeded stents

Chuck,

I don't think we should use him at all in the US. The media and lawyers in the Maryland area are really making this very problematic.
I would let the leadership in APJ know the situation and make a decision whether to use him or not.

Sam

Sent from my BlackBerry Wireless Handheld

From: Simonton, Charles A
To: Scott, Lance C
Cc: Pacitti, David C; Conaway, Sam L; Hance, Chip B
Sent: Fri Jan 15 13:09:05 2010
Subject: Re: Baltimore Sun: Patients learn they might have unneeded stents

Lance and All:

Is this really big enough that he couldn't support some 1-on-1's out west with [redacted] or [redacted]? If you think not, then certainly I would agree and we can have him work only in-house in Santa Clara or in APJ.

Thoughts from everyone? This is a tough one.

Chuck

Sent using BlackBerry

From: Scott, Lance C
To: Simonton, Charles A
Cc: Pacitti, David C; Conaway, Sam L
Sent: Fri Jan 15 10:39:25 2010
Subject: FW: Baltimore Sun: Patients learn they might have unneeded stents

Chuck,
Sam, Dave, and I discussed this morning and we recommend that we not use Dr. Midei in the US at this time (the press is just too hot). We recommend that we use Dr. Midei in the field in Japan / China as well as home office activities (including slide development, etc.).

Do you support our recommendation? Can you communicate to Dr. Midei?

From: [redacted]
Sent: Friday, January 15, 2010 8:24 AM
To: [redacted]
Subject: Baltimore Sun: Patients learn they might have unneeded stents

US Team: Below is an article appearing in today's Baltimore Sun regarding an investigation at St. Joseph Medical Center in Towson that hundreds of patients unnecessarily received coronary stents. The hospital's review, which began in May 2009, found that some patients were told they had a 90+ percent blockage and treated with a stent, when they actually had less than a 10 percent blockage. The primary doctor implicated in the review is Dr. Mark Midei, who abruptly stopped practicing and lost his privileges at the hospital last summer.
The article does not mention any specific products or companies, and does include a positive patient testimonial towards the end of the article.

[redacted]
Manager, Public Affairs
Abbott Vascular
Phone: [redacted]
Mobile: [redacted]

Patients learn they might have unneeded stents
Some St. Joseph's patients given cardiac implants they didn't require
Baltimore Sun 01/15/2010
Author: Robert Little

St. Joseph Medical Center in Towson, whose cardiology business is a focus of a continuing federal health-care fraud investigation, has notified hundreds of its heart patients that they may have received expensive and potentially dangerous coronary implants they didn't need.

An internal review, begun last May at the behest of federal investigators and in response to a patient complaint, has turned up 369 patients with stents that appear to have been implanted in their arteries unnecessarily, CEO Jeffrey K. Norman said in an interview yesterday. Patients began receiving letters alerting them to the finding early last month, and more notifications are expected as the review continues.

"We take our interaction and the care of our patients with the utmost seriousness, and so we wanted to alert patients and their physicians to what we found," said Norman.

In several cases reviewed by The Baltimore Sun, patients who received coronary stents at St. Joseph - purportedly to open a clogged artery to correct a severe blockage - have since learned they had only minor blockage, if any. One 69-year-old man was told his artery had a 95 percent blockage, yet the new review suggests something closer to 10 percent, which is considered insignificant. A 55-year-old woman who agreed to receive a stent after being told she had a 90 percent blockage has since learned she had virtually no problem and that she never suffered from the heart diagnosis that has consumed her life for the past 18 months.

St. Joseph calls itself the busiest heart catheterization center in Maryland, and it is regarded as one of the primary cardiac care facilities in the region. The center typically performs about 6,500 cardiac procedures a year - an average of 18 a day. Last year St. Joseph highlighted the placement of its 100,000th coronary stent since 1980.

Hospital officials say the only doctor implicated in their review is one of the center's marquee physicians, Dr. Mark G. Midei, who abruptly stopped practicing and lost his privileges at the hospital last summer without notice to his patients or any comment from hospital officials.

Midei declined to discuss the matter in detail but released a statement Thursday saying he expects to be exonerated and to return to medical practice.

"I am confident that I have always acted in the best interest of my patients, and when all the facts are presented, I will continue providing quality medical care to my patients," he said.

Coronary stents are cylindrical devices that can open arteries clogged with plaque or create a bridge across areas of damage. They are typically inserted during a procedure called cardiac catheterization, in which a tool is inserted into the bloodstream at a small incision in the leg and threaded up to the arteries near the heart.

An alternative to open-chest surgery, cardiac catheterization with stent placement is a lucrative business for hospitals in the United States, which often charge $10,000 or more for the procedure. Most clinical guidelines, and reimbursement rules for Medicare and private insurance, set minimum thresholds for the procedure, often requiring at least 70 percent blockage of an artery before a stent should be placed. St. Joseph's guidelines regard blockage of 50 percent or less to be "insignificant."

Letters began arriving at patients' homes last month, alerting them to "differences" or "variances" uncovered in their medical files, and advising them to call their cardiologists. Packages sent to their cardiologists contained copies of the patients' X-ray images, along with the written laboratory report prepared when the stent was placed.

Jay D. Miller, a prominent medical malpractice attorney in Towson, said he has spoken with people who received letters and that many are contemplating legal action.

"A very substantial number of people received coronary artery stents they did not need," Miller said.

"And they not only had a procedure that wasn't needed, they have a stent in their artery for the rest of their life, they're on a serious blood-thinning drug, and there's the psychological effect of being led to believe that you have heart disease."

Vicki Marrs, a 55-year-old patient from Conowingo, is typical. She got a stent in July 2008 after arriving at St. Joseph's with chest discomfort and being told one of her arteries was 90 percent blocked. Now doctors and lawyers who have reviewed her files say Marrs had only a 10 percent blockage at most, and that she never suffered from the kind of heart disease described by Midei 18 months ago.

"I'm angry and I'm upset," said Marrs, after telling of the changes in her emotions and lifestyle following that diagnosis. Patients who receive stents must take blood thinners, and she said she battles fatigue from her daily dose of the drug.

"You go to a doctor thinking he's going to take care of you and make you better, and now I have this thing that I don't need and that can't be removed," she said. "I trusted him."

Norman, while acknowledging the hospital has enountered patients "who've been upset and angry," said the hospital's investigation and patient notification process has been conducted in the interest of getting information to patients quickly so they can consult with their cardiologists. The investigation focused solely on Midei after a random sampling raised questions about him, Norman said, and it will include reviews of patient records over the past two years - the time during which potential complications from the procedure would be expected to surface.

While stent placement is a common and relatively safe procedure, it is not without complications and

potential hazards. One study published four years ago in the Netherlands reported a 5.7 percent rate of "major" complications from stent placement, including a 2.3 percent death rate. Physicians with more experience at the procedure had fewer complications, it concluded.

Norman said that no other employees of the hospital have been implicated in the review.

"The physician is the captain," he said. "The physician is in charge."

Asked if the hospital bears any additional liability for the patients who received stents they didn't need, Norman said:

"I suppose we do. I think that we'll see what comes from these attorneys that are looking for cases, and we'll respond to that."

Doctors and hospitals in other parts of the country who placed stents when that blockage threshold wasn't met have faced lawsuits, fines and even prison time.

In 2007, a doctor at Peninsula Regional Medical Center in Salisbury was accused of performing unnecessary stent procedures and is being sued by 24 patients. The doctor, John R. McLean, resigned from practice, citing deteriorating eyesight.

Last year, a Louisiana doctor was sentenced to 10 years in federal prison on health-care fraud charges for placing unnecesary coronary stents and then billing Medicare and private insurance companies. Two hospitals where he worked paid a combined $5.7 million penalty to the federal government, and one paid an additional $7.4 million to settle a class action lawsuit brought by the doctor's patients.

St. Joseph announced in July that it had negotiated a settlement with federal health-care fraud investigators related to the hospital's relationship with MidAtlantic Cardiovascular Associates, the dominant cardiology practice in suburban Baltimore. Details of that settlement were not disclosed and are expected to be announced soon, but court records have speculated that the hospital will pay a fine that exceeds $5 million.

When federal subpoenas arrived at St. Joseph in June 2008 seeking records related to the cardiology business, the hospital's then-CEO, John Tolmie, was suspended along with two other top executives. All of them have since resigned.

Norman said the federal investigation is not directly related to the issues with stent placements. But Midei was a founding member of MidAtlantic, who left in January 2008 to become an employee of St. Joseph. In statements sent to The Baltimore Sun last year, St. Joseph's officials repeatedly said the federal investigation "has nothing to do with the quality of patient care." Yesterday, they noted that statements from the hospital ceased to include that claim around mid-2009.

When St. Joseph opened its new cardiac care center in early 2008, Midei was regarded as one of its big draws. His recruitment by the hospital, away from the MidAtlantic practice just as it was poised to enter a lucrative merger with Medstar Health, created tension among doctors and executives at the hospital that boiled over into the court system. In one court record, then-CEO of MidAtlantic, Hank Yurow, said he threatened in 2008 to "make it my mission to destroy him [Midei] personally and professionally."

In interviews with attorneys and other patients, it is clear that some of Midei's patients - even after getting letters from the hospital - reject the suggestion that he has done anything wrong.

Peggy Lambdin, 66, of Timonium describes waking up in July 2008 feeling as if she were drowning, and being diagnosed at St. Joseph a few days later with a 90 percent blockage. Midei placed a stent, and the symptoms cleared up almost immediately, she said.

She has since received a letter suggesting the blockage was less than 50 percent, but said she considers the details immaterial.

"No one can ever tell me that I didn't need that stent," Lambdin said. "I feel like he saved my life."

She also recounted another trip to the St. Joseph's lab during which Midei performed a heart catheterization but decided that no stent or other treatment was needed.

"I trusted him, and I still trust him," Lambdin said. "If I needed another stent, I would want Dr. Midei to do it."

Norman said he hopes the hospital's efforts to inform patients about the investigation demonstrate they can trust St. Joseph's.

"Like anything in healthcare, heart care is a team effort. And if there's any one individual on the team who isn't performing at the highest level, you take action, as we have in this case," Norman said. "We're confident that we still provide the highest quality care."

FOOTNOTE 46

From: [redacted]
Sent: Monday, January 18, 2010 04:42 AM
To: Simonton, Charles A
Subject: Re: Meeting with Dr Midei to review " Let's Talk About Xience V Safety"

Chuck,
That is great information. We could not answer the question on drug potency, so this information will give us options.
We are hoping to have Mark help with the Polymer deck, we talked about that during our call. Any of the presentation content being developed for ML8 would be an option and any other content that requires a fresh physician perspective! This is a unique opportunity and Mark"s very good at critical review and helping to shape the story we want to tell.

[redacted]

Sent using BlackBerry

From: Simonton, Charles A
To: [redacted] Scott, Lance C; Pacitti, David C
Sent: Sun Jan 17 11:44:38 2010
Subject: RE: Meeting with Dr Midei to review " Let's Talk About Xience V Safety"

[redacted]
Thanks for the feedback. Glad it worked out so well. Like the suggestions, with one thought: on the sirolimus and zotarolimus and everolimus dosing and potency, according to our scientists they are essentially "equipotent" drugs (similar efficacy per ug of drug).
Can Dr Midei help with any other decks or messages? We're still trying to fill his time.
Chuck
Chuck Simonton, M.D., FACC, FCAI
Chief Medical Officer
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA, 95054, USA
Tel [redacted]
Fax [redacted]
[redacted]
www.abbottvascular.com

From: [redacted]
Sent: Saturday, January 16, 2010 5:40 PM
To: Simonton, Charles A; Scott, Lance C; [redacted]
Subject: FW:Meeting with Dr Midei to review " Let's Talk About Xience V Safety"

Dr Simonton,
I wanted to follow-up after my meeting with Dr Midei yesterday in Baltimore. As you know our primary goal was to review the "Lets talk about XV Safety" deck that our team has been working on for the upcoming STAR meeting. Dr Midei and I met for lunch before our conference call and this was a perfect chance for me ask him about his thoughts on XV deployment as well as IVUS assessment. This was timely because next week I am planning to spend some time in Springfield with Dr[redacted] on Thursday and Friday. Dr [redacted] has expressed concerns about XV recoil by IVUS post deployment. He is a long time Cypher user I am sure he is trying to understand the difference between the devices and I appreciated Dr Midei thoughts. I think you might be trying to meet with Dr[redacted] next week on Wednesday, that would be outstanding if it works out!
After lunch [redacted] and I had a great call with Dr Midei. We spent 2.5 hours on the call and accomplished everything we hoped and more, he provided some great insight and wording from a clinician's perspective. Dr. Midei did a fantastic job reviewing our slides with very thoughtful and insightful feedback. [redacted] and I talked after the call and we agree that our slide deck is

better and more impactful based on his perspective.
A few of his thoughts:
Refer to ID TLR not just TLR
Include the primary endpoints for Compare and SIV to claim superiority as recent large studies
Do not put Sirolimus and Zotarolimus dosing on the same slide as XV. You may get into discussions around drug potency differences. He offered some suggestions as alternatives
Add the Chandler Blood Loop test to the polymer section
New final slide to simply summarize that over time XV is a Vision with a safe polymer

This was a valuable opportunity! This was a perfect fit for Dr Midei and [redacted] plans to provide him the updated version shortly so he can see the result of his effort
Thanks,
[redacted].

FOOTNOTE 47

From: [redacted]
Sent: Monday, February 01, 2010 06:21 PM
To: Conaway, Sam L; Pacitti, David C; Scott, Lance C
CC: [redacted]

Subject: DES STAR breakout
Attachments: Let's Talk About Xience V Safety ROUTED FINAL2.ppt

Dear Sam, Dave and Lance,
Prior to our Wednesday dry run with you, we want to ensure you have the latest slide deck we are rolling out at STAR - "Let's talk about Xience V Safety".
The purpose of this deck is to tell our best Xience V safety story. This is a "global slide deck" with input from Dr. Simonton, Dr. Midei, Clinical Marketing, Global Marketing, US Marketing, and the CSI team. We also incorporated key slides & "storylines" from the physicians who attended the Apothicom meeting in New York.
This is a "living safety slide deck" that will get updated with new/better thrombosis and DAPT data cuts coming from CRT and ACC. The purpose of our breakout is to familiarize the field with this deck, practice key summary slides, and learn more about the Marketing safety campaign for 2010.
In addition, there is a compendium "Polymer Safety" deck that will be created for reps and customers who want additional polymer and related pre-clinical data. There is an internal cross functional team (with R&D, pre-clincal, marketing) currently exploring the best Xience V Polymer data to tell a "fresh" story on this topic. This team includes [redacted] who is now on [redacted] US DES Marketing team. Stay tuned for updates on this topic.
This Safety deck is for your review prior to the breakout dry run because there is not enough time to go thru every slide. We look forward to your continued support of our DES Safety breakout.

[redacted]
<<...>>

[redacted]
Clinical & Sales Integration Manager
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054-2807
Cell [redacted]
[redacted]
www.abbottvascular.com

FOOTNOTE 48

From: Hance, Chip B
Sent: Monday, January 25, 2010 05:39 AM
To: Simonton, Charles A
Subject: RE: Mark Midei

Ok. Thanks. Chip
-----Original Message-----
From: Simonton, Charles A
Sent: Sunday, January 24, 2010 8:04 PM
To: Hance, Chip B
Subject: Mark Midei
Chip,
Just spoke with Dan who has spoken with Mark. Mark understands the sensitivities and is returning to Baltimore today. He understands that you and I will be calling him later this week.
Chuck

Sent using BlackBerry

FOOTNOTE 49

From: Simonton, Charles A
Sent: Tuesday, February 02, 2010 09:09 AM
To: [redacted]
Subject: RE: Mark Midei

I would continue to work with him, behind the scenes, at this point. We've just decided not to have him doing any public type work in the U.S. right now.
Chuck

Chuck Simonton, M.D., FACC, FCAI
Chief Medical Officer
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA, 95054, USA
Tel [redacted]
Fax [redacted]
[redacted]
www.abbottvascular.com
-----Original Message-----
From: [redacted]
Sent: Tuesday, February 02, 2010 7:52 AM
To: Simonton, Charles A
Subject: Mark Midei
Chuck, what is the status of Mark? Will we be working with him? If yes, I want to move forward with the MR slide deck. Thx
[redacted]

FOOTNOTE 54

Medical Advisory Board
The Americas
October 13-14, 2007

Summary Report

January 2008

Abbott
A Promise for Life

Meeting Objectives

Abbott Vascular

Physicians

MODERATORS

[redacted]

- Charles Simonton

[redacted]

- Mark Midei

[redacted]

TBD

- +2 Canadian
- +2 Latin American

***Potential Moderator

Abbott Vascular

Meeting Agenda

Friday, Oct 12

Optional cocktail reception 7 pm

Saturday, Oct 13

Opening Session 8.00-9.30

- **Introduction, AV Structure and Vision, Objective of Meeting**

Breakout Sessions rotating groups of 7-8 MDs 9.30-4.00 (includes lunch and break)

- **DES Success – Winning with XIENCE V**
- **Sustained DES Leadership – Building beyond XIENCE™ V**
- **Core Products Today and Tomorrow**

Summary of Findings 4.00-5.30

Dinner 7.00-9.00

Sunday, Oct 14

General Session Hot Topic 9.00-11.00

- **Changing Landscape of Interventional Cardiology moderated b[redacted]**

Other 11.30-12.00

- **PCI Coalition Initiative**

Key Takeaways, Action Items and Plan for Next Meeting 12.00-1.00

Departure by 2.00

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Key Findings

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Key Findings

[redacted]

- **The MAB members were evenly split, with half thinking the drop in DES usage and PCI volume represents a swing in the pendulum and the other half thinking it represents a new plateau (i.e., this was a necessary correction). Many cited the need to improve relationships with the cardiology community in order to help turn this around.**

[redacted]

Abbott Vascular

DES Success: Winning with XIENCE™ V

Question

Key Takeaways

Recommendations

[redacted]

Abbott Vascular

DES Success: Winning with XIENCE™ V

Question

Key Takeaways

Recommend ations

[redacted]

Abbott Vascular

DES Success: Winning with XIENCE™ V

Question

Key Takeaways

Recommend ations

[redacted]

Abbott Vascular

Sustained DES Leadership – Building Beyond XIENCE™ V

Question

Key Takeaways

Recommend ations

[redacted]

Abbott Vascular

Sustained DES Leadership – Building Beyond XIENCE™ V

Question	[redacted]
Key Takeaways	

Abbott Vascular

Sustained DES Leadership – Building Beyond XIENCE™ V

Abbott Vascular

Cardiovascular Leadership Outside of DES

Question	[redacted]
Key Takeaways	
Recommendations	

Abbott Vascular

Cardiovascular Leadership Outside of DES

Question	[redacted]
Key Takeaways	
Recommendations	

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The Changing Landscape of Interventional Cardiology [redacted]

Question

- There have been significant changes in the PCI market following the frenzy around DES safety concerns and the publication of COURAGE data. Where does the market go from here? How are you managing your practices in light of these changes? What are the implications for industry?

Key Takeaways

- The MAB members were evenly split, with half thinking the drop in DES usage and PCI volume represents a swing in the pendulum and the other half thinking it represents a new plateau (i.e., this was a necessary correction)
- Panelists revealed candidly that they're profession has done a better job promoting PCI than policing it and that some of these practices have alienated their fellow cardiologists
- Most feel that the interventional community was ill equipped to respond quickly enough to the COURAGE data

The Changing Landscape of Interventional Cardiology [redacted]

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FOOTNOTE 59

From: Pacitti, David C
Sent: Saturday, January 23, 2010 01:15 PM
To: Conaway, Sam L
Subject: Fw: Baltimore Sun: Heart-stent popularity is costly in many ways

Don't you have connections in Baltimore????? Someone needs to take this writer outside and kick his ass! Do I need to send the Philly mob?

David Pacitti
Abbott Vascular
----- Original Message -----
From: [redacted]
To: [redacted]
Sent: Sat Jan 23 13:00:47 2010
Subject: Baltimore Sun: Heart-stent popularity is costly in many ways
Below is an article from the Baltimore Sun using an ongoing investigation as to whether hundreds of patients at St. Joseph Medical Center received unnecessary stents and the "extraordinary promotion and advertising" of stents as an "illustration of why American health care costs more but delivers less."
The article includes comments from Bill Boden (COURAGE PI) and Michael Ozner (author of "The Great American Heart Hoax") related to the overuse of stents, and points to Cordis' "Life Wide Open" ad campaign as an example of aggressive marketing, which helped increase revenues for both the industry and hospitals.
The full article is below.

Heart-stent popularity is costly in many ways
Baltimore Sun 01/22/2010
Author: Jay Hancock

Did hundreds of patients at St. Joseph Medical Center get heart stents when they weren't called for under accepted medical standards?
That's a disturbing question. But for taxpayers, insurers and most medical consumers, it pales next to this one: Are millions of patients getting stents that are unnecessary even when the rules give doctors a green light?
Accumulating evidence says the answer is yes.
"In many instances we're seeing it overused and in some instances abused," says Dr. William E. Boden, a professor at the University at Buffalo Schools of Medicine & Public Health who led a major study on stent effectiveness. "Surgeons and hospitals get reimbursed handsomely for doing procedures."
Don't let the situation at St. Joseph, where patients received stents when they might have had only slightly blocked arteries, obscure the big picture. Most people getting stents don't need them even if scans show substantial blockage, studies suggest. Stents can be dangerous, too.
"You're trading one disease for another - the disease of having a blockage for the disease of having a metallic stent in your heart. And that is a disease, make no mistake," says Dr. Michael Ozner, medical director of the Cardiovascular Prevention Institute of South Florida. "These procedures are not without risk."
Thanks to extraordinary promotion and advertising, stents have become a multibillion-dollar business, substantially contributing to soaring medical-insurance costs and federal deficits.
They're a perfect illustration of why American health care costs more but delivers less.
The popularity of the tiny tubes, intended to prop open clogged heart vessels, took off when companies began coating them with drugs to prevent arteries from reclogging. But the coated versions cost as much as three times more than bare-metal stents.
Dr. Mark Midei, the surgeon associated with the implants questioned by Towson-based St. Joseph, was an early proponent.
"This is the hottest thing in cardiology in years," he told The Sun in 2003, referring to the drug-coated Cypher stent made by Johnson & Johnson's Cordis division.
Cordis turned up the buzz with an expensive TV-ad campaign for Cypher that ran nationwide in 2007 but also aired exclusively in Baltimore in early 2008.
Health-policy professionals were used to companies hawking pills directly to patients. Even so, J&J's "Life Wide Open" stent commercial shocked them because it expanded the pitch to medical hardware.
Baltimore "was apparently a key market for Cordis at the time, given the proximity of a lot of hospitals in that region," said J&J spokeswoman Carol Goodrich.

Boy, was it. Last fiscal year, Maryland hospitals did $222 million in stent-related business, a two-thirds increase from fiscal 2002, just before the launch of the coated stents, according to the Health Services Cost Review Commission. And that doesn't count doctor charges.
Stent business at St. Joseph jumped even higher, going from $22 million to $38 million in the same period, the commission says.
Competition for stent spoils helped set off a bitter split at MidAtlantic Cardiovascular Associates, a big Baltimore cardiology practice. It also prompted a federal investigation that preceded the revelation of alleged clinical irregularities at St. Joseph.
Did patients benefit as much as the medical industry? Nobody suggests stents don't save lives when somebody is having a heart attack. But Boden's study and others show little benefit and lots of risk for patients with partly-blocked vessels who aren't in cardiac distress, doctors say. That's most stent cases.
"There has never been a study showing that people who are stable who get stents live one day longer or have fewer heart attacks" than patients with similarly blocked arteries who don't, said Ozner, author of "The Great American Heart Hoax."
In fact, medicine is revisiting the whole Roto-Rooter model that assumes vessel blockage is the main predictor of a heart attack. The worse culprits are often inflammation and smaller plaques that break off and cause clots.
Numerous patients getting stents would be better off exercising, changing diet, losing weight and taking appropriate drugs, says Boden. That way they won't risk the surgical complications of implants and, in the case of coated stents, won't have to take blood thinners for years.
But nobody makes money giving patients sensible and conservative advice.

[redacted]
Abbott Vascular
[redacted]

FOOTNOTE 60

From: [redacted]
Sent: Tuesday, March 09, 2010 09:33 AM
To: [redacted]
Subject: Baltimore Trends

[redacted]
I hope you both are doing well.
[redacted] as you are aware of, there has been a multitude of events in the Baltimore marketplace that has impacted the interventional space. This impacted has resulted in a decline in interventions throughout Baltimore. Although the decline was first noted at the time Dr.Midei was dismissed of his duties at St.Josephs in May, the most devastating impact occurred in November into December when the media, OIG and lawyers became involved in a very aggressive manner.
The purpose of this communication is to continue to keep everyone informed, although there may be national trends affecting our space, the situation in Baltimore is clearly unique and affecting interventional volume at a much greater level.
[redacted] I understand a lot of effort goes into defining our "number" but as long as a component of that number includes a percentage of the Total Available Market, I believe we should try to provide the most accurate data for this market.
The good news is our customers remain extremely loyal and we continue to appreciate very high market share throughout the Baltimore marketplace. Having said that, I did look at a Year on Year comparison through the end of February (per your request[redacted] to try to capture true trends) and the overall decline in numbers were ugly.
Here are a few

Hospital	Wires	DES
St. Joes	-59% (594 vs 242)	because of the bulk the data was not on salescast but I
		according to the inventory mg. the stent utilization is @ 135 unit/mo
		vs 250/mo in '09
JHH	-20% (348 vs 275)	-6.9% (174 vs 162)
Union	-21% (396 vs 311)	-21% (199 vs 157)
U of Md.	-10% (260 vs 234)	-7% (106 vs 98)
Sinai	26%	-15% (80 vs 68) (I placed a call to the inventory mg because of the wire vs stent relationship and he did confirm that the stent decline more closely reflected their volume trends)

I can appreciate addressing this situation may be very difficult and we must be very strategic in being this to light.
But I look to both of you, [redacted], you having been intimately involved in this mess for awhile and [redacted], sorry, this now concerns you too, as to what we do with this information.
Thank you, as always, for all your help and support.
Please advise
[redacted]