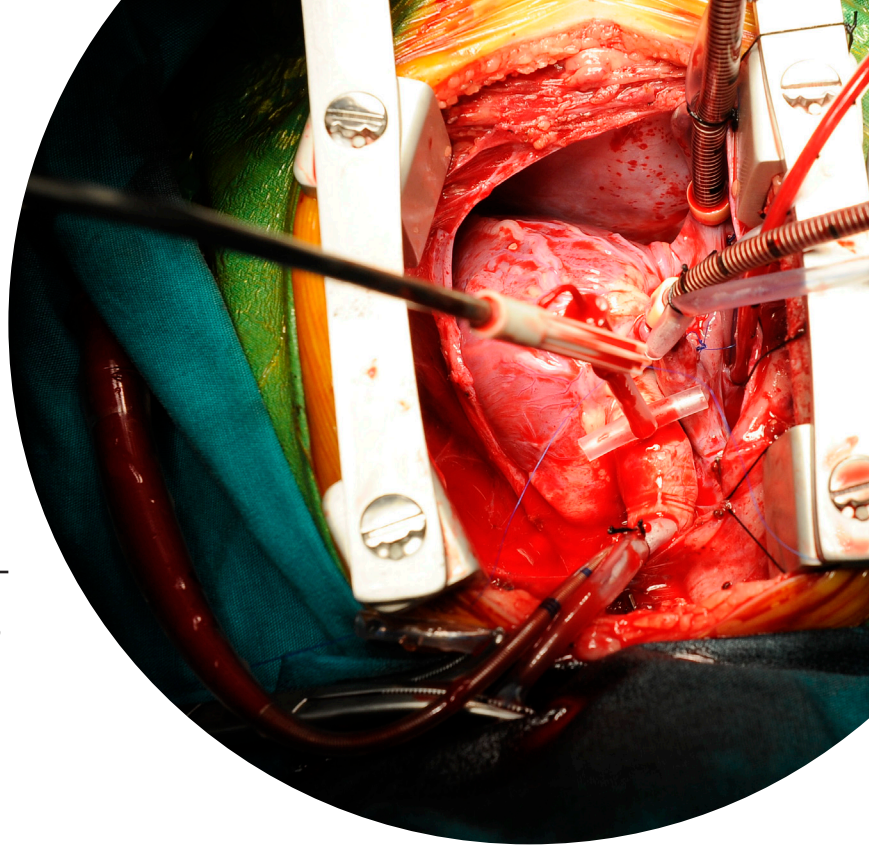

TACKLING THE HEART OF THE PROBLEM

Prosecuting Medically Unnecessary Stent Procedures

BY WILLIAM M. SULLIVAN JR. AND FABIO LEONARDI

Over the past 10 years, Department of Justice (DOJ) Criminal Division "Strike Force" teams have dramatically increased their efforts to combat public health care fraud by seeking to reduce what the Centers for Medicare & Medicaid Services (CMS) estimates to be an annual loss of $60 billion to waste, fraud, and abuse through improper payments. DOJ prosecutors have also greatly benefited from the assistance of the Department of Health and Human Services (HHS), with which they established a joint Health Care Fraud Prevention and Enforcement Action Team (HEAT) in 2009 to combat health care fraud. As a result, as of June 2015, Strike Force teams have commenced over 2,300 health care fraud prosecutions resulting from a broad range of allegations including false billing based on unnecessary or nonexistent medical treatment, illegal kickbacks, self-referrals, and other misconduct including obstructing health care fraud investigations.

As publicized by recent high-profile enforcement actions and investigations, federal prosecutors have been targeting the entire health care industry, including hospital networks and individual practitioners, and are now focusing on one of the most common and generally successful medical procedures employed to prevent the country's leading cause of death: heart stenting. This article provides an overview of such criminal and civil enforcement efforts and discusses the medical and legal controversy surrounding what federal prosecutors and some experts believe are unnecessary stent procedures.

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DEFINING STENT PROCEDURES

In February 2010, former president Bill Clinton was urgently hospitalized at NewYork-Presbyterian Hospital's Columbia campus in New York City after experiencing brief periods of discomfort in his chest. While an electrocardiogram and a blood test showed no evidence of a heart attack, images revealed that a portion of a graft blood vessel from a quadruple bypass surgery that Clinton underwent in 2004 was blocked. To open Clinton's clogged artery and restore blood flow, doctors placed two stents inside his artery.

Similarly, in the spring of 2013, former president George W. Bush visited his doctors for a routine checkup. However, while undergoing several medical tests, a treadmill exercise stress test alerted the medical staff of a condition that was immediately confirmed by a chest CT scan: Bush had a coronary blockage. The following day, doctors successfully implanted a stent to prop open the former president's narrowed artery.

The success of both of Clinton's and Bush's medical procedures hinged on the application of a stent, a tiny wire mesh tube that is permanently placed inside an artery for the purpose of keeping it open. Indeed, when a coronary artery is narrowed by a buildup of fatty deposits called plaque, it can reduce blood flow to the heart muscle, thus resulting in chest pain. However, if a blood clot forms over the plaque and completely blocks the blood flow to part of the heart muscle, it will cause a heart attack. Stents are thus particularly common and useful for people with heart disease because they keep the

coronary artery open, thus reducing the chance of a heart attack.

Like Clinton and Bush, over one million Americans undergo stent procedures every year, sometimes without even a night in the hospital.

CONTROVERSY AND ENFORCEMENT

Since the first coronary stent was introduced in 1994, the technology has dramatically transformed the treatment of blocked coronary arteries, enabling millions of patients with heart conditions to delay or even avoid undergoing heart bypass surgery. However, its arrival has also sparked a long-lasting controversy over whether cardiologists resort to stents too soon or too often. Indeed, according to various medical organizations, the procedure commonly used to place a stent, called percutaneous coronary intervention or angioplasty, is one of the five highly overused medical interventions. (*See* Anahad O'Connor, *Heart Stents Still Overused, Experts Say,* N.Y. Times, Aug. 15, 2013, http://tinyurl.com/h75ofw7.) In particular, critics argue that stent procedures performed on patients with stable coronary artery disease are generally no better at preventing a heart attack than taking medication alone, and yet many patients continue to undergo such procedures even if there is a prospect of harm and an unlikely benefit. (*Id.*) While experts often blame a flawed medical theory for allegedly unnecessary stenting, numerous medical professionals have raised allegations that doctors may be motivated to overuse stents because of the significant revenue streams that stent procedures bring to hospitals and individual cardiologists. *(See, e.g.,* Steve Sternberg & Geoff Dougherty, *Are Doctors Exposing Heart Patients to Unnecessary Cardiac Procedures?,* U.S. News & World Rep. (Feb. 11, 2015), http://tinyurl.com/qy7mszg.)

Intent on reducing and preventing Medicare and Medicaid financial fraud by investigating unnecessary medical procedures, DOJ has been focusing on the medical controversy surrounding stenting and has recently taken significant enforcement actions against medical facilities and personnel performing allegedly unnecessary stent procedures.

For instance, between 2006 and 2013, at least 11 hospitals settled federal allegations that they billed public health programs for unnecessary stents. (Peter Waldman, *Needless Stents Alleged at Kentucky Hospital amid 2-Year Probe*, Bloomberg (Oct. 7, 2013), http://tinyurl.com/zn8pal2.)

Moreover, in October 2013, a Kentucky doctor, Sandesh Patil, became the third cardiologist in the nation to be federally prosecuted for health care fraud related to the placement of heart stents. After pleading guilty to a single charge of Medicaid fraud, Dr. Patil was sentenced to 30 months behind bars. (Peter Hasselbacher, *Kentucky Cardiologist Sentenced to 30 Months Imprisonment for Fraudulent Billing*, Ky. Health Pol'y Inst. (Oct. 1, 2013), http://tinyurl.com/z7rsx4n.) That same year, Dr. Elie H. Korban, a Tennessee-based cardiologist, agreed to pay $1.15 million to the government to resolve allegations that he billed Medicare and Medicaid for medically unnecessary cardiac stent placements. (Press Release, DOJ, Tennessee Cardiologist to Pay $1.15 Million to Settle Allegations That He Performed Medically Unnecessary Heart Procedures (Dec. 19, 2013), http://tinyurl.com/hzsb8af.)

More recently, in May 2014, a Kentucky hospital (KDMC) that had been among the nation's leaders in the rate of coronary stenting agreed to pay $40.9 million to resolve allegations that, among other things, it submitted false claims to the Medicare and Kentucky Medicaid programs for medically unnecessary coronary stents. (Press Release, DOJ, King's Daughters Medical Center to Pay Nearly $41 Million to Resolve Allegations of False Billing for Unnecessary Cardiac Procedures and Kickbacks (May 28, 2014), http://tinyurl.com/zmnbndt.) In particular, the government alleged that, between 2006 and 2011, KDMC billed for numerous unnecessary coronary stents and diagnostic catheterizations performed by KDMC physicians on Medicare and Medicaid patients who did not need them, thus generating millions of dollars in Medicare and Kentucky Medicaid reimbursements for KDMC. As part of the settlement with DOJ, the HHS Office of Inspector General, and the commonwealth of Kentucky, KDMC further agreed to undertake substantial internal compliance reforms and commit to a third-party review of its claims to federal health care programs for the next five years.

While concluding its investigation of KDMC, federal prosecutors also indicted KDMC's chief cardiologist, Dr. Richard E. Paulus. According to the government, Dr. Paulus performed more stent placement procedures than any cardiologist in Kentucky and, at times, more than any cardiologist in the United States, and allegedly billed for medically unnecessary cardiac stent procedures on hundreds of his patients. In addition, DOJ filed a parallel civil complaint against Dr. Paulus, alleging that he knowingly submitted hundreds of false or fraudulent claims, seeking payment for medically unnecessary cardiac stent procedures, to Medicare and Medicaid in violation of the False Claims Act. (Press Release, FBI, Ashland Cardiologist Indicted for Performing and Billing for Medically Unnecessary Procedures (Sept. 4, 2015), http://tinyurl.com/jjoyvyc.)

Similarly, in September 2015, an Ohio cardiologist, Dr. Harold Persaud, was convicted of, among other things, performing unnecessary stent insertions as part of a scheme to overbill Medicare and other insurers by over $7 million. (Press Release, FBI, Westlake Cardiologist Convicted of Overbilling Medicare and Others of $7.2 Million for Unnecessary Procedures (Sept. 25, 2015), http://tinyurl.com/zfk43ql.)

Finally, in May 2016, a Newark, New Jersey, hospital settled allegations that it falsely billed Medicare and Medicaid for medically unnecessary cardiac procedures, including percutaneous coronary interventions, catheterizations, and stents, by paying $450,000 to the U.S. government. (Press Release, DOJ, Newark Hospital to Pay $450,000 for Allegedly Billing Health Care Programs for Unnecessary Procedures (May 31, 2016), http://tinyurl.com/h5nuxtr.)

FIGHTING HEALTH CARE FRAUD

To prosecute its war on Medicare fraud, including unnecessary stent procedures, the federal government has been relying on an array of civil and criminal laws including, in particular, the False Claims Act (31 U.S.C. §§ 3729 et seq.), the Stark Law (42 U.S.C. § 1395nn), health care fraud statutes (18 U.S.C. §§ 1347 et seq.), and the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)).

Generally, by imposing both criminal and civil liability for defrauding the government, the False Claims Act is perhaps the most popular tool for prosecuting health care fraud. In addition, DOJ has been resorting to the Stark Law, a self-referral law, to impose civil penalties on, and obtain damages from, physicians—and sometimes medical facilities—who refer Medicare patients to hospital networks with which the physicians have a financial relationship. Further, federal prosecutors have often invoked criminal health care fraud laws that generally prohibit the knowing and willful execution, and attempted execution, of schemes to fraudulently obtain payments from a health care benefit program. Under these criminal statutes, penalties may include fines, prison, or both. Finally, health care prosecutors may charge defendants with violating the Anti-Kickback Statute, a law criminalizing the act of financially incentivizing a party to refer federal health care business. A violation of this statute may generally result in up to five years in prison and a fine of up to $25,000. Importantly, though, while the alleged kickback may itself be illegal, a violation of the Anti-Kickback Statute does not necessarily indicate that the referring patient's treatment is also fraudulent. (*See, e.g.*, United States v. Medina, 485 F.3d 1291 (11th Cir. 2007).)

UNNECESSARY STENT PROCEDURES

Several recent health care fraud prosecutions have focused on medical treatments that, according to the government, failed to satisfy Medicare's "medical necessity" requirement. *(See, e.g.,* United States v. McLean, 715 F.3d 129 (4th Cir. 2013).) Indeed, CMS generally excludes from its Medicare coverage any treatment that is not medically reasonable and necessary for the diagnosis or treatment of an illness or injury. (42 U.S.C. § 1395.) Therefore, even where a treatment or procedure is approved for Medicare billing, a cardiologist or medical facility may be engaging in misconduct by billing Medicare for an approved treatment, such as an angioplasty, that is not deemed a medical necessity for the patient.

In particular, with regard to stent procedures, CMS limits carotid artery stenting to patients with specific medical conditions. Indeed, CMS's coverage generally is limited to patients who are at high risk for carotid endarterectomy, a surgical procedure to remove plaque from the artery, and who also have symptomatic carotid artery stenosis at or above 70 percent. Nonetheless, according to CMS, if patients have symptomatic carotid stenosis at 50 percent, stenting procedures may be covered by Medicare if the stenosis relates to the main coronary artery. (CMS Decision Memo for Carotid Artery Stenting (CAG-00085R) (Mar. 17, 2005).)

CMS's 70 percent general threshold for approval of carotid artery stenting procedures is primarily based on what the government has often presented as the medical community's consensus, apparently supported by the National Institute of Health's National Institute of Neurological Disorders and Stroke, that stent placement has limited efficacy, and thus is generally not medically necessary, until a patient has at least 70 percent stenosis and shows other symptoms of blockage. (*See*, *e.g.*, *McLean*, 715 F.3d at 133; *Questions and Answers about Carotid Endarterectomy*, Nat'l Inst. of Neurological Disorders & Stroke, http://tinyurl.com/356ocno (last modified Mar. 21, 2016).) Indeed, according to various members of the medical community, if an angiogram shows blockage of less than 70 percent, common treatments should include monitoring and medicating for blood pressure, prescribing statins for cholesterol, antiplatelet medications, and lifestyle changes. (*See, e.g.*, Kelly Brewington, *Whether a Stent Is Needed Can Be Tough Call*, Balt. Sun, Jan. 25, 2010, http://tinyurl.com/gu86ane.) Moreover, symptomatic patients with blockage between 50 percent and 70 percent may also be candidates for carotid endarterectomy instead of undergoing stenting procedures. (*See, e.g.*, *Carotid Stenosis (Carotid Artery Disease)*, Mayfield Brain & Spine, http://tinyurl.com/jejbklj (last updated Apr. 2016).)

PROVING UNNECESSARY STENTING

While most instances of Medicare fraud allegations, including those involving unnecessary stent placements, often result in settlements with no determination of liability, recent criminal trials in which cardiologists have been convicted of fraud in connection with medically unnecessary stent procedures provide a glimpse into the current state of stenting prosecutions.

Generally, proving cardiac stenting overuse in court is often a difficult task, as jurors are generally reluctant to convict a physician in instances where medical experts disagree with a physician's medical decision. Therefore, criminal cases that have gone to trial typically involve at least circumstantial evidence of wrongful intent.

For instance, in the unpublished case of *United States v. Patel*, 485 F. App'x 702 (5th Cir. 2012), Louisiana cardiologist Dr. Mehmood Patel was convicted of 51 counts of health care fraud relating to placing medically unnecessary stents into patients, for which he was reimbursed about $89,000. Despite defense counsel's argument that blockage measurements are inherently subjective, the Fifth Circuit Court of Appeals found that, even considering a broad margin of error, based on the severe differences between Dr. Patel's estimates and the government expert's measurements of the same patients, the jury was entitled to conclude that Dr. Patel had falsified the records by deliberately overstating the blockage. (*Id.* at 707.)

Similarly, in the *McLean* case, Dr. John McLean, an interventional cardiologist, was convicted of several counts of health care fraud and making false statements about medical treatments by submitting claims for medically unnecessary stent procedures to Medicare, Medicaid, and private insurers (DOJ brought charges against Dr. McLean after a Maryland hospital with which Dr. McLean held privileges had concluded an internal investigation into the doctor's practices). In particular, Dr. McLean was found to have committed fraud by placing stents into patients that had little to no blockage but recording the patients as having severe blockage. Indeed, according to the Fourth Circuit Court of Appeals, Dr. McLean would often falsely record patients with stenosis of under 30 percent as having blockage as high as 95 percent. (*McLean*, 715 F.3d at 133.) While several of Dr. McLean's arguments centered on the idea that the government lacked a standard for the medical necessity of coronary stents, the *McLean* court held that a reasonable person in Dr. McLean's position

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court had used the government's proposed instruction that a statement would be considered material if it was capable of influencing a *reasonable person*, instead of the defendants' proposed instruction that a statement was material if it was capable of influencing the *specific decision maker* to which the statement had been directed. (*Id.* at 11, 20.) Relying extensively on *Escobar*, the defendants contended that a jury instruction on materiality must point to the effect on the actual decision maker to which the statements were addressed—not a nebulous "reasonable person" standard.

Rigsby. On May 31, 2016, the Court granted certiorari in another FCA case, *State Farm Fire & Casualty Co. v. United States ex rel. Rigsby* (*Rigsby*), from the Fifth Circuit. (794 F.3d 457, 479 (5th Cir. 2015), *cert. granted*, 136 S. Ct. 2386 (2016) (No. 15-513).) In *Rigsby*, the Fifth Circuit applied the collective knowledge doctrine—which originates from criminal cases and allows the aggregation of the knowledge of different employees to find a corporation "collectively" had the requisite scienter for a violation—in finding the defendant liable, and therefore created a circuit split on the issue of collective knowledge as applied to the FCA. The defendant sought certiorari on this issue and another relating to the potential consequences stemming from violating the FCA's statutory sealing provisions. Unfortunately for FCA-watchers and the criminal defense bar, the Court ultimately declined to review the collective knowledge issue, the issue on which the NACDL had focused in its amicus brief. The Court instead heard argument only on the sealing issue. This is an FCA-only issue but is nonetheless an example of an FCA case presenting a potential vehicle for deciding an issue of crucial importance to criminal lawyers. Additionally, the Supreme Court's decision not to decide the issue leaves intact the current split between the circuits on whether or not the collective knowledge doctrine may be applied to the FCA. Because the Supreme Court itself has never passed on the validity of the collective knowledge doctrine either civilly or criminally, it is possible the Court later will take up this issue.

CONCLUSION

The FCA will likely continue to spark issues of interest to criminal practitioners. As evidenced by the DOJ's recent announcements in 2014 and 2015, there is no sign that FCA enforcement will abate. As a fraud statute—sharing elements in common with criminal fraud statutes—the FCA will generate precedent that will impact the interpretation of criminal laws, as demonstrated by the NACDL's interest in serving as amici in FCA cases. Escobar has already reshaped conceptions of materiality under the FCA and criminal statutes. Given that Rigsby failed to resolve the "collective knowledge" issue, expect future disagreement and "percolation" relating to this crucial concept in the courts of appeals with the potential for the Supreme Court to revisit it in the future.

Expect also further interplay between the FCA and criminal matters on these and other issues. In light of the DOJ's express announcements that it will continue to foster cooperation and information sharing among the Civil and Criminal Divisions with respect to the FCA, there will continue to be parallel investigations and proceedings and fodder for future precedent affecting the course of the criminal law. For these reasons among others, the FCA is one civil statute worth watching. ■

Tackling the Heart of the Problem

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would have had fair notice that recording and submitting for payment for severely overstated diagnoses was illegal. (Id. at 137.) Further, the court found that the government's experts sufficiently showed that stents are not justified for a patient who has less than 70 percent blockage and does not suffer the symptoms of blockage. At a minimum, continued the court, stents are not appropriate for those with less than 50 percent blockage. (*Id.* at 141.) Finally, the court concluded that the case was one of fraud and not malpractice, and thus even if Dr. McLean's diagnoses had been within the 10–20 percent range of variability for stenosis measurements, Dr. McLean broke the law by submitting claims that the court found he knew to be inaccurate. (*Id.* at 138.)

Interestingly, while both the Patel and McLean courts generally deferred to the government's 70 percent stenosis and corresponding symptoms threshold, they found that their respective defendant had gone beyond placing allegedly unnecessary stents in low-risk patients by subsequently (or initially) falsifying the patients' records to give the appearance of dire blockage. Therefore, while effectively avoiding the need to define what constitutes a medical necessity within the precise context of stenting, DOJ was able to successfully prosecute Dr. Patel and Dr. McLean on the theory that their diagnoses were so gravely inaccurate and intentional as to be the result of fraud.

CONCLUSION

As a jury recently convicted KDMC's former chief cardiologist, Dr. Paulus, the controversy over medically unnecessary stenting will certainly continue within both the legal and medical communities nationwide. Indeed, while hard-and-fast rules such as CMS's 70 percent threshold may provide convenient enforcement tools, they also raise concerns about the appropriateness of questioning a physician's judgment and criminally prosecuting physicians based on hindsight that might not have been available during treatment, especially where there is no evidence of deliberate falsification of patient records. However, as the federal government continues to focus on heart stents because of the supposedly "clear" standards governing their use along with the high cost of the procedure, doctors and hospitals around the country should expect increased DOJ inquiries into their stenting practices and testing procedures. ■