Clin Orthop Relat Res (2016) 474:887–891 / DOI 10.1007/s11999-016-4725-3

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Published online: 8 February 2016

Medicolegal Sidebar

The Law and Social Values: Medical Necessity and Criminal Prosecution

B. Sonny Bal MD, JD, MBA, Lawrence H. Brenner JD

Introduction

Where criminal law and medicine intersect, complexity arises. An ever-shifting foundation of case law makes this territory dangerous but also interesting to explore. Perhaps no subject is on more physicians' minds than the risk of prosecution for Medicare fraud, particularly with respect to the performance of unnecessary procedures. At the heart of this question exist two controversial issues in medicine and law: (1) How does one differentiate between a necessary and unnecessary medical procedure given the uncertainty in the practice of medicine; and (2) what constitutes a healthcare crime?

Medical Necessity and Crime

The medical necessity dilemma has spawned many books [1, 5, 10–12] by authors who raise concerns about whether or not medical and surgical practice patterns reflect custom and culture, rather than well-established scientific evidence. Accordingly, author Shannon Brownlee in *Overtreated* [1] proposes that one-third of the medicine that patients receive is unnecessary. She states, "Doctors lack the evidence they need to know which treatments are most effective and which drugs and devices really work" [1]. The late Kerr White MD, the founding chair of The Department of Health Policy and Management at Johns Hopkins University and the Deputy Director for Health Care Services for the Rockefeller Foundation stated it another way in *Medicine & Culture* [11], "About 15% of all contemporary clinical interventions are supported by objective scientific evidence that they do more good than harm." In orthopaedic surgery specifically, questions have been recently raised about the effectiveness of common operations such as knee arthroscopy [7], knee replacement [13], and spinal surgery [9].

The second question appears simple, but is highly complex—what constitutes a healthcare crime? The question of healthcare criminal conduct can be easy to resolve within a certain context.

Note from the Editor-in-Chief: We are pleased to publish the next installment of "Medicolegal Sidebar" in Clinical Orthopaedics and Related Research®. *The goal of this quarterly column is to encourage thoughtful debate about how the law and medicine interact, and how this interaction affects the practice of orthopaedic surgery. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinorthop.org.*

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B. S. Bal MD, JD, MBA,
L. H. Brenner JD
BalBrenner/Orthopaedic Law Center, Chapel Hill, NC, USA

L. H. Brenner JD
Department of Orthopaedics and Rehabilitation, Yale University, New Haven, CT, USA

B. S. Bal MD, JD, MBA (✉)
University of Missouri, 1100 Virginia Ave., Columbia, MO 65212, USA
e-mail: balb@health.missouri.edu

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For example, if a physician or surgeon bills for procedures that are not performed, then that physician or surgeon has committed a crime. This is no different from stealing directly from Medicare or other third-party insurers. But the question of whether a physician or surgeon has committed a crime because his or her procedures are deemed to be medically unnecessary is much more complicated and fraught with the potential for prosecutorial abuse. Prosecutions based on lack of medical necessity are not premised on improper billings, but rather the often-obscure criteria regarding whether the procedures would benefit the patient.

Criminal prosecutions of surgeons based on allegations of medical necessity are rare enough to be sensationalized in newspaper headlines, if and when they do occur. The legal standard for proving crime is far more stringent than that needed to prove a civil wrong-doing, such as medical negligence. Indeed, when it comes to medical practice, our legal system has maintained a traditional, and some would say, an extreme deference toward physician judgment. Thus, criminal prosecutions for unnecessary surgery, as in the case below, are triggered only when some element of the practice pattern defies accepted norms in a particularly egregious way, or when the harm is perceived to be systemic and recurrent. These considerations do not apply to the overwhelming majority of physicians in practice.

United States v McLean

A recent legal case, *United States v McLean* [14], demonstrated the problems inherent in prosecuting a physician or surgeon for unnecessary procedures. Following a review from a hospital peer-review committee, the federal government charged Dr. McLean, an interventional cardiologist from Maryland, with performing medically unnecessary coronary stent procedures. He was indicted under 18 U.S.C. § 1347, a federal statute that states that if a person commits healthcare fraud, he or she shall be fined and/or imprisoned up to 10 years. If the violation results in bodily injury or death, he or she can be imprisoned up to 20 years or for life, respectively [8].

At trial, the federal government introduced testimony from two expert cardiologists who testified that it was generally accepted that coronary stents were not medically necessary in the absence of 70% stenosis, and symptoms such as chest pain or a positive stress test. Dr. McLean's former patients who had received stents testified that they never experienced chest pain even though Dr. McLean recorded chest discomfort in his medical records [14].

It was Dr. McLean's contention that the government's medical standard for coronary stents was incorrect. He also argued that evaluating degrees of stenosis by angiograms is highly subjective, and that his stent placements were appropriate and necessary. He called an expert witness who testified that during the relevant period of time, elective stents are considered medically appropriate if a patient had at least 50% stenosis and evidence of ischemia or angina. This expert's review of five cases that were named in the indictment was that four had met the standard of care. Many grateful patients of Dr. McLean also testified on his behalf.

Following 10 days of trial, a jury convicted Dr. McLean of healthcare fraud, sentencing him to more than 8 years in prison, with monetary restitution of USD 579,070.

On appeal, the Fourth Circuit Court of Appeals affirmed Dr. McLean's conviction [14].

Analysis of the Appellate Decision

In his appeal, Dr. McLean had argued that his conviction was unconstitutional because of the doctrine of "constitutional vagueness." Under American constitutional law, a legal statute can be void for vagueness. There are a variety of reasons why this protective constitutional doctrine exists. One reason is that

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no one should be punished as a criminal under laws that do not explicitly and definitively identify a proscribed conduct. As the US Supreme Court clarified in the 1926 legal case, *Connally v General Construction Co*, "[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law" [2].

The *McLean* decision raises difficult questions that are relevant to all physicians. Was Dr. McLean sufficiently on notice that his implantations of coronary stents were so inappropriate that his conduct constituted a federal crime? Most physicians will agree that there is seldom a bright line in medicine that clearly differentiates medically unnecessary versus medically necessary procedures. While it is true that in any community or large hospital, there is a range of surgical indications practiced by aggressive, high-volume surgeons versus those who favor a conservative, nonoperative approach, it is worth remembering that the *McLean* litigation represents conduct that was clearly an outlier. While the appeal was made on the argument that the precise amount of coronary stenosis, or lack thereof, which would make stent placement a criminal act is not sufficiently settled among professionals, the facts of the case showed that Dr. McLean had systematically engaged in other misconduct, such as altering entries in the medical records to justify billing for stent procedures, and falsifying billing for surgery and followup care. Thus, as the appellate court correctly concluded, Dr. McLean's argument that no one really knows how aggressive a stent-placing cardiologist has to be in order to end up with a criminal conviction based on medical necessity was simply disingenuous.

Even so, *McLean* represents a tension between two competing principles of law. On the one hand, if medical necessity is interpreted broadly, many, if not most, physicians or surgeons can be prosecuted on the whim of the justice department, at least in theory. On the other hand, if medical necessity is construed narrowly, then physicians and surgeons can engage in highly questionable procedures for profit without fear of prosecution or accountability. There has been an interesting epilogue to the *McLean* case. In 2015, *The New York Times* published an article that begins by stating, "At a time of increasing scrutiny of procedures to open blocked heart arteries, cardiologists are turning to—and reaping huge payments from—controversial techniques that relieve blockages in the arms and legs" [3]. The article went on to state, "Medical experts are questioning the necessity of some of these treatments, and many believe the condition is more safely treated with drugs and exercise" [3].

A maxim of good trial law is that for every good argument, there is an equally good counter-argument. For the sake of argument therefore, is it possible that the experts who testified against Dr. McLean were engaged in negligent activity themselves? In other words, were these testifying experts so conservative in their approach that patients in their care were dying from unnecessary withholding of coronary stenting? If so, and absent clearly-defined gold-standard criteria for the implantation of coronary stents, is it fair to say that Dr. McLean's professional conduct should not have been prosecuted? Perhaps so, but in the *McLean* litigation, it was not simply the medical practice that raised questions, rather, it was the efforts to cover up misconduct that triggered further inquiry and led to criminal proceedings. The fact is that if the prosecutor had nothing more to offer than expert arguments and counter-arguments about how much coronary stenosis is needed to make a stenting procedure a criminal act, there is no question that Dr. McLean would not even have been indicted. This reflects the threshold needed to bring about a criminal indictment in our legal system. Instead, the facts in *McLean* showed a clear pattern of alteration of records, including factual data that were falsified to create justifications for stent surgery, and fraudulent billing that was inconsistent with the operations

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performed, and the followup care provided.

Discussion

Most of the physician concern about liability in medicine surrounds medical malpractice litigation. Physician leaders have argued that medical malpractice lawsuits contribute to increasing healthcare costs [6], and subsequent reforms, such as those targeted at limiting damage awards in medical malpractice litigation have been enacted in many states. In contrast, the potential consequences of healthcare fraud for alleged medically unnecessary procedures have attracted little attention so far, aside from the occasional, sensational newspaper article.

Medical negligence lawsuits may affect the majority of physicians in some specialties, such as orthopaedic surgery. Assuming the plaintiff is successful, the resolution of medical malpractice lawsuits is always measured in monetary damages that are indemnified through insurance. In contrast, criminal prosecutions of physicians, such as for allegations of medically unnecessary procedures or fraudulent billing, are vanishingly rare and require a high standard of proof for successful prosecution. The penalties associated with such litigation are serious however, and can include a prison sentence, in addition to monetary damages.

While rare, healthcare fraud is a crime, and should be a concern to those familiar with the American criminal justice system [4].

In light of the *McLean* litigation, if an orthopaedic surgeon, for example, were to perform total knee or hip procedures and a group of his peers alleged that 25% of the procedures he performed were unnecessary, should the orthopaedic surgeon be indicted for healthcare fraud? The facts of the *McLean* case offer some guidance to this question, and reassurance. An outlier physician with an egregious volume of surgery, questionable indications, or unusually high incidence of patient injury would be reported to the hospital system, or to the local medical board. Indeed, this was the case with Dr. McLean, and an internal inquiry by his peers did identify serious and systemic concerns with his patient selection criteria. Further inquiry then revealed fraudulent billing patterns, patient record alteration, and other conduct that crossed the threshold for criminal behavior, on a repetitive basis.

While there is no quick answer to the question of when our justice system should indict physicians and surgeons for medically unnecessary procedures, the first line of inquiry toward maintaining quality and patient safety is peer-driven, such as from a peer-review committee, or similar body. Depending upon the circumstances, peer review may identify correctable practice patterns that are amenable to proctoring, further training, or mentorship. Credible, independent peer review is a powerful tool available to the medical community to identify physicians who might stray outside the bounds of proper indications for a procedure, and take corrective action in a timely manner. The medical community should strive to ensure that the peer-review process is truly independent, fair, and not driven by competitive or political motives. Data concerning physician operative volumes, outcomes, and complications should be available to peer-review bodies so that outliers can be identified, and patient harm avoided.

While the *McLean* case reflects the successful prosecution of a physician for improper surgery and billing, and the appellate component of the litigation addressed the provocative subject of medical necessity, for the overwhelming majority of physicians, the threat of criminal prosecution from medically unnecessary procedures is entirely avoidable.

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