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Overtreatment and Informed Consent: A Fraud-Based Solution to Unwanted and Unnecessary Care

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OVERTREATMENT AND INFORMED CONSENT: A FRAUD-BASED SOLUTION TO UNWANTED AND UNNECESSARY CARE

ISAAC D. BUCK[†]

ABSTRACT

According to multiple accounts, the administration of American health care results in as much as \$800 billion in wasted spending due largely to the provision of overly expensive, inefficient, and unnecessary services. Beyond inflicting fiscal pain on the nation's pocketbook, this waste has no clinical benefit—and often results in unnecessary hospital stays, cascading follow-up procedures, and time-wasting inconvenience for American patients. But aside from the mere annoyance of unnecessary care, the administration of overtreatment—that is, unnecessary care in and of itself—causes harm to the patient. Excessive care is deficient care. Unnecessary care risks potential medical error and infection, and often subjects the patient to excessive recovery and rehabilitation. In addition to the fiscal reasons, it is not a stretch to observe that it makes little or no sense for American patients to desire unnecessary care.

But yet, as a general matter, today's modern and patient-protective legal and bioethical framework governing American health care purportedly forcefully protects patients from undesirable care by requiring their informed consent before any procedure or service. The importance of informed consent is well settled, and it is recognized as a sacred value in American health care. In law and bioethics, this value is so sanctified that in cases where providers fail to achieve informed consent, legal recourse is available for the wronged patient.

The prevalence of overtreatment, when juxtaposed with the sanctity of informed consent, is a perplexing legal and policy-based problem. Specifically, this disconnect that results—between the robust protection of informed consent and patient autonomy on one hand, and the nagging problem of undesirable and harmful overtreatment on the other—calls out for a reasoned legal resolution. While overtreatment plagues American health care, the legal academy has yet to creatively and sufficiently examine the role that the doctrine of informed consent, when coupled with the enforcement tools employed by the Department of Justice, could play in reining in unnecessary care.

This Article fills that gap. By suggesting a path forward that bolsters the legal force of informed consent to provide a patient-centered “backstop” and thereby prevent unnecessary procedures in American health care, this Article argues that a stronger version of informed consent must contain the answer to the intractable problem of overtreatment. Building on previous scholarship that sought to impose different legal and policy-based controls on providers to prevent overtreatment, this piece shifts the focus to the other side of the hospital bed, making clear that viable legal tools are available to the federal government and can be employed to protect patients from undesirable care. The patient's protections can be expanded in an effort to limit the injurious effects of American overtreatment.

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I. INTRODUCTION

*“Unwanted treatment is American medicine’s dark continent. No one knows its extent, and few people want to talk about it. The U.S. medical system was built to treat anything that might be treatable”*¹

In what has been called perhaps “the most influential magazine article of the past decade”²—and one year before American health care radically changed with the passage of the Patient Protection and Affordable Care Act of 2010 (“ACA”)³—bestselling author and surgeon Atul Gawande profiled the curious case of McAllen, Texas in *The New Yorker*.⁴ At the time, this border town, located in the county with “the lowest household income in the country,” was known for having the second-highest health care costs of any locality in the United States.⁵ After searching extensively for the main driver of the high costs in McAllen, Gawande settled on a relatively simple cause: rampant

1. Jonathan Rauch, *How Not to Die*, ATLANTIC (May 2013), <http://www.theatlantic.com/magazine/archive/2013/05/how-not-to-die/309277/>.

2. Bob Kocher & Farzad Mostashari, Opinion, *A Health Care Success Story*, N.Y. TIMES (Sept. 23, 2014), <http://www.nytimes.com/2014/09/24/opinion/a-health-care-success-story.html>.

3. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of the U.S. Code).

4. Atul Gawande, *The Cost Conundrum*, NEW YORKER (June 1, 2009), <http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum>.

5. *Id.*

overutilization of medical services.⁶ According to Gawande, “Compared with patients in El Paso and nationwide, patients in McAllen got more of pretty much everything—more diagnostic testing, more hospital treatment, more surgery, more home care.”⁷ The data were striking.⁸

In the years that followed health reform in 2010, and after Gawande’s “article became mandatory reading in the White House,”⁹ the amount and cost of health care in McAllen radically changed; its Medicare Accountable Care Organization (“ACO”)—the Rio Grande Valley ACO—has reportedly saved \$20 million annually with a focus on proper preventive care and increased coordination.¹⁰ Not only has the ACO saved money, but it has also improved health in the region;¹¹ it is undoubtedly an ACA “success story.”¹² And McAllen *should* be viewed as a health reform success story, as well as an illustration of the structural change the ACA is seeking to make to the administration of American health care.

But beyond the structural financial changes, the story of McAllen—particularly the reality of the rampant overutilization of medical ser-

6. *Id.* But see *New Health Care Spending Study Offers Rosier Picture of McAllen*, MONITOR (Dec. 7, 2010, 12:00 AM), http://www.themonitor.com/news/local/new-health-care-spending-study-offers-rosier-picture-of-mcallen/article_392a5740-b79d-5e21-abb-ac70041de82d.html (finding that spending for patients with private insurance was much lower than the Medicare population in McAllen).

7. Gawande, *supra* note 4.

8. See *id.* Specifically, the data indicated the extent to which McAllen patients were overtreated:

Medicare patients received almost fifty per cent more specialist visits in McAllen than in El Paso, and were two-thirds more likely to see ten or more specialists in a six-month period. In 2005 and 2006, patients in McAllen received twenty per cent more abdominal ultrasounds, thirty per cent more bone-density studies, sixty per cent more stress tests with echocardiography, two hundred per cent more nerve-conduction studies to diagnose carpal-tunnel syndrome, and five hundred and fifty per cent more urine-flow studies to diagnose prostate troubles. They received one-fifth to two-thirds more gallbladder operations, knee replacements, breast biopsies, and bladder scopes. They also received two to three times as many pacemakers, implantable defibrillators, cardiac-bypass operations, carotid endarterectomies, and coronary-artery stents. And Medicare paid for five times as many home-nurse visits. The primary cause of McAllen’s extreme costs was, very simply, the across-the-board overuse of medicine.

Id.

9. Kocher & Mostashari, *supra* note 2.

10. See Christy Daggett, *ACA Cost Saving Measures Help Turn McAllen, Texas from National Basket Case to Bellwether in Five Years*, ME. CTR. ECON. POL’Y (Sept. 25, 2014), <http://blog.mecep.org/2014/09/aca-cost-saving-measures-help-turn-mcallen-texas-from-national-basket-case-to-bellwether-in-five-years/>; see also Kocher & Mostashari, *supra* note 2.

11. See *id.*

12. *Id.*

vices—can also serve as an illustration of a related and pervasive problem that poses an “enormous” but “largely hidden” challenge to American health care.¹³ Most notably, McAllen highlights the current legal mismatch—and, perhaps, deficiency—that exists in American health care between patients and providers when it comes to devising and administering health care in modern America. It raises a compelling question focused on how, exactly, America’s purportedly patient-protective and patient-centered health system is tolerant of such excess—particularly when that excess does not lead to better health, is likely harmful,¹⁴ and when American patients themselves feel that they are too often overtreated by health care providers.¹⁵

After the extensive comparison data Gawande presented, showing that McAllen patients underwent multiple times more care than their counterparts in El Paso 800 miles to the northwest, the story of McAllen clearly serves as an illustration of the uniquely American problem of overtreatment—for which, at least to date, legal solutions have been focused on the provider’s side of the hospital bed, and not the patient’s. Ultimately, McAllen is not only an exemplar of the importance of preventive and coordinated care, but it is also the story of how little legal investment has been made in arming the patient to protect himself from overtreatment in the modern American health care system.

Even as America’s health care system experiences an unprecedented slowdown in overall cost growth¹⁶—the likes of which has never

13. Peter Eisler & Barbara Hansen, *Doctors Perform Thousands of Unnecessary Surgeries*, USA TODAY (June 20, 2013, 1:34 AM), <http://www.usatoday.com/story/news/nation/2013/06/18/unnecessary-surgery-usa-today-investigation/2435009/>.

14. Tara Parker-Pope, *Overtreatment Is Taking a Harmful Toll*, N.Y. TIMES (Aug. 27, 2012, 2:37 PM), http://well.blogs.nytimes.com/2012/08/27/overtreatment-is-taking-a-harmful-toll/?_r=0 (noting that overtreatment is “taking a human toll in pain, emotional suffering, severe complications and even death”).

15. See discussion *infra* Sections III.B, III.C and accompanying notes.

16. The slowdown has accelerated since 2011. See Mary Agnes Carey, *Think Health Care Costs Are Soaring? Think Again.*, CNN MONEY (Dec. 4, 2014, 12:19 AM), <http://money.cnn.com/2014/12/04/news/economy/healthcare-costs/> (noting that for 2013, national health spending grew 3.6% from 2012—the lowest increase ever); Annie Lowrey, *Slower Growth of Health Costs Eases Budget Deficit*, N.Y. TIMES (Feb. 11, 2013), http://www.nytimes.com/2013/02/12/us/politics/sharp-slowdown-in-us-health-care-costs.html?_r=0 (“A sharp and surprisingly persistent slowdown in the growth of health care costs is helping to narrow the federal deficit The [Congressional Budget] Office now projects that spending on [Medicare and Medicaid] in 2020 will be about \$200 billion, or 15 percent, less than it projected three years ago.”); Anne B. Martin et al., *National Health Spending in 2012: Rate of Health Spending Growth Remained Low for the Fourth Consecutive Year*, 33 HEALTH AFF. 67, 67 (2014), <http://content.healthaffairs.org/content/33/1/67.full> (noting that the health spending rate increased 3.7% in 2012); Robert Pear, *Growth of Health Spending Stays Low*, N.Y. TIMES (Jan. 7, 2013), <http://www.nytimes.com/2013/01/08/us/health-spending-growth-stays-low-for-third-straight-year.html> (noting that health spending increased just 3.9% in 2011—at the time,

been seen¹⁷—it continues to administer and pay for care that is unnecessary at an eye-popping rate.¹⁸ A primary cause of the national debt,¹⁹ America wastes at least \$750 billion within its health care system each year—and about \$210 billion of that is specifically spent on “[u]nnecessary services.”²⁰ Various examples of unnecessary services include administering multiple colonoscopies within ten years on the same patients, offering MRIs to patients who present with fainting spells but who have not experienced seizures, and overusing imaging and scanning machinery for back pain.²¹ Exactly why the tool of informed consent—a seemingly viable tool for limiting unnecessary health procedures—has not been bolstered and utilized to address the prevalence of unnecessary procedures remains an unanswered question.²²

This analysis presents the idea that the doctrine of informed consent *can* be used to address overtreatment and proposes a fraud-based

“the lowest annual rates recorded in the 52 years the government has been collecting such data”).

17. Lowrey, *supra* note 16 (“From 2009 to 2011, total health spending grew at the lowest annual pace since the government started keeping records 52 years ago In the 2012 fiscal year, Medicare spending per beneficiary grew just 0.4 percent.”); see RICHARD KRONICK & ROSA PO, U.S. DEP’T OF HEALTH & HUMAN SERVS., GROWTH IN MEDICARE SPENDING PER BENEFICIARY CONTINUES TO HIT HISTORIC LOWS (2013), <http://aspe.hhs.gov/health/reports/2013/medicarependinggrowth/ib.cfm>.

18. See Eisler & Hansen, *supra* note 13 (“Tens of thousands of times each year, patients are wheeled into the nation’s operating rooms for surgery that isn’t necessary”); Tara Parker-Pope, *Too Much Medical Care?* N.Y. TIMES (July 25, 2012, 12:20 PM), well.blogs.nytimes.com/2012/07/25/too-much-medical-care/.

19. See Adrianna McIntyre, *Solving the Mystery of Health-Care Prices Could Save \$100 Billion*, VOX (May 21, 2014, 7:00 AM), <http://www.vox.com/2014/5/21/5723452/could-more-price-transparency-in-health-care-really-save-100-billion> (showing the projected \$41 trillion in health care spending).

20. See Sarah Kliff, *We Spend \$750 Billion on Unnecessary Health Care. Two Charts Explain Why.*, WASH. POST (Sept. 7, 2012), <http://www.washingtonpost.com/blogs/wonkblog/wp/2012/09/07/we-spend-750-billion-on-unnecessary-health-care-two-charts-explain-why/>.

21. Brian Fung, *How the U.S. Health Care System Wastes \$750 Billion Annually*, ATLANTIC (Sept. 7, 2012), <http://www.theatlantic.com/health/archive/2012/09/how-the-us-health-care-system-wastes-750-billion-annually/262106/>.

22. See Benjamin Moulton & Jamie S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J.L. MED. & ETHICS 85, 95 (2010) (asking “[w]hy then do we tolerate a system that prevents identification of the ‘right’ patients due to insufficient information and avoidable ignorance? . . . Noting less than this disclosure fully complies with the provider’s legal and ethical obligation to the patient”).

tool to do so. Shifting from my previous analyses that identify the problems with,²³ and a potential solution to,²⁴ the current legal regulation of overtreatment, the analysis flips the focus to the patients' side of the hospital bed. Assuming that no patient would, when well informed, voluntarily choose to undergo unnecessary treatment, informed consent can provide a viable platform from which to launch a fraud-based enforcement regime, reliant particularly on the federal civil False Claims Act ("FCA"). Nevertheless, this piece does not purport to provide an answer to the often-thorny challenges associated with *proving* a lack of informed consent at trial;²⁵ instead, it simply provides the legal framework for linking the doctrine to the Department of Justice's ("DOJ") enforcement tools.

In other works, I have discussed the concerns inherent in using the fraud statutes—specifically the FCA—as the primary tools for regulating cases of overtreatment, particularly where the medical necessity or appropriateness of a given procedure is either in question or unclear. But where sufficient informed consent has not been achieved—that is, it is demonstrable that the patient, had she been fully informed, would have not elected to go through with a proposed therapy or procedure—the anti-fraud tools, and specifically the FCA, may be an attractive and effective tool to be used to provide a much-needed block to the administration of unnecessary care. This solution lacks the government-provider conflict that often characterizes other uses of the FCA in this context; indeed, when used to protect the patient's wishes, many of the practically based concerns—such as “backdoor rationing” and government standard-setting—wither. Deficient informed consent *could* constitute the platform necessary for a FCA action—it is simply up to the DOJ to bring the cases, and the courts to interpret the FCA's wide-ranging applicability. Under

23. See generally Isaac D. Buck, *Caring Too Much: Misapplying the False Claims Act to Target Overtreatment*, 74 OHIO ST. L.J. 463 (2013) [hereinafter Buck, *Caring Too Much*] (highlighting the problems of the federal government's solution of applying the FCA against providers who engage in overtreatment); Isaac D. Buck, *Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259 (2015) [hereinafter Buck, *Enforcement Overdose*] (arguing that the unique factors of overtreatment enforcement, coupled with the easy resolution of health care fraud investigations lead to a risk of overuse).

24. See generally Isaac D. Buck, *Breaking the Fever: A New Construct for Regulating Overtreatment*, 48 U.C. DAVIS L. REV. 1261 (2015) (arguing to improve America's overtreatment problem by shifting the focus from medical necessity to excess utilization and that the DOJ should pursue providers who are administering “too much” care).

25. These challenges may be difficult to overcome. For a summary of the proof challenges facing this framework, see *infra* Section V.C.

this scheme, providers and hospitals that administer overtreatment could open themselves up to fraud liability for a failure to secure sufficient informed consent from each patient.²⁶

To date, a debate within the legal academy—a discussion that typically focuses on informed consent as a tool used to guarantee the wishes of the patient who is seeking a *more* expensive or complex procedure—has taken place.²⁷ Academic hand wringing has largely focused on the insidious threat—typically from third parties—of limiting the rights of the patient to choose a more complex or expensive therapy.²⁸ The debate has presented the conflict as between the rights of the patient and the attempt of the insurance company or health management organization (“HMO”) to limit care to that patient.²⁹

However, this discussion has largely left out an analysis of the opposite and perhaps more pervasive current concern. Recent studies show that patients are subject to care they would not choose.³⁰ Other data demonstrates an overtreatment crisis at the end of life.³¹ These concerns have caused some—particularly Professors Jamie King and Benjamin Moulton—to submit that, with a retooled and robust notion of informed consent that employs a shared decision-making model, more patients would elect to either decline unnecessary care or opt for less expensive care.³² But few have proposed a legal solution for bol-

26. This Article does not purport to define what “sufficient informed consent” is and how it should be achieved. That topic, although vitally important to this overall analysis, is beyond the scope of this Article.

27. See Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 363 (1999) (“Much of the commentary assumes that fully informed patients will always opt for the more expensive therapy.”).

28. See generally Mark A. Hall, *A Theory of Economic Informed Consent*, 31 GA. L. REV. 511 (1997) (discussing the fundamental conflict between medical ethics and medical economics).

29. See, e.g., Hall, *supra* note 28, at 511; Krause, *supra* note 27, at 281-89.

30. See discussion *infra* notes 125-37 and accompanying text.

31. See discussion *infra* Section III.C.

32. See Krause, *supra* note 27, at 363 (noting that “informed decision making could, in theory, assist in health care cost containment efforts” and that “it is quite possible that a truly informed patient who is fully cognizant of the potential risks, benefits, and costs of the therapeutic options might instead choose to receive a less expensive but viable treatment”); Moulton & King, *supra* note 22, at 88 (“In the absence of complete information, individuals frequently opt for procedures they would not otherwise choose. Mounting clinical evaluative evidence suggests that the number of surgical procedures performed, even when justified by practice guidelines, actually exceeds patients’ desires when they are fully informed through a shared decision-making process.”); John E. Wennberg et al., *Extending the P4P Agenda, Part 1: How Medicare Can Improve Patient Decision Making and Reduce Unnecessary Care*, 26 HEALTH AFF. 1564, 1566-67 (2007), <http://content.healthaffairs.org/content/26/6/1564.full.pdf+html> (“Although the argument for informed patient choice is based on ethical principles of patient autonomy, the clinical trial data suggest that implementing high-quality shared decision making could also result in Medicare savings via a drop in utilization.”).

stering informed consent to grow the doctrine—within the current legal framework—so it can be used as a formidable tool against the threat of overtreatment within American health care.³³ This Article undertakes both whether this is possible and points the way forward by linking informed consent to the government’s anti-fraud tools, ultimately seeking to fill that gap.

This Article is organized in four parts. Part II provides an overview of the problem of overtreatment. Part III demonstrates and explores the reasons behind the conflict between robust informed consent doctrine and the data that show America’s major overtreatment problem. Part IV probes weaknesses in current informed consent doctrine and argues in support of a third-party informed consent remedy. Finally, Part V presents a plausible fraud-based theory of FCA liability.

II. THE PROBLEM

America’s \$210 billion spent on unnecessary services is caused by a number of factors,³⁴ most of which are presented immediately below. Subsequently, the roles of three actors within the health care system—and their potential responsibility for overtreatment—are highlighted. First, the health care delivery system requires a provider, who must suggest, recommend, or acquiesce in the provision of the unnecessary or nonbeneficial service; second, a patient, who must consent to the unnecessary or nonbeneficial service; and third, the payer that must

33. A search within “law reviews and journals” on Westlaw for (“informed consent” /s “false claims act”) yielded just two articles—both of which gave a minor amount of focus to a fraud-based solution for care administered without informed consent. See Trudo Lemmens & Paul B. Miller, *The Human Subjects Trade: Ethical and Legal Issues Surrounding Recruitment Incentives*, 31 J.L. MED. & ETHICS 398 (2003); Thaddeus Mason Pope, *Clinicians May Not Administer Life-Sustaining Treatment Without Consent: Civil, Criminal, and Disciplinary Sanctions*, 9 J. HEALTH & BIOMEDICAL L. 213, 277-79 (2013) (noting the viability of the FCA to cases involving a lack of informed consent).

34. See Buck, *Caring Too Much*, *supra* note 23, at 473-82; Buck, *Enforcement Overdose*, *supra* note 23.

approve and pay the bill for the unnecessary or nonbeneficial service.³⁵ After these actors are briefly introduced, the disjointed promise and reality of informed consent is summarized.

A. *The Ongoing Story: Overtreatment*

Long free of any meaningful legal regulation and, perhaps, spurred by reimbursement policy itself, overtreatment—defined as the provision of unnecessary, comparatively too expensive, or nonbeneficial care—is a uniquely American problem.³⁶ Recent attempts at regulating overtreatment through the anti-fraud statutes—and at widening the FCA generally—has brought critique,³⁷ but without any other means by which to regulate overtreatment in American health care, there may not be a perfectly satisfactory solution.³⁸

Overtreatment remains a major driver of excess cost in American health care. The causes are easy to peg: financial incentives, demanding patients, technological advances and, to a lesser extent, physicians' fear of legal liability.³⁹ Overtreatment contributes to the problem of the United States spending nearly 18% of its GDP on health care,⁴⁰ outpacing every other industrialized nation on earth by a substantial

35. See Nicole Cafarella Lallemand, *Reducing Waste in Health Care*, HEALTH AFF. (Dec. 13, 2012), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=82 (noting that overtreatment “includes care that is rooted in outmoded habits, . . . is driven by providers' preferences rather than those of informed patients, . . . ignores scientific findings, . . . [and] is motivated by something other than provision of optimal care for a patient”); see also Eric Heisig, *Lawsuit Accuses Cleveland Clinic of Performing Unnecessary Tests on Patients to Reap Medicare Benefits*, CLEVELAND.COM (Jan. 22, 2015, 2:04 PM), http://www.cleveland.com/court-justice/index.ssf/2015/01/lawsuit_accuses_cleveland_clin.html (describing lawsuit accusing the Cleveland Clinic of performing unnecessary medical tests in order to obtain more Medicare payouts); *Two Companies to Pay \$3.75 Million for Allegedly Causing Submission of Claims for Unreasonable or Unnecessary Rehabilitation Therapy at Skilled Nursing Facilities*, U.S. DEPT JUSTICE (Sept. 5, 2014), <http://www.justice.gov/opa/pr/two-companies-pay-375-million-allegedly-causing-submission-claims-unreasonable-or-unnecessary> (documenting government allegations that the settling party provided “unreasonable or unnecessary therapy to patients in order to increase Medicare reimbursement to the facilities”).

36. See *Why Is Health Spending in the United States So High?*, OECD 1, 1 <http://www.oecd.org/unitedstates/49084355.pdf> (last visited Feb. 20, 2016) (noting that American health spending per person per capita totaled \$7960 in 2009, while the second-highest country, Norway, was at \$5352, and the United Kingdom was at \$3487). Unnecessary surgeries have been described as belonging to one of three categories: immoral, incompetent, or indifferent. Eisler & Hansen, *supra* note 13.

37. See John T. Boese & Beth C. McClain, *Why Thompson Is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 ALA. L. REV. 1, 2 (1999) (arguing against the widening application of the FCA); Buck, *Caring Too Much*, *supra* note 23, at 468-69 (noting the potential practical problems in applying the FCA to cases of overtreatment).

38. See Buck, *supra* note 24, at 1266-67.

39. See Buck, *Caring Too Much*, *supra* note 23, at 473.

40. See *Health Expenditure, Total (% of GDP)*, WORLD BANK, <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS> (last visited Feb. 20, 2016). See *gen-*

margin.⁴¹ According to the Organisation for Economic Co-operation and Development, American providers use a lot of expensive machinery and administer a lot of elective surgery.⁴² They also use screening equipment more than any other country.⁴³ Every year seemingly common procedures are either deemed overused or nonbeneficial: questionable stent placements caught the attention of the media in 2006⁴⁴ and, later, federal prosecutors;⁴⁵ rapid increases in the use of computed tomography (“CT”) scans in the nation’s emergency rooms raised eyebrows in 2011;⁴⁶ overuse of various “advanced . . . cancer treatments” grabbed headlines in 2013;⁴⁷ and “Choosing Wisely,” a campaign launched by the American Board of Internal Medicine Foundation and *Consumer Reports* magazine, noted the unnecessary nature of requiring pelvic exams for women seeking contraception in 2013.⁴⁸

Two characteristics of America’s overtreatment challenge are particularly striking. First, as has been noted before, “[m]uch of the waste in [America’s] health care system stems from costly procedures with

erally Sabriya Rice, *Reform Update: Doctors Order Unnecessary Tests Without Even Realizing It*, MOD. HEALTHCARE (Sept. 15, 2014), <http://www.modernhealthcare.com/article/20140915/NEWS/309159965> (noting that “[n]early a third of the orders that the surveyed physicians [in the study] placed were defensive on some level.”); Michael B. Rothberg et al., *The Cost of Defensive Medicine on 3 Hospital Medicine Services*, JAMA INTERNAL MED. (Nov. 2014), <http://archinte.jamanetwork.com/article.aspx?articleid=1904758> (study noting that “a large portion of hospital orders had some defensive component” but that “few orders were completely defensive and that physicians’ attitudes about defensive medicine did not correlate with cost”).

41. See *Why is Health Spending in the United States so High?*, *supra* note 36.

42. See *id.* at 5.

43. OECD, HEALTH AT A GLANCE 2013: OECD INDICATORS 125 tbl.5.9.1 (2013), <http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf>. The United States ranks first in the amount of women aged 20–69 who underwent a cervical cancer screening, *id.*, but eighteenth out of twenty-two for cervical cancer five-year relative survival, *id.* at tbl.5.9.2. The United States was third in the amount of mammography screening, *id.* at tbl.5.10.1, and first in breast cancer five-year relative survival, *id.* at tbl.5.10.2.

44. See Reed Abelson, *Heart Procedure Is off the Charts in an Ohio City*, N.Y. TIMES (Aug. 18, 2006), http://www.nytimes.com/2006/08/18/business/18stent.html?pagewanted=all&_r=0.

45. See *U.S. Attorney’s Office Collected Nearly \$24 Million in FY 2013*, DEP’T JUST. (Jan. 10, 2014), <http://www.justice.gov/usao/ohn/news/2014/10jancollect.html> (noting settlements paid by health care providers for allegations that they performed unnecessary cardiac procedures on Medicare patients).

46. See Phil Galewitz, *ER Use of CT Scans Rises Sharply, Raising Questions About Costs and Benefits*, KAISER HEALTH NEWS (Aug. 10, 2011), <http://kaiserhealthnews.org/news/er-use-of-ct-scans-rises-sharply-raising-questions-about-costs-and-benefits/>.

47. See, e.g., Dennis Thompson, *New, Pricy Prostate Cancer Treatments May Be Overused: Study*, HEALTHDAY (June 25, 2013), <http://consumer.healthday.com/cancer-information-5/mis-cancer-news-102/pricy-prostate-cancer-treatments-may-be-overused-study-677713.html>.

48. See Susan Perry, *Unnecessary or Overused Medical Tests, Treatments: New ‘Choosing Wisely’ Lists*, MINNPOST (Sept. 25, 2013), <http://www.minnpost.com/second-opinion/2013/09/unnecessary-or-overused-medical-tests-treatments-new-choosing-wisely-lists>.

either weak supporting evidence, high-risk complications or other significant tradeoffs.”⁴⁹ That is, most of the cause of America’s overtreatment crisis can be blamed on procedures that are of questionable clinical defensibility. As a result, a belief that a more robust notion of informed consent would curtail the number of these procedures offered to American patients makes intuitive sense.

Second, overtreatment presents problems beyond the financial. In fact, overtreatment can lead to serious medical complications, adverse psychological effects on patients, and—particularly for overused testing equipment “progressively invasive and expensive diagnostic tests required to disprove a false positive result.”⁵⁰ Where an unnecessary medical test indicates a potential false positive for a health condition, “[s]ometimes the test leads you down a path, a therapeutic cascade, where you start to tumble downstream to more and more testing, and more and more invasive testing, and possibly even treatment for things that should be left well enough alone.”⁵¹

As has been mentioned before, more health care does not result in better health.⁵² In a 2014 Commonwealth Fund survey, the United States health care system was once again rated as the most expensive in the world,⁵³ but the report concluded that America “underperforms relative to other countries on most dimensions of performance.”⁵⁴ In the results, the United States ranked last of the eleven countries surveyed,⁵⁵ as it did in previous surveys in 2010, 2007, 2006, and 2004.⁵⁶ And America’s life expectancy—albeit not a perfect arbiter of a country’s health—is 78.7 years, good enough for twenty-sixth out of forty OECD countries.⁵⁷ Even after the passage of the ACA, more stunning

49. Moulton & King, *supra* note 22, at 93.

50. See Krause, *supra* note 27, at 280.

51. Parker-Pope, *supra* note 14 (quoting Shannon Brownlee, acting director of the health policy program at the New America Foundation).

52. See Olga Khazan, *U.S. Healthcare: Most Expensive and Worst Performing*, ATLANTIC (June 16, 2014), <http://www.theatlantic.com/health/archive/2014/06/us-healthcare-most-expensive-and-worst-performing/372828/> (noting that “when it comes to healthcare, Americans get neither quality nor affordability”).

53. KAREN DAVIS ET AL., THE COMMONWEALTH FUND., 2014 UPDATE: MIRROR, MIRROR ON THE WALL: HOW THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 7 Exhibit ES-1 (2014), <http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror>.

54. *Id.*

55. These countries are Australia, Canada, France, Germany, Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States. See *id.* at Exhibit ES-1.

56. *Id.* at 7.

57. OECD, *supra* note 43, at 25 tbl.1.1.1.

is America's failure to provide insurance for all of its citizens.⁵⁸ A fractured and bloated system results; a chart comparing life expectancy at birth with health spending per capita puts the United States in a plane by itself.⁵⁹

But the view is not necessarily universal. Recent surveys have shown that health care providers do not deny that the United States has an overtreatment problem. In a survey sponsored by the Robert Wood Johnson Foundation, 73% of surveyed physicians called the "frequency of unnecessary tests and procedures" in American health care either a "very . . . or somewhat . . . serious problem."⁶⁰ Starkly, when asked what the physician would do when a patient came to you convinced he or she needed a specific test that was unnecessary but the patient was quite insistent, 53% of respondents answered that they would either order the test or order it but advise against it.⁶¹ That number grew to 61% of responding physicians who saw more than 100 patients each week.⁶² Further, only 41% of responding physicians

58. According to Gallup, as of the fourth quarter of 2014, the number of Americans who remained uninsured was 12.9%. Jenna Levy, *In U.S., Uninsured Rate Sinks to 12.9%*, GALLUP (Jan. 7, 2015), <http://www.gallup.com/poll/180425/uninsured-rate-sinks.aspx> (showing that, granted, this number was substantially lower than the uninsured rate of 17.1%, measured in the fourth quarter of 2013). As of March of 2016, nineteen states were still firmly refusing to expand their Medicaid programs. *See Status of State Action on the Medicaid Expansion Decision*, HENRY J. KAISER FAM. FOUND., <http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/> (last visited Feb. 20, 2016).

59. OECD, *supra* note 43, at 25 tbl.1.1.3.

60. *See* PERRYUNDEM RESEARCH/COMMC'N, ABIM FOUND., UNNECESSARY TESTS AND PROCEDURES IN THE HEALTH CARE SYSTEM: WHAT PHYSICIANS SAY ABOUT THE PROBLEM, THE CAUSES, AND THE SOLUTIONS 3 (2014), https://kaiserhealthnews.files.wordpress.com/2014/05/042814_final-choosing-wisely-survey-report.pdf.

61. *Id.* at 4.

62. *Id.* at 5.

noted that they always, almost always, or often talk to their patients about the costs of a procedure; 44% answered that they do not discuss costs too often, rarely, or never do so.⁶³

Nevertheless, physicians think they are in the best position to prevent unnecessary care,⁶⁴ but “empirical research demonstrates that physicians are highly inaccurate at predicting the goals and preferences of their patients.”⁶⁵ Surveys conclude by summarizing that “[p]hysicians clearly recognize the problem of unnecessary tests and procedures in the health care system” and “are not placing the problem or blame on patients.”⁶⁶ According to physicians themselves, the causes of the overtreatment problem are “malpractice concerns and the physician’s [sic] own desire to reassure themselves.”⁶⁷ Only 5% of physician respondents said “they are influenced by the presence of new technology in their offices,”⁶⁸ and similarly, 5% answered that the fee-for-service (“FFS”) reimbursement system was a cause of overtreatment.⁶⁹ Of course, whether or not physicians themselves believe they are the cause of the overtreatment crisis—and what, exactly, the causes of the crisis are—are not completely relevant to the analysis; indeed, physicians remain a vital actor within a system consumed by overtreatment.

B. *The Decision-Makers in American Health Care*

Payers. One way to clamp down on the provision of unnecessary and nonbeneficial services is to entrust the third party in the health care chain—the payer—to impose strict reimbursement standards. It makes sense that the payer would have an incentive to limit unnecessary care; after all, a private payer’s financial incentives push it to cut

63. *Id.* at 7.

64. Tellingly, 15% of respondents answered that the government “is in the best position to help address the problem of unnecessary tests and procedures,” 7% of respondents answered that trial lawyers would be in the best position, and 0% answered that Medicare would be in the best position. *Id.* at 8.

65. Moulton & King, *supra* note 22, at 86.

66. PERRYUNDEM RESEARCH/COMMC’N, *supra* note 60, at 13.

67. *Id.*

68. Jordan Rau, *Doctors Think Others Often Prescribe Unnecessary Care*, KAISER HEALTH NEWS (May 1, 2014), <http://kaiserhealthnews.org/news/doctors-think-others-often-prescribe-unnecessary-care/>.

69. *Id.*

costs where it can. A payer that denies coverage for unnecessary services is a payer that is making money⁷⁰—at least it was in the pre-ACA world.⁷¹

This was the suggested solution to the health care cost crisis in the 1990s;⁷² third-party health maintenance organizations (“HMOs”) were empowered to deny care to Americans with private insurance, and in order to keep costs low, HMOs employed tactics that were intended to limit care.⁷³ While this practice worked to bend and slow the exponential growth of the cost of American health care,⁷⁴ patients—cognizant

70. See Sharona Hoffman, *A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments*, 78 OR. L. REV. 203, 209-10 (1999) (noting that the administrator has incentives to “enhance the insurer’s profits by declining to pay the claims of policyholders and thus might be tempted to construe coverage provisions very narrowly to deny claims as often as possible”); Jessica L. Roberts, *Health Law as Disability Rights Law*, 97 MINN. L. REV. 1963, 1970 (2013) (noting that coverage was denied to “one in seven applicants” based on a preexisting condition); Arthur Nussbaum, Comment, *Can Congress Make You Buy Health Insurance? The Affordable Care Act, National Health Care Reform, and the Constitutionality of the Individual Mandate*, 50 DUQ. L. REV. 411, 442-43 (2012) (“[I]nsurance companies either deny coverage, charge increased premiums based on past and current medical history, exclude coverage of pre-existing conditions, or limit the amounts of coverage afforded.”).

71. The ACA outlaws discrimination, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2704, 124 Stat. 119, 154 (2010), and prevents lifelong or annual caps in health care. § 2711, 124 Stat. at 131; see also Cass R. Sunstein, *The Limits of Quantification*, 102 CALIF. L. REV. 1369, 1383 (2014) (noting that the ACA “forbids insurance companies from denying people coverage because of preexisting conditions and also disallows lifetime limits on coverage”); Sarah McDaniel, *The Costs of Early-Onset Alzheimer’s Disease and the Federal Benefits Dilemma*, 113 W. VA. L. REV. 133, 162 (2010) (noting that the ACA “eliminates the ability of private insurance companies to deny coverage to people because of an [early-onset Alzheimer’s Disease] diagnosis”). The ACA also limits the amount of profit health insurance companies can bank; at least 85% of premiums collected must go toward spending money on beneficiaries’ health care and quality improvement. *Explaining Health Care Reform: Medical Loss Ratio (MLR)*, HENRY J. KAISER FAM. FOUND. (Feb. 29, 2012), <http://kff.org/health-reform/fact-sheet/explaining-health-care-reform-medical-loss-ratio-mlr/>.

72. Before the ACA attempted to address some of the cases of the “health care cost crisis,” it had been an ongoing, unaddressed threat spanning at least thirty years. In 1976, President Jimmy Carter famously remarked, “We’ve built a haphazard, unsound, undirected, inefficient non-system, which has left us unhealthy and unwealthy at the same time. So we must plan and decisively phase in, simultaneous reform of services and refinancing of cost.” David Levering, *Unite for Health Reform*, HIGHBEAM RES. (July 22, 2009), <http://www.highbeam.com/doc/1P2-20564571.html>; Interview by Bill Moyers with Dr. Sidney Wolfe, President, Public Citizen & Dr. David Himmelstein, Harvard Medical School (May 22, 2009), <http://www.pbs.org/moyers/journal/05222009/watch2.html>.

73. See Christopher G. Gegwich, Note, *Medicare Managed Care: A New Constitutional Right to Due Process for Denials of Care Under Grijalva v. Shalala*, 28 HOFSTRA L. REV. 185, 188 (1999) (presenting the cost-containment efforts of HMOs, including the ability to “negotiate lower fees than traditional insurance,” the limitation of patient access to both physicians and procedures, limiting choice, and the addition of the primary care physician “gatekeeper” meant to “coordinate treatment and determine its medical necessity”).

74. See Michael S. Jacobs, *When Antitrust Fails: Public Health, Public Hospitals, and Public Values*, 71 WASH. L. REV. 899, 910 (1996) (“HMOs have been successful in wresting price reductions from competing local hospitals . . .”); Frank J. Vandall, *An Examination of*

of the fact that their care was being limited and that their providers' expertise was too often being "trumped" by third-party technocrats being paid to deny them care—recoiled.⁷⁵ By the late 1990s, the American public had had enough; the HMO as the viable cost containment solution was largely abandoned.⁷⁶

Medicare could have been a major player in cost containment for American health care but was never structured in a way to limit cost.⁷⁷ Attempts at limiting cost have been blocked; Medicare's most powerful cost containment strategy—specifically the sustainable growth rate—has been overridden by Congress nearly annually.⁷⁸ Further, medical necessity determinations within Medicare can be subject to erroneous conclusions.⁷⁹ Finally, beyond the procedural concerns of establishing Medicare as the primary decision-maker in American health care, Medicare is not the expert party for clinical practice; installing the

the Duty Issue in Health Care Litigation: Should HMOs Be Liable in Tort for "Medical Necessity" Decisions?, 71 TEMP. L. REV. 293, 294 (1998) ("The HMO concept has been successful in halting the medical-cost explosion and in making health care widely available at affordable rates."); Matthew Yglesias, *The Health Care Cost Curve Is Bending*, SLATE (Aug. 2, 2013, 4:20 PM), http://www.slate.com/blogs/moneybox/2013/08/02/the_health_care_cost_curve_is_bending.html (noting that the cost curve was bent "in the late-1990s . . . when HMOs were containing health care spending").

75. See Charles Bierbauer, *Doctors and Managed Care – Are HMOs Good Medicine?*, CNN (July 15, 1998, 8:13 PM), <http://www.cnn.com/HEALTH/9807/15/hmo.docs.prognosis/> (stating that "some doctors can barely control their anger" toward HMOs and noting, poignantly, that some doctors would like to see "a better balance between the physician-patient relationship dictating what the service should be, as opposed to the HMO dictating what the service should be" (quoting Dr. Bruce Rushbaum)). By 1998, 85% of the American work force was enrolled in a managed care plan, up from 50% just four years earlier. Peter T. Kilborn, *Voters' Anger at H.M.O.'s Plays as Hot Political Issue*, N.Y. TIMES (May 17, 1998), <http://www.nytimes.com/1998/05/17/us/voters-anger-at-hmo-s-plays-as-hot-political-issue.html>.

76. See Kilborn, *supra* note 75.

77. See Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 521 (2013); Buck, *supra* note 24, at 1268, 1270-73, 1275, 1277.

78. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 790 (7th ed. 2013) ("CMS upped the ante, adopting the Sustainable Growth Rate (SGR) formula which imposes cumulative forced reductions in physician payments when total physician spending exceeds a fixed spending. That is, if the total spending on physician services in a given year exceeds an aggregate target based on the GDP and other factors, the formula requires recouping that excess spending by reducing fee levels the next year. . . . Each year since 2001 except one, Congress has passed legislation that overrode fee reductions.") (citation omitted).

79. See Buck, *supra* note 24, at 1273.

payer as the decision-maker—or even giving it the appearance of decision-making capacity—is an unpopular supposition for American patients.⁸⁰

Providers. Providers, the first actors in the chain, are a chief target of modern cost containment efforts within the ACA.⁸¹ After decades of failing to align provider incentives with those of Medicare due largely to structural weaknesses in the program,⁸² grants for the creation of ACOs—like the one seen in McAllen—and stepped-up efforts to bundle payments to providers and hospitals⁸³ within the ACA are examples of tools that seek to incentivize providers to provide more cost-effective care—perhaps signaling the “death” of fee-for-service reimbursement.⁸⁴ Studies show that ACOs may save the system a substantial amount of money.⁸⁵

Outside of these modern reforms, the current structure—which still rewards overuse and overtreatment—has an impact on the total amount and expense of administered clinical care.⁸⁶ Specifically as to

80. See Jon Greenberg, *Health Law Puts Government in Between Patient and Doctors, Mitt Romney Says*, POLITIFACT (July 9, 2012, 10:58 AM), <http://www.politifact.com/truth-o-meter/statements/2012/jul/09/mitt-romney/health-law-puts-government-between-patients-and-do/> (noting that presidential candidate Mitt Romney claimed that “Obamacare puts the federal government between you and your doctor” but concluding that the statement was “false”).

81. See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2706, 124 Stat. 119, 325 (2010) (codified at 42 U.S.C. § 1396a note (2012)) (establishing the Pediatric Accountable Care Organization Demonstration Project).

82. See Bagley, *supra* note 77, at 541-44; Buck, *supra* note 24, at 1271-75, 1277.

83. See Jayne O'Donnell, *Feds Step up Changes to Hospital Payments*, USA TODAY (Jan. 26, 2015, 6:07 PM), http://www.usatoday.com/story/news/nation/2015/01/26/medicare-alternative-payments-hhs/22347975?elq_cid=1306202 (noting that Health and Human Services “hopes to tie 30% of traditional Medicare payments to quality or value through . . . ‘alternative payment models’ by the end of 2016, up from 20%”); Louise Radnofsky & Melinda Beck, *Medicare to Rework Billions in Payments*, WALL ST. J., http://www.wsj.com/articles/medicare-to-rework-billions-in-payments-1422293419?elq_cid=1306202 (last updated Jan. 26, 2015, 1:14 PM) (noting that Health and Human Services Secretary Sylvia Burwell wants to move to a quality-based payment method).

84. See Robert Pear, *Health Care Enrollment Appears to Be Near Goal*, N.Y. TIMES (Jan. 27, 2015), http://www.nytimes.com/2015/01/28/us/politics/health-care-enrollment-appears-to-be-near-goal.html?_r=0 (noting that 20% of reimbursement within Medicare was “linked to doctors’ abilities to coordinate care” [“(\$7.4 billion of \$362 billion)] and that Sylvia Burwell wanted the proportion to rise to “50 percent by the end of 2018”).

85. See *New Affordable Care Act Tools and Payment Models Deliver \$372 Million in Savings, Improve Care*, (Sept. 16, 2014), <http://www.hhs.gov/news/press/2014pres/09/20140916a.html> (noting that the Pioneer ACO Model and Medicare Shared Savings Program ACO generated over \$372 million); see also Henry Davis, *New Accountable Care Organizations Save Medicare \$372 Million*, BUFFALO NEWS (Sept. 23, 2014, 9:08 PM), <http://www.buffalonews.com/city-region/new-accountable-care-organizations-save-medicare-372-million-20140923> (noting Buffalo’s ACO saved nearly \$28 million in 2013).

86. See Julie Barnes, *Moving Away From Fee-for-Service*, ATLANTIC (May 7, 2012), <http://www.theatlantic.com/health/archive/2012/05/moving-away-from-fee-for-service/256755/> (“In a FFS model, payers reimburse for all services, regardless of their impact on patient health. Little or no countervailing pressure to discourage the delivery of unnecessary

Medicare patients, the DOJ has reviewed medical decisions while relying on its anti-fraud tools, as have other third-party payers.⁸⁷ Where evidence of waste is clear, the DOJ has relied on the allegation that care was either not “medically necessary” or not part of Medicare’s National Coverage Determination (“NCD”) to target providers who provide too much health care.⁸⁸ For various reasons, the government’s usage of Medicare’s practice standards or prosecutors’ conceptions of medical necessity leaves the enforcement regime subject to criticism on a number of fronts.⁸⁹

Patients. A number of pressures act on the patient—the most intense of which may be the pressure of pain and anxiety.⁹⁰ However, aside from these inherent challenges, relying on patients to be a viable solution to the problem of overtreatment has not been fully explored. The ACA has increased cost-sharing within its provisions, and other scholars have suggested proposals for making patients more aware of and pressured by the cost of health care,⁹¹ but linking the solution to overtreatment with the patient’s desires by using the anti-fraud statutes has not yet been proposed.

The patient’s chief legal protection is the doctrine of informed consent—patients have the exclusive right to decline treatment, and must positively consent to it, before the provider can administer care—even for life-sustaining treatment.⁹² Beyond satisfying the bioethical tenet of autonomy and the law’s concern with bodily integrity, it may simply be the case that patients just make better decisions as they are free from notable pressures.⁹³ Presumably, the insured patient is the only

services exists in this system.”); Eisler & Hansen, *supra* note 13 (“The fee-for-service nature of U.S. health care, where the hospitals and doctors get more money for every operation they perform, essentially rewards those that put more patients under the knife.”).

87. See Moulton & King, *supra* note 22, at 93 (noting that “both private and public insurers have begun to review physician recommendations for necessity and reasonableness in making coverage determinations” but that during these reviews, “insurers have generally made coverage decisions based on physicians’ opinions regarding clinical benefit, without consideration of the individual patient’s preferences”).

88. See Buck, *Caring Too Much*, *supra* note 23, at 492.

89. See *id.* at 469; Buck, *Enforcement Overdose*, *supra* note 23, at 292-309.

90. See Krause, *supra* note 27, at 273 (“Patients commonly seek medical attention when they are ill or injured, when their ability to understand and participate in care may be hindered by anxiety about their physical well-being or by the physical effects of their medical problems.”).

91. See, e.g., Christopher Robertson, *The Split Benefit: The Painless Way to Put Skin Back in the Health Care Game*, 98 CORNELL L. REV. 921, 930-31 (2013).

92. See Pope, *supra* note 33, at 260 (presenting a list of potential legal remedies and penalties available for treating individuals—even with life-sustaining measures—without consent).

93. This assumption is limited to patients who are enrolled in the Medicare program and do not have substantial cost sharing or deductible requirements.

actor in the system that is sufficiently free from any perverse financial incentives one way or the other—both free of incentives to increase the amount and expense of care (providers), and decrease the amount of care administered (payers).⁹⁴

Further, establishing an enforcement framework that respects patients' wishes as paramount erects a second hurdle for the provision of unnecessary or nonbeneficial care: for cases in which informed consent is needed, the care must have already been determined to be medically necessary by the treating physician, or else it is fraudulent.⁹⁵ Placing the patient's clinical decision at the center of a fraud-based enforcement framework would take advantage of the fact that the provider had already determined the potential procedure to be medically necessary because, theoretically at least, patients cannot consent to unnecessary care.

III. INFORMED CONSENT

Legal scholars have argued the attributes and deficiencies of informed consent at great length; this paper will not delve too deeply into those arguments. On a practical level, one would think the protection of informed consent could serve as an important tool in American health care that could be used to limit the amount of unnecessary or nonbeneficial care that providers administer.⁹⁶ After all, the ultimate clinical decision rests with the patient, and unnecessary treatment—given its deleterious financial and potential health effects on individuals⁹⁷—should rarely be desired by the patients themselves.

But the analysis is more complicated than that. The patient's capacity to make an informed judgment is clouded by a number of factors—namely, the patient may be inappropriately influenced, one way or another, by cost pressures; may be desperately seeking resolution

94. Moral hazard may act on the patient to request health care that they do not actually need, just because they have health insurance that will foot the bill. But no financial incentive—that is, the patient does not make more money—exists that works on them to either increase or decrease the amount of health care they use.

95. See discussion and accompanying notes *infra* Section V.A.4.

96. David Wennberg has recommended “a paradigm shift from informed patient consent to informed patient choice.” INST. OF MED. OF THE NAT'L ACADS., *THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES* 18 (Pierre L. Yong et al. eds., 2010). This inculcates the tenets of shared decision-making in order to ensure active participation of the patient, which ultimately empowers the patient. See generally HEALTH DIALOG, *SHARED DECISION MAKING* (2015), <http://www.healthdialog.com/sites/default/files/resources/Shared%20Decision%20Making.pdf>.

97. See Linda C. Fentiman, *Patient Advocacy and Termination from Managed Care Organizations. Do State Laws Protecting Health Care Professional Advocacy Make Any Difference?*, 82 NEB. L. REV. 508, 522 (2003) (noting that unnecessary care “can be merely unhelpful or actively harmful”); Victor R. Fuchs, Commentary, *No Pain, No Gain: Perspectives on Cost Containment*, 269 JAMA 631, 631 (1993) (defining unnecessary care as “care that on balance does patients more harm than good”).

to a frightening health concern or problem; and may not understand all the clinical complexities of the alternative treatments they have been offered.⁹⁸ In short, the protection of informed consent may not be a perfect fit for patients, especially when the allegation of a lack of informed consent is based upon a failure to disclose treatment alternatives.⁹⁹ This is particularly the case when it comes to the requirement that the patient demonstrate compensable harm.¹⁰⁰

Nevertheless, informed consent has been called “the hallmark of the modern era in medical ethics,”¹⁰¹ occupying a position of primacy within the field of bioethics,¹⁰² but has also been called “little more than a legally worthless piece of paper with signatures obtained and filed away in the medical record.”¹⁰³ It has been noted for being “weak”¹⁰⁴ as well as “vital to the ethics of imposing risk on patients.”¹⁰⁵ It has been called “the bedrock of contemporary health law”¹⁰⁶ but is nearly universally criticized for its unworkability and inapplicability to the time

98. Cf. Wendy K. Mariner, *Can Consumer-Choice Plans Satisfy Patients? Problems with Theory and Practice in Health Insurance Contracts*, 69 BROOK. L. REV. 485, 495 (2004) (listing patient characteristics as compared to general consumers).

99. See Krause, *supra* note 27, at 308-22 (calling the doctrine’s “[v]estiges of [b]attery,” variant disclosure standards, causation standard, and the compensable harm requirement “problematic”).

100. *Id.* at 321 (noting that “[i]n a case involving the nondisclosure of treatment alternatives . . . the ‘harm’ may be far less tangible. To the extent that the physician fails to inform the patient of a therapy that has fewer risks or a better outcome than the proposed treatment, the patient should be able to proceed under the traditional theory. But what if the nondisclosed therapy was more risky than the proposed therapy, yet had a lower risk of certain side effects that were particularly important to that patient?”).

101. Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths About Informed Consent*, 156 ARCHIVES INTERNAL MED. 2521, 2521 (1996).

102. See *Informed Consent*, STAN. ENCYCLOPEDIA PHIL. (Sept. 20, 2011), <http://plato.stanford.edu/entries/informed-consent/> (noting that “[f]ew principles are as often identified with bioethics as informed consent”).

103. Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, 28 J. LEGAL MED. 91, 99 (2007) (footnote omitted).

104. DAN J. TENNENHOUSE, 1 ATTORNEYS MEDICAL DESKBOOK § 10:41, Westlaw (database updated Oct. 2015) (“As a result, even though it is a very common secondary theory of liability in medical negligence cases, informed consent itself is usually a weak theory unless the risk is of an extremely sensitive nature such as loss of childbearing or sexual capacity, cosmetic deformity or severe neurologic impairment.”).

105. Stephen R. Munzer, *How to Integrate Administrative Law and Tort Law: The Regulation of Stem Cell Products*, 64 ADMIN. L. REV. 743, 778 (2012); see Abilash A. Gopal et al., *Dynamic Informed Consent Processes Vital for Treatment with Antidepressants*, 35 INT’L J.L. & PSYCHIATRY 392 (2012) (proposing a “dynamic concept of informed consent”); see also Editorial, *Informed Consent Vital in Epilepsy Treatment*, GAINESVILLE.COM, (Mar. 23, 2008, 6:01 AM), <http://www.gainesville.com/article/20080323/OPINION01/803220328?Title=Editorial-Informed-consent-vital-in-epilepsy-treatment>.

106. Wendy E. Parmet, *Unprepared: Why Health Law Fails to Prepare Us for a Pandemic*, 2 J. HEALTH & BIOMEDICAL L. 157, 173 (2006).

pressures that characterize modern medicine.¹⁰⁷ Notwithstanding the withering critique, the American Medical Association (“AMA”) notes that the doctrine “is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent.”¹⁰⁸

In order to achieve adequate informed consent, the provider is required to share with the patient relevant clinical information.¹⁰⁹ Through the development of case law, courts have imposed a number of disclosure requirements on physicians¹¹⁰—including the relevant health condition, proposed treatment, possible alternatives,¹¹¹ risks,¹¹² individual or financial interests,¹¹³ and perhaps even the physician’s own experience.¹¹⁴ The specific standards are governed by state law—and are heterogeneous.¹¹⁵ Nonetheless, “every state imposes statutory

107. See Kapp, *supra* note 103, at 101 (citing Steven H. Woolf et al., *Promoting Informed Choice: Transforming Health Care to Dispense Knowledge for Decision Making*, 143 ANNALS INTERNAL MED. 293, 294 (2005)).

108. *Opinion 8.08 - Informed Consent*, AMA, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion808.page?> (last updated Nov. 2006).

109. See George J. Annas, *THE RIGHTS OF PATIENTS* 116 (3d ed. 2004) (noting that the physician is required to disclose “(1) A description of the recommended treatment or procedure; (2) [a] description of the risks and benefits of the recommended procedure, with special emphasis on risks of death or serious bodily disability; (3) [a] description of the alternatives, including other treatments or procedures, together with the risks and benefits of these alternatives; (4) [t]he likely results of no treatment; (5) [t]he probability of success, and what the physician means by success; (6) [t]he major problems anticipated in recuperation, and the time period during which the patient will not be able to resume his or her normal activities; and (7) [a]ny other information generally provided to patients in this situation by other qualified physicians.”).

110. See *id.* at 117.

111. See, e.g., *Jandre v. Physicians Ins. Co. of Wis.*, 792 N.W.2d 558, 560 (Wis. Ct. App. 2010) (requiring the provider to disclose ultrasound test as a possible option).

112. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (noting that the physician is required to “warn of the dangers lurking in the proposed treatment” and what is in the patient’s best interest and that that a physician has a “duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved”); *Barcai v. Betwee*, 50 P.3d 946, 959-63 (Haw. 2002) (discussing the requirement that the physician disclose any risks involved); *Gates v. Jensen*, 595 P.2d 919, 922-23 (Wash. 1979) (requiring disclosure of abnormality); see also Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 AMA J. ETHICS 563 (2012), <http://journalofethics.ama-assn.org/2012/07/hlaw1-1207.html> (discussing legal standards and defining the types of risks that physicians must disclose).

113. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) (finding that a physician has a duty to disclose a financial interest).

114. See, e.g., *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996) (requiring that the physician disclose his surgical experience).

115. See Marshall B. Kapp, *A Legal Approach to the Use of Human Biological Materials for Research Purposes*, 10 RUTGERS J.L. & PUB. POL’Y 1, 23 (2013) (“The particular details of informed consent vary according to individual state laws.”); see also Suzanne Sangree, *Control of Childbearing by HIV-Positive Women: Some Responses to Emerging Legal Policies*, 41 BUFF. L. REV. 309, 366 (1993) (noting that “[v]arying levels of specificity of consent are required depending upon the type of procedure involved”).

requirements that health care professionals obtain patients' informed consent before proceeding with *any* type of medical treatment."¹¹⁶ The key requirement under the doctrine is that the patient has "all information necessary to make a knowledgeable choice" for his or her health.¹¹⁷ After the provider or practice guidelines have determined that the procedure is necessary—or at least arguably medically necessary—the decision then moves into the patient's hands.

A. A Lack of Information

Nevertheless, just because patients have the right to informed consent doesn't mean they will choose what is best. For sure, patients subject to overtreatment—or clearly non-beneficial care—may be patients who steadfastly cling to the belief that more care¹¹⁸ or more expensive care¹¹⁹ is better care, or may be patients who are so preoccupied with their emergent condition that they cede all decision-making power to

116. Danielle C. Le Jeune, Note, *An "Exception"-ally Difficult Situation: Do the Exceptions, or Lack Thereof, to the "Speech-and-Display Requirements" for Abortion Invalidate Their Use As Informed Consent?*, 30 GA. ST. U. L. REV. 521, 523-24 (2014) (emphasis added).

117. *Id.* at 527.

118. See Tammy C. Hoffman & Chris Del Mar, *Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests: A Systematic Review*, 175 JAMA INTERNAL MED. 274, 274 (2015), <http://archinte.jamanetwork.com/article.aspx?articleid=2038981> (noting a recent study that examined participants in studies and concluding that a "majority of participants overestimated intervention benefit and underestimated harm"). *But see* Keerthi Gogineni et al., *Patient Demands and Requests for Cancer Tests and Treatments*, 1 JAMA ONCOLOGY 33, 33 (2015), <http://oncology.jamanetwork.com/article.aspx?articleid=2108852> (noting that the vast majority of patients who request a particular procedure request "clinically appropriate" care); Howard Gleckman, *The Myth of the Demanding Patient*, FORBES (Feb. 25, 2015, 3:00 PM), <http://www.forbes.com/sites/howardgleckman/2015/02/25/the-myth-of-the-demanding-patient/> ("Ask a physician why he prescribes unnecessary tests or treatments, and he's likely to say he's responding to demands from his patients (or trying to avoid a lawsuit). But a new study in the journal *JAMA Oncology* finds that perception may be wildly wrong."); Shefali Luthra, *Study: Physicians Report Few Requests by Patients for 'Unnecessary' Treatments*, KAISER HEALTH NEWS (Feb. 12, 2015), <http://kaiserhealthnews.org/news/study-physicians-report-few-requests-by-patients-for-unnecessary-treatments/> (noting that "patient demands are likely not the impetus for unnecessary procedures").

119. See Chapin White et al., *Understanding Differences Between High- and Low-Price Hospitals: Implications for Efforts to Rein in Costs*, 33 HEALTH AFF. 324, 324 (2014), <http://content.healthaffairs.org/content/33/2/324.full.pdf+html> ("High-price hospitals fared much better than low-price hospitals did in *U.S. News & World Report* rankings, which are largely based on reputation, while generally scoring worse on objective measures of quality, such as postsurgical mortality rates. Thus, insurers may face resistance if they attempt to steer patients away from high-price hospitals because these facilities have good reputations and offer specialized services that may be unique in their markets."); Sarah Kliff, *Half of Americans Think Expensive Medical Care is Better. They're Wrong.*, VOX (July 21, 2014, 12:30 PM), <http://www.vox.com/2014/7/21/5922835/half-of-americans-think-expensive-medical-care-is-better-theyre-wrong> (noting that a recent poll found 48% of Americans believed higher quality care costs more to deliver).

the provider involved. But data demonstrates that these patients are rare.¹²⁰ Nevertheless, for the patient involved in an emergency condition, the protections of informed consent are weak, at best.¹²¹

This analysis assumes that the majority of patients, when presented with complete information, would make better clinical decisions. For these purposes, the prototypical patient lacks information that would be helpful in understanding that the proposed procedure is likely to be nonbeneficial.¹²² Perhaps the patient simply does not know that this particular procedure is unlikely to confer any clinical benefit or is operating under the mistaken belief—a mistake that could be

120. See Jamie Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 468-69 (2006).

121. In a striking piece for *Time* magazine in January 2015, journalist Steven Brill—a leading commenter on, and critic of, America's health care system—describes his experience with open-heart surgery during the previous year. Steven Brill, *What I Learned From My \$190,000 Open-Heart Surgery*, TIME, Jan. 19, 2015, at 34, 38. Clearly illustrative of the patient for whom the protection of informed consent does not match the clinical reality, Brill's article personalizes the challenges facing the effort to control cost in American health care. *Id.* In it, he notes:

Fear of illness. Or pain. Or death. And wanting to do something, anything, to avoid that for yourself or a loved one.

. . . .

There were occasions during those eight days in the hospital when the non-drug-addled part of my brain wondered, when nurses came in for a blood test twice a day, whether one test was enough and what the chargemaster cost for both was going to look like.

But most of the time the other part of my brain took over, the part that remembered my terror during those blackouts and the overriding fear . . . that lingered in someone whose chest had been sawed open and whose heart had been stopped. As far as I was concerned, they could have tested my blood 10 times a day if they thought that was best. They could have paid as much as they wanted to that nurse's aide with the scale or to the woman who flawlessly, without even a sting, took my blood. The doctor who had given me an angiogram the afternoon before the surgery and then came in the following week to check on me became just a nice guy who cared, not someone who might be trying to add on an extra consult bill.

Id. Brill's first-person account serves as a narrative of the complicated challenges that often face patients when confronted with a health concern—even the most well informed, consumer-savvy patients. Stories like Brill's are a reminder of the major differences between health care and *every other* consumer good; the same robust consumer protections in other industries are simply untranslatable to health care. See Mariner, *supra* note 98, at 494-95 & fig.1.

In that narrative, the patient is helpless and weak, believing in—and dependent on—the heroic goodness of the American provider. See Brill, *supra* note 121, at 39. No matter what legal or patient protections are in place, they are likely far from the patient's mind; she's not thinking about whether she's been adequately informed of alternatives, the amount of her deductible, or the hospital's price for the aspirin she is about to take. She, like Brill, is thinking about the pain—and experiencing the fear and uncertainty that accompany a health concern.

122. This could be referred to as health literacy. See Jessica J. Flinn, Comment, *Personalizing Informed Consent: The Challenge of Health Literacy*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 379, 379-87 (2009).

caused by the provider's disclosure or lack thereof—that the treatment will be beneficial as compared with other treatment alternatives. If this patient had more information about the procedure—and particularly more information about the clinically reasonable alternatives—she would not have consented to it.

The patient's lack of information may be a result of many different causes. First, the provider may be able to take additional action that would address the lack of information on the part of the patient. Perhaps the provider has not adequately conveyed risks, benefits, and alternatives to the patient. This could be intentional—a product of the provider feeling that either the risks and benefits are not worth disclosure, or this may occur in situations in which the provider strongly supports the procedure and does not want to dissuade the patient from choosing that course of care. It could also be negligent; perhaps the provider unreasonably believes that the additional information is of no value. Or, perhaps, the provider is simply ignorant as to whether or not the procedure is beneficial; here, she is unaware of the information—it is not readily known even to the experts.

Ultimately, this patient consents to a procedure without fully grasping that the procedure will confer no clinical benefit. In this scenario, the informed consent given is incomplete; a patient cannot consent to a procedure for which he is not sufficiently aware of the risks, benefits, and alternatives. As a result, this patient may delegate decision-making because of his or her lack of expertise. As scholars have noted, some patients do not feel qualified to make a medical decision on their own behalf. Indeed, “in everyday practice, patients typically delegate decision making to their physicians, leading to some decisions that are made without good information on the patient's true preferences.”¹²³ Where the patient feels uncertain or uncomfortable in his ability to make a decision, it is the provider's opinion that fills the vacuum.¹²⁴ The patient intentionally cedes the protection of informed consent.

In these situations, it is clear how unsatisfying the legal and patient protections of informed consent can be. The study of bioethics trumpets the importance of patient autonomy,¹²⁵ but in these situations, the patient wants to trust and follow. The law recognizes the fundamental nature of informed consent,¹²⁶ but unknowledgeable and stressed patients do not adequately deliberate. And the most shrewd patient may

123. See Wennberg et al., *supra* note 32, at 1565.

124. See *id.*

125. See Kapp, *supra* note 103, at 93 (noting that “autonomy is the preeminent bioethical value” in the United States).

126. See Clark Freshman, *Privatizing Same-Sex “Marriage” Through Alternative Dispute Resolution: Community-Enhancing Versus Community-Enabling Mediation*, 44 UCLA L. REV. 1687, 1767 (1997) (noting that informed consent is “a fundamental value in much

know that computed tomography (“CT”) scans are overused, or that brand name pharmaceuticals are often no more effective than generics, but may—in these situations—want to be “better safe than sorry.” As a result, many clinical situations may still resemble scenes from the pre-*Canterbury* days.¹²⁷ However, as the subsequent Section argues, in certain scenarios, increased informed consent should save the system money by limiting excessive health care. It is these scenarios in which fraud-based overtreatment enforcement may be beneficial.

B. *The Emerging Conservatism of the American Patient*

Surprisingly perhaps, when given the ability to choose, recent data support the conclusion that Americans are actually quite conservative in their treatment decisions. Numerous recent studies have demonstrated that Americans’ treatment wishes are too often not reflected in the type of care they ultimately receive¹²⁸—giving rise to a problem of “unwanted care,” especially at the end of life.¹²⁹ As has been noted, “the amount of surgery that can be justified on the basis of traditional practice guidelines actually exceeds the amount of surgery that patients want when fully informed.”¹³⁰

American patients, when presented with accurate information, often choose to abstain from treatment.¹³¹ According to a recent survey, more than 51% of respondents would elect not to consent to a cancer screen if told that the screen resulted in one or more patients who were overtreated *per* one life saved from cancer.¹³² Even though between 35

American political theory and legal practice”); Donald T. Ridley, *Informed Consent, Informed Refusal, Informed Choice – What Is It That Makes a Patient’s Medical Treatment Decisions Informed?*, 20 MED. & L. 205, 205 (2001) (calling informed consent a “fundamental ethical and legal doctrine”).

127. *See Canterbury v. Spence*, 464 F.2d 772, 776-77 (D.C. Cir. 1972) (establishing physicians’ obligation to disclose various information to a patient before taking action).

128. *See Moulton & King*, *supra* note 22, at 94.

129. Rauch, *supra* note 1 (documenting the work of Dr. Angelo Volandes, who strives to achieve better informed consent through the use of videos and conversation when making treatment decisions). “Unwanted treatment is a particularly confounding problem because it is not a product of malevolence but a by-product of two strengths of American medical culture: the system’s determination to save lives, and its technological virtuosity.” *Id.*

130. Wennberg et al., *supra* note 32, at 1566; *see also* Eisler & Hansen, *supra* note 13 (noting that the existence of “mandatory second opinion program[s]” result in a notable drop in the amount of surgeries performed that were more likely to be done unnecessarily).

131. Moulton & King, *supra* note 22, at 88 (“In the absence of complete information, individuals frequently opt for procedures they would not otherwise choose. Mounting clinical evaluative evidence suggests that the number of surgical procedures performed, even when justified by practice guidelines, actually exceeds patients’ desires when they are fully informed through a shared decision-making process.”).

132. *See* Odette Wegwarth & Gerd Gigerenzer, *Overdiagnosis and Overtreatment: Evaluation of What Physicians Tell Their Patients About Screening Harms*, 173 JAMA INTERNAL MED. 2086, 2086-87 (2013) (defining overdiagnosis as “the detection of pseudodisease—

and 30% of respondents would still elect the cancer screening, even if there were between ten and one hundred patients who, as a result of that screening, were overtreated and only one patient saved from cancer,¹³³ 69% of patients surveyed “indicated that they would not start screening if overdiagnosis was as high (i.e., ≥ 10 cases per 1 life saved) as it is in mammography and PSA testing.”¹³⁴

When patients are fully informed, or when they are provided with a shared decision-making model, their consent to surgery plummets—from knee surgery (“only 15 percent of those with symptoms and x-ray evidence of degenerative changes indicating surgery actually wanted it after being fully informed”¹³⁵) to seven afflictions “commonly” addressed by surgery, where, following shared decision-making, consent to surgery dropped 21 to 44%.¹³⁶ Again, these data demonstrate that when given an opportunity to deliberate, patients decline treatment at a substantial rate.

Part of the patients’ problems stem from the failure of providers to adequately inform them of important information—information that may not have anything to do with traditional side effects or threats, but information that specifically deals with the risk of overtreatment and overdiagnosis.¹³⁷ Importantly, in a recent study, only 9.5% of patients “said that their physician had informed them about the possibility of overdiagnosis and overtreatment when discussing cancer screening,”¹³⁸ but “80% said they wanted to hear about potential harms before undergoing screening.”¹³⁹ Unsurprisingly, “[w]hen a national sample of 412 US primary care physicians . . . was asked about the extent of overdiagnosis for mammography screening and PSA testing[,] only 33.9% and 42.9%, respectively, were able to provide a correct estimate.”¹⁴⁰

C. An Example of the Conflict: End of Life Care

A specific example of the conflict between what patients want and the clinical care they ultimately receive is care administered at the end of life.¹⁴¹ At the end of life, overtreatment is defined as the administra-

screening-detected abnormalities that meet the pathologic definition of cancer but will never progress to cause symptoms”).

133. *Id.* at 2087 & fig.

134. *Id.* at 2087.

135. Wennberg et al., *supra* note 32, at 1566.

136. *Id.*

137. See Wegwarth & Gigerenzer, *supra* note 132, at 2087.

138. *Id.* at 2086.

139. Laurie Barclay, *Physicians Mum About Overdiagnosis Risks, Patients Say*, MEDSCAPE (Oct. 23, 2013), <http://www.medscape.com/viewarticle/813034> (on file with author).

140. See Wegwarth & Gigerenzer, *supra* note 132, at 2087.

141. See Lallemand, *supra* note 35, at 3.

tion of “intensive care . . . when alternative care would have been preferred by the patient and family” and “excessive use of antibiotics.”¹⁴² This conflict may not be abating in any meaningful way; with a recent Brown University study noting that “[a]lthough the CDC reports that decedents aged 65 years and older are more likely to die at home, [the] results are not consistent with the notion that there is a trend toward less aggressive care.”¹⁴³ Specifically,

[a]dvocates hoped that the continued spread of hospice and palliative care would reduce the observed patterns of aggressive care. However, our findings in a population of fee-for-service Medicare beneficiaries do not bear this out. . . . Despite expansion of hospice care and previously reported growth of hospital-based palliative care teams, there were increases in the use of an ICU; hospitalizations in the last 90 days of life; and the rates of transitions, including transitions in the last 3 days of life, from 2000 to 2009.¹⁴⁴

Medicare spending at the end of life constitutes a large overall percentage of total expenditures in the program. A recently published study concluded that the average per capita spending for Medicare beneficiaries peaked at age ninety-six at \$16,145.¹⁴⁵ This is more than double the average Medicare per capita spending for beneficiaries at age seventy—that amount was \$7,566 for the year.¹⁴⁶ Overall, 28%—about \$170 billion of the \$554 billion in total expenditures for the Medicare program in 2011—was spent during the beneficiaries’ last six months of life.¹⁴⁷

The authors of the study noted that the results could “inform efforts to improve care management for Medicare’s oldest beneficiaries” and wondered “whether Medicare’s oldest old beneficiaries are getting the appropriate mix of services in the most appropriate setting, and

142. *Id.*

143. Joan M. Teno et al., *Change in End-of-Life Care for Medicare Beneficiaries*, 309 JAMA 470, 476 (2013) (noting, for example, that intensive care unit use in the last month of life increased from 24.3% (in 2000) to 26.3% (in 2005) to 29.2% (in 2009)).

144. *Id.* at 474 (footnote omitted); see also Christian Nordqvist, *End-of-Life Care for Elderly Often Too Aggressive*, MNT (Feb. 6, 2013), <http://www.medicalnewstoday.com/articles/255991.php> (“We need to transform our health care system, from one based on fee-for-service medicine for the majority of Americans, to one where people are not paid for just one more ICU day. Instead we need a system where doctors and hospitals are paid for delivering high-quality, patient-centered care that understands the dying patient’s needs and expectations and develops a care plan that honors them. We need publicly reported quality measures that hold institutions accountable to the standard of patient-centered care for the dying.” (quoting Joan M. Teno)).

145. See Patricia Neuman et al., *Medicare per Capita Spending by Age and Service: New Data Highlights Oldest Beneficiaries*, 34 HEALTH AFF. 335, 336 (2015).

146. *Id.*

147. Jason Millman, *It’s Time to Bury the ‘Death Panel’ Myth for Good. Is this the Way to Do It?*, WASH. POST (Sept. 17, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/09/17/its-time-to-bury-the-death-panel-myth-for-good-is-this-the-way-to-do-it/>.

whether more could be done to improve the management and quality of their care.”¹⁴⁸ At the same time, commentators decry the treachery that comes with dying in modern America—made all the more confounding where “[m]ost people want to drift gently from life, optimally at home, surrounded by people they love” but that “[e]pidemiological and health service studies paint an alarmingly different picture.”¹⁴⁹

Surveys of American patients back up this sentiment—as has been noted, most “patients who recognize that they are dying do not want [aggressive] care.”¹⁵⁰ A 2014 poll sponsored by Compassion and Choices, the end-of-life advocacy organization, found that 24% of older Americans said “that either they or a family member [had] experienced excessive or unwanted medical treatment, the equivalent of about 25 million people.”¹⁵¹ A second recent study, reliant upon family members’ responses to a loved one’s recent death, concluded that suffering at end of life is actually increasing, based largely upon overly aggressive and often unnecessary treatments near the end of life.¹⁵² Finally, the Institute of Medicine’s (“IOM”) *Dying in America* report, published in the fall of 2014, presented a number of recommendations—including calling for a reduction in the “use of expensive and unnecessary medical services that don’t actually match up with what the patient wants.”¹⁵³ The report “blamed a fee-for-service medical system in which ‘perverse incentives’ exist for doctors and hospitals to choose the most aggressive

148. Neuman et al., *supra* note 145, at 338.

149. Ira Byock, Opinion, *Dying Shouldn't Be So Brutal*, N.Y. TIMES (Jan. 31, 2015, 2:30 PM), http://opinionator.blogs.nytimes.com/2015/01/31/dying-shouldnt-be-so-brutal/?_r=1.

150. Jennifer W. Mack et al., *Associations Between End-of-Life Discussion Characteristics and Care Received Near Death: A Prospective Cohort Study*, 30 J. CLINICAL ONCOLOGY 4387, 4389, 4394 (2012) (concluding that patients who had end of life conversations were “less likely to receive aggressive [end of life] care”); see also *Terminally Ill Cancer Patients Who Discuss End-of-Life Care Early Can Avoid Needlessly Aggressive Treatment Later on, Study Finds*, DANA-FARBER CANCER INST. (Nov. 13, 2012), <http://www.dana-farber.org/Newsroom/News-Releases/terminally-ill-cancer-patients-who-discuss-end-of-life-care-early-can-avoid-needlessly-aggressive-treatment.aspx> (noting that the decision to opt for “less aggressive care, less chemotherapy, and less acute care” can “often bring a higher quality of life to a dying individual’s final days”).

151. See *25 Million Older Americans Have Experienced Unwanted or Excessive Medical Treatment, Survey Suggests*, COMPASSION & CHOICES (July 29, 2014), <http://www.prnewswire.com/news-releases/25-million-older-americans-have-experienced-unwanted-or-excessive-medical-treatment-survey-suggests-269070531.html> [hereinafter *25 Million Older Americans*].

152. See Jenny Gold, *Study: Suffering at the End of Life Getting Worse, Not Better*, KAISER HEALTH NEWS (Feb. 3, 2015), <http://kaiserhealthnews.org/news/study-suffering-at-end-of-life-getting-worse-not-better/>.

153. Millman, *supra* note 147. The report noted a “mismatch between the services most readily available to people near the end of life . . . and what they most often say they want.” *Id.*

care” and “inadequate training for those caring for the dying and physicians who default to life-saving treatment because they worry about liability.”¹⁵⁴

There are signs, however, that these results represent more than just observational data of America’s unique problem of overtreatment; perhaps, these data demonstrate American patients’ increasing resolve to address unwanted care at the end of life. Interestingly, the recent Compassion and Choices poll found that “older Americans strongly support holding doctors accountable when they fail to honor patients’ end-of-life healthcare wishes.”¹⁵⁵ This includes “both incentives and sanctions to ensure physicians respect patients’ preferences.”¹⁵⁶

Specifically, 65% supported “withholding payment to healthcare providers who fail to honor [patients’] end-of-life medical wishes,” and 41% responded that “they would ‘take legal action’ . . . in response to unwanted medical treatment.”¹⁵⁷ Chief Program Officer Mickey MacIntyre, responding to the survey results, noted, “We need carrot-and-stick policies that encourage medical providers to learn their patients’ end-of-life healthcare wishes, and to honor them.”¹⁵⁸ A presentation of one such plausible legal “stick”—linking a bolstered informed consent doctrine to the anti-fraud tools commonly employed by the DOJ—follows below.

IV. ENFORCEMENT FRAMEWORKS

It may not necessarily be the case that the *substance* of the doctrine of informed consent is weak—because it is not, at least on paper—but the limitations and challenges imposed on the actual *enforcement* of the doctrine have hamstrung its robustness.¹⁵⁹ Granted, the doctrine’s provisions—focused on patient-protective autonomy and disclosure from the provider to provide an opportunity for rational deliberation—

154. Matt Sedensky, *Study: Americans Endure Unwanted Care near Death*, YAHOO! NEWS (Sept. 17, 2014, 2:13 PM), <http://news.yahoo.com/study-americans-endure-unwanted-care-near-death-181105405.html>.

155. *25 Million Older Americans*, *supra* note 151.

156. *Id.*

157. *Id.*

158. *Id.*

159. See Jessica Berg, *All for One and One for All: Informed Consent and Public Health*, 50 HOUS. L. REV. 1 (2012) (documenting the limitations to the doctrine in the public health context); Gary E. Marchant & Rachel A. Lindor, *Prudent Precaution in Clinical Trials of Nanomedicines*, 40 J.L. MED. & ETHICS 831, 835 (2012) (noting the “limitations of . . . informed consent” in clinical trials); Andrew Iverson Almand, Note, *A Mother’s Worst Nightmare, What’s Left Unsaid: The Lack of Informed Consent in Obstetrical Practices*, 18 WM. & MARY J. WOMEN & L. 565, 574 (2012) (“Given the currently weak state of the doctrine of informed consent in obstetrics, a physician need not do much to comport with applicable state law and judicial precedent on the subject.”).

do not always fit perfectly in every clinical situation.¹⁶⁰ But beyond any faults in its makeup, it has arguably been the enforceability of its protections that have lagged. These limitations—many of them court-made constraints that arise as a result of the doctrine being channeled into a medical malpractice theory—are briefly explored before the argument for a fraud-based solution is presented.

A. *The Malpractice Theory*

The channeling of informed consent into the negligence-based medical malpractice action that it currently resembles has erected roadblocks that are “particularly problematic for plaintiffs who sue based on failure to disclose treatment alternatives.”¹⁶¹ As a result, these limitations have led to a general consensus that the doctrine is weak.¹⁶² Patients, required to carry the mast of the ultimate autonomy-protective doctrine, are often faced with long odds in bringing a negligence tort action based upon a lack of informed consent.¹⁶³ The obstacles include the variant and vague disclosure standards,¹⁶⁴ the constricting causation standard,¹⁶⁵ and the requirement that the plaintiff prove that she suffered demonstrable harm.¹⁶⁶

But beyond limiting the applicability of the doctrine for patient enforcement, these limitations also prevent other interested parties—particularly, payers—from using the doctrine as a platform from which to bring legal claims against providers or entities. If providers fail to achieve adequate informed consent—perhaps, failing to disclose alternative and more cost-effective treatments—before treating a patient,

160. See, e.g., Brill, *supra* note 121, at 38-39.

161. Krause, *supra* note 27, at 308.

162. See TENNENHOUSE, *supra* note 104 (“As a result, even though it is a very common secondary theory of liability in medical negligence cases, informed consent itself is usually a weak theory unless the risk is of an extremely sensitive nature such as loss of childbearing or sexual capacity, cosmetic deformity or severe neurologic impairment.”). See generally Jacquelyn Ann K. Kegley, *Challenges to Informed Consent*, 5 EUR. MOLECULAR BIOLOGY ORG. REP. 832 (2004) (documenting various weaknesses of the doctrine).

163. See TENNENHOUSE, *supra* note 104 (discussing the weaknesses of the informed consent doctrine).

164. See Krause, *supra* note 27, at 314-17.

165. See *id.* at 317-20; see also TENNENHOUSE, *supra* note 104 (“In cases based on lack of informed consent, causation is often difficult to prove because the plaintiff must show that the indicated intervention would have been refused had the patient known of a specific risk or other factor that was not disclosed by the physician.”).

166. See Krause, *supra* note 27, at 321 (“To the extent that a physician fails to inform the patient of a therapy that has fewer risks or a better outcome than the proposed treatment, the patient should be able to proceed under the traditional theory. But what if the nondisclosed therapy was more risky than the proposed therapy, yet had a lower risk of certain side effects that were particularly important to that patient? For example, a patient with breast cancer may be told that her only surgical option is a radical mastectomy, and not informed of the possibility of a less disfiguring lumpectomy. If the mastectomy cures her cancer, what ‘injury’ has she sustained?”).

they are not just disrespecting the patient's autonomy which may result in harm to the patient, but they are also causing financial harm to the third-party payer. Clearly, from the third-party payer's perspective, it should not be reimbursing the provider for *any* administered care lacking in complete informed consent. This is particularly the case, however, when both the service provided is of questionable clinical value and the patient was not adequately made aware of reasonable alternatives—including the alternative to abstain from a procedure altogether. In fact, by administering care before discussing all relevant information regarding treatment alternatives, the provider could be tainting the entire episode of care for the patient.

As a result, even when the patient is unable to claim demonstrable physical harm as a result of the provider's failure to disclose reasonable alternative treatment options, the payer may still experience financial harm. To the extent the third-party payer is a government entity—particularly, to the extent the third-party payer is the federal government administering the Medicare program—powerful anti-fraud tools are available. These tools may be utilized by the federal government to prevent and punish care that—while maybe not resulting in physical harm to the patient—is financially harmful to the federal government because of the existence of a reasonable, more cost-effective alternative treatment.¹⁶⁷

B. Enforceable Informed Consent and the FCA

Under the current construct, for many cases in which the patient struggles to articulate both (1) a demonstrable harm, and (2) the fact that the harm is caused by deficient informed consent, the third-party payer is left without any legal remedy. And, as a result, in these situations—typically when the payer (Medicare) reimburses the physician for treatment following allegedly incomplete or deficient disclosure of reasonable treatment alternatives—the current regime fails to provide a remedy for the payer as well. But by linking the regulatory framework to the third-party payer and not just the patient (i.e., recognizing that an additional party is harmed by the lack of adequate informed consent), the doctrine could provide a number of advantages.

By virtue of the provider's failure to secure informed consent by adequately disclosing treatment alternatives, the episode of care is in some way deficient or defective. Here, the third-party payer would emphasize the primacy of informed consent within law and bioethics and

167. For a discussion of what showing of harm is required under the FCA, see Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121 (2001).

the stress medical care places upon the doctrine.¹⁶⁸ Where the provider has failed to present all treatment alternatives, he has failed to secure adequate informed consent, and the care is either substandard or unnecessary (or both), and therefore, should not be care that is reimbursable.¹⁶⁹

More likely to be potentially legally viable,¹⁷⁰ a slightly different argument focuses on those cases in which the physician has failed to disclose treatment alternatives, but the plaintiff is unable to prove either the harm necessary (under the current malpractice-based standard) or meet the daunting causation requirement. Again, the argument here is that the harm experienced by the Medicare program may be wholly unconnected to whether or not the patient can demonstrate a malpractice-based tort claim.

Under a new theory of informed consent suggested by this instant analysis, the third-party payer would be able to bring an FCA claim based upon a lack of informed consent against defendants (1) who radically overly-administered procedures when compared to other providers, (2) whose patients would not have elected to undergo those procedures had they been made aware of the comparison data, and (3) who failed to disclose that an eminently reasonable clinical alternative existed. The payer here—the federal government—suffers harm as a result of the provider failing to present the complete picture of treatment alternatives; but under the current construct of informed consent, neither the patient nor the payer have any adequate legal recompense. The federal government, as third-party payer, however, under this new construct, would be able to pursue an FCA claim.

Resembling other fraud-based regulation, the question of whether taxpayer harm occurred in these cases is a wholly separate and unrelated question from whether or not patient harm occurred,¹⁷¹ indeed,

168. See *Informed Consent*, *supra* note 102 (explaining the doctrine of informed consent and highlighting its significance in clinical practice and bioethics).

169. This is the foundation of the DOJ's certification theory under the FCA, wherein some aspect of care is deficient, and the DOJ argues that the care should not be reimbursable. See *infra* Part V. Here, where sufficient informed consent is not achieved, the same argument would take hold.

170. See *infra* Part V. Indeed, the argument that the payer is reimbursing for a medical service that is clinically worthless or nonbeneficial is typically more cognizable in these cases than the simpler argument that Medicare simply should not pay for deficient care.

171. In most FCA-based anti-fraud actions, whether or not patients were harmed—suffered a legally-compensable harm—is legally irrelevant. Indeed, in the DOJ's newest enforcement regime, whereby federal prosecutors target providers who may have knowingly retained an overpayment, an action can lie regardless of whether patient harm occurred or not. See generally Scott Stein & Brenna Jenny, *Reply Briefs in Continuum Litigation Continue to Debate Over Nature of an "Obligation" Under FCA*, SIDLEY AUSTIN LLP (Dec. 17, 2014), <http://fcablog.sidley.com/reply-briefs-in-continuum-litigation-continue-debate-over-nature-of-an-obligation-under-fca/> (discussing dispute over obligations under the False Claims Act).

the questions are often completely unrelated. Undoubtedly, the Medicare program is harmed whenever a provider administers a procedure that is nonbeneficial and potentially unnecessary regardless of whether or not the patient suffers any physical harm as a result. Reconceiving of the harm in these cases from required patient harm to recognizing that whenever overtreatment is administered, the payer is harmed, gives the payer—here, the Medicare program—an enforceable legal remedy and a powerful tool to use against American overtreatment. This tool would force providers into being cognizant about less costly clinical alternatives and push them into being as forthcoming about utilization and cost as they are about supposed clinical benefits for a proposed procedure. If a fully informed consumer-savvy patient would not want it, and the procedure is nonbeneficial (and exposes that patient to risks associated with overtreatment), then why is Medicare paying for it?

C. Potential Benefits of Enforceable Informed Consent

A more powerful notion of informed consent in this situation produces three desired results: it should (1) provide a remedy for the payer for those cases in which the current malpractice-based conception of informed consent is inapplicable; (2) force providers to disclose more information—with a particular focus on reasonable alternative treatments (including, potentially, suggesting doing nothing in some cases); and (3) result in increased access to relevant information for patients, ultimately improving their clinical decisions. A strengthened doctrine, bolstered by the specter of fraud-based penalties looming over a provider for failing to disclose reasonable alternatives, would force more information into patients' hands, consequently leading to smarter and more efficient health care decisions. If nothing else, increased information in the hands of patients will lead to decisions by patients that more closely track their true wishes—which is, by itself, a positive development.¹⁷²

First, this extended enforcement provides a remedy (and punishment) for those “gap” cases that currently exist—those cases where informed consent is clearly defective, but plaintiffs cannot meet the strictures of negligence-based malpractice requirements like causation and harm. For these cases, the payer—here the federal government—would have a clear remedy against the provider for failing to present all potential alternative treatment options. Further, and

172. This is particularly the case, given the recent disappointing data on end-of-life care. See *supra* Section III.C.

perhaps more importantly, the provider would be punished for failing to secure adequate informed consent regardless of whether traditional patient harm occurs.

Second, this new conception of informed consent pushes providers to ratchet up the amount of disclosures they make prior to performing a potentially nonbeneficial (or at least clinically borderline) procedure. This does not *foreclose* the possibility that a patient, after receiving complete information regarding potential treatment alternatives, would still choose to undergo a particular procedure, but it simply ensures that patients are receiving information relating to cost and alternatives that may influence their choices of whether to undergo treatment in the first place. Again, the threat of enforcement—an FCA-led overtreatment investigation with the alleged violation based on a lack of informed consent—forces the provider to internalize that risk and increase the amount of disclosure he or she makes to the prospective patient.

Third, this extended enforcement framework would give patients more information to make the best clinical decision. As it exists now, patients may be easily swayed by the clinical opinion of their provider without sufficient and adequate legal protection. Currently, these patients have very little check on the power and persuasion of the provider. And in the end, neither the patient nor the taxpayer is well served by this non-system of enforcement.

Coupling this observation with the current challenge and prevalence of overtreatment in American medicine makes clear that the provider's failure to disclose all reasonable treatment alternatives may likely lead to further unnecessary treatments and excess expense within the American health care industry.¹⁷³ Granted, using the statutory tools available to the federal government for a failure to secure informed consent would constitute a departure from the historical use of the informed consent doctrine—and, to some extent, would subject a new enforcement regime to a critique that it is stretching the uses of the doctrine—indeed, still reliant on overtreatment regulation's primary tool of the FCA—would not constitute a major departure from the DOJ's chosen tool to regulate and punish overtreatment. Further, using the FCA to protect the autonomy of the *patient*—not to punish or overrule the expertise of the provider—seems to be an entirely

173. See Lallemand, *supra* note 35, at 3 (noting that “[o]vertreatment can . . . result from overdiagnosis, which results from efforts to identify and treat disease in its earliest stages when the disease might never actually progress and when a strategy such as watchful waiting may have been preferred” and that “[e]xcessive treatment . . . leads to unnecessary harms”).

different exercise altogether. Again, if the patient chooses a nonbeneficial treatment that is marginally medically necessary, this regime would not apply.

At root, the theory here is focused on the fact that the provider administered care to the patient who, had she been aware of both (1) all of the alternatives, and (2) the clinical “aggressiveness”—based upon comparative information—with which her provider approached her health issue, would have never consented to undergo the procedure. And at the heart of the proposal, such application of the FCA makes intuitive sense; the American Bar Association had submitted a proposal mirroring these suggestions—but it was ultimately withdrawn.¹⁷⁴

However, beyond reconceptualizing usage of the FCA to target providers who fail to present alternative treatment options to their patients, there are formidable legal hurdles that this new overtreatment regulation theory must clear. And, in some ways, the law would have to evolve to allow this extended application of the informed consent doctrine. These important legal arguments—focused exclusively on using the FCA to regulate and investigate the failure to secure adequate informed consent—are presented below.

V. THE NEW LEGAL DOCTRINE

A federal district court recently dismissed a relator’s FCA claim against medical device manufacturer Medtronic, Inc. (“Medtronic”).¹⁷⁵ The lawsuit was based upon Medtronic’s alleged failure to disclose conflicts of interest and for allegedly engaging in off-label marketing.¹⁷⁶ In the opinion, the court unequivocally denied one of the relator’s main arguments—specifically, that Medtronic violated the FCA because it failed to secure adequate informed consent from patients.¹⁷⁷ Noting that the relator’s “informed consent ‘scheme’” could not “form the basis for FCA liability because payment of Medicare claims does not require informed consent,” the court granted the dismissal.¹⁷⁸ This decision

174. See JEFFERY SNELL, ABA COMM’N ON LAW & AGING, REPORT TO THE HOUSE OF DELEGATES, 106B, at 4-7 (2010); Pope, *supra* note 33, at 278 n.423 (noting that “recommendations were eventually withdrawn”).

175. United States *ex rel.* Hartwig v. Medtronic, Inc., No. 3:11CV413-CWR-LRA, 2014 WL 1324339, at *1 (S.D. Miss. Mar. 31, 2014).

176. *Id.* at *2.

177. *Id.* at *10-12.

178. *Id.* at *12. As strange as the decision may read to the layperson—that care administered without the patient’s informed consent is reimbursable by Medicare—the *Hartwig* case tracks the current legal structure that governs what is known as “certification” theory. One of the theories by which the federal government seeks to assert a quality of care-based violation of the FCA, prosecutors have to allege that the violation was material to the government’s decision to pay on the Medicare claim. See United States *ex rel.* Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1510, 1512 (M.D. Tenn. 1996) (noting that the certification must be material to the decision to pay in order to be actionable under the FCA).

demonstrates the most daunting challenge for informed consent-based liability under the FCA—that informed consent has never been treated like a material component of the government’s reimbursement decisions. And, given the current makeup of the legal regime, multiple pathways for fraud-based liability may be blocked.

Generally, when seeking to regulate overtreatment or prevent the administration of unnecessary health services through the FCA, federal prosecutors have advanced three primary theories of liability.¹⁷⁹ Courts—including, most recently, the U.S. Supreme Court¹⁸⁰—have shaped the application of these theories over the last fifteen years as the federal anti-fraud tools have been employed to regulate American providers that are allegedly administering overtreatment and providing unnecessary health care. These include (1) express certification, (2) implied certification, and (3) worthless services theories.¹⁸¹

For this proposal, which seeks to use informed consent as the basis upon which to bring an FCA claim, there are four main legal arguments—based on these three theories—upon which federal prosecutors could rely. Specifically, these four potential theories of liability center on allegations that, as a result of the provider’s failure to obtain adequate informed consent: (1) the care was not administered in accordance with the general rules and regulations of the Medicare program and was made fraudulent by an express certification to the federal government, (2) the care administered was in some way deficient or defective in quality, and billing for the care was made fraudulent under an implied certification theory, (3) the care administered was medically “worthless,” and the federal government was defrauded for having to pay for the worthless service, or (4) the care administered was not medically necessary and was made fraudulent by an express certification to the federal government.

A. *The Legal Classification*

All four of these potential theories of liability feature a legal argument that relies on the fact that the failure to achieve adequate informed consent in some way taints the claim for reimbursement. At bottom, for these arguments, when the provider who fails to secure informed consent submits a claim for reimbursement, the federal

179. See PollyBeth Hawk, *Ready or Not: Hospital Value-Based Purchasing Poised to Transform Healthcare Reimbursement Model and Introduce New Fraud Targets Under the False Claims Act*, 22 ANNALS HEALTH L. 43, 67 (2013) (noting that quality-based fraud investigations are “generally based on” three theories).

180. See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

181. See Hawk, *supra* note 179, at 67.

government is defrauded by paying for that service. To the casual observer, any of these four theories could seemingly be alleged successfully.

However, based upon current precedent, not all of these theories of liability have a substantial chance of success when raised in federal court. And while these arguments may have an intuitive attractiveness, as the theories are currently construed, federal prosecutors alleging violations of the FCA based upon insufficient informed consent likely face an uphill battle due to a number of court-made limitations on the theories. The first three of these theories—arguments based solely upon express certification, implied certification, and worthless service theories—are presented first, followed by the one theory—based upon medical necessity—that may be most likely to succeed.

1. *Express Certification*

The first potential theory of liability that could be alleged is a violation of the FCA by virtue of the provider's express certification that the care administered "comple[d] with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment."¹⁸² For the instant analysis, this can be referred to as the "express certification" theory of liability.

Generally, express certification claims have been referred to as claims "that contain[] a false affirmative declaration of compliance with a contract provision, statute, or regulation material to the government's decision to pay."¹⁸³ This allegation would not depend upon whether or not the care administered was deemed reasonable and necessary by the Medicare program, but instead would allege that the fail-

182. See HEALTH INSURANCE CLAIM FORM, CMS, <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> (last visited Feb. 20, 2016).

183. Christopher L. Martin, Jr., Comment, *Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CALIF. L. REV. 227, 239 (2013).

ure to secure informed consent violates Medicare regulations—because, indeed, it does.¹⁸⁴ A provider who fails to achieve sufficient informed consent clearly violates Medicare’s rules.¹⁸⁵

Consequently, by attesting to the fact that the care was administered in compliance with all of Medicare’s governing rules when submitting the claim form for reimbursement, the provider transforms that failure to comply with Medicare’s informed consent rules into a false statement to Medicare. This becomes a false claim to the federal government—and an alleged violation of the FCA. However, in order to demonstrate the express certification theory on this claim, the DOJ would have to show that this certification was in some way material to the government’s decision to pay.¹⁸⁶

Even though application of this theory seems relatively straightforward, there are court-made limitations that will present challenges for the application of express certification theory here. Most prominently, courts have limited the application of express certification theory to claims that certify compliance with a statute or regulation that is material to the government’s decision to pay the claim.¹⁸⁷ That is, if the provider certifies compliance with a Medicare statute or regulation and that certification is not material to the government’s decision to pay on the claim, express certification theory is inapplicable. In some ways, this limitation resembles the causation requirement in the current malpractice regime; similarly, if the government would have paid the claim anyway—regardless of the certification of compliance—then the false attestation could not have *caused* harm to the Medicare program.

The DOJ would allege that the provider who failed to achieve sufficient informed consent made a false statement when he certified compliance with all of Medicare’s rules and regulations.¹⁸⁸ But very

184. See 42 C.F.R. § 482.13(b)(2) (2015) (“The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.”). For surgeries, a Medicare condition of participation requires “[a] properly executed informed consent form for the operation” that “must be in the patient’s chart before surgery.” 42 C.F.R. § 482.51(b)(2) (2015).

185. See 42 C.F.R. § 482.51(b)(2).

186. See John T. Brennan, Jr. & Michael W. Paddock, *Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards*, 2 J. HEALTH & LIFE SCI. L. 37, 48 (2008); Martin, *supra* note 183, at 239; see also *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1510 (M.D. Tenn. 1996) (stating that withholding of information critical to the government’s decision to pay claims is the essence of a false claim).

187. See Brennan & Paddock, *supra* note 186, at 48; Martin, *supra* note 183, at 239.

188. See HEALTH INSURANCE CLAIM FORM, *supra* note 182. The certification contains the following: “In submitting this claim for payment from federal funds, I certify

quickly, this argument may hit a snag.¹⁸⁹ Medicare has two different types of conditions—conditions of payment¹⁹⁰ and conditions of participation (“CoP”).¹⁹¹ CoPs have been described as “federal regulations with which particular healthcare facilities must comply in order to participate” in the Medicare program.¹⁹² Beyond being important for entrance into the program, providers must comply with CoPs “to maintain good standing in the Medicare program.”¹⁹³

Medicare includes its informed consent requirement as a CoP within its regulations—not a condition of payment.¹⁹⁴ One of Medicare’s CoPs clearly requires that each patient “has the right to make informed decisions regarding his or her care.”¹⁹⁵ Historically, as a result of this classification, the requirement of informed consent would not be material to the government’s decision to pay¹⁹⁶ because “Medicare COPs are not explicitly referred to in the relevant claims’ certifications, and have not been determined to be material to the payment decision on any ad hoc, case-by-case basis.”¹⁹⁷ However, with the recent Supreme Court decision in *Escobar*, where the court noted that the

that . . . this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment . . .” *Id.*

189. It remains uncertain what the effect of the *Escobar* case will be on this analysis for express certification. Under *Escobar*, it appears that the distinction between a condition of payment and condition of participation is irrelevant as to whether or not the decision to pay was material. See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1994, 1996 (2016). In so holding, the Court does not appear to limit its decision on this question only to implied certification (the question of the case before it), suggesting it may reach express certification. *Id.*

190. See generally 42 C.F.R. § 424 (2015) (providing conditions of payment regulations within Medicare).

191. See generally 42 C.F.R. § 482 (2015) (delineating conditions of participation for hospitals).

192. See *Medicare CoPs and Interpretive Guidelines*, AM. ASSOCIATION NURSE ANESTHETISTS, <http://www.aana.com/advocacy/federalgovernmentaffairs/Pages/Medicare-Conditions-of-Participation.aspx> (last visited Feb. 20, 2016).

193. See Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX: J.L.-MED. 243, 280 (2004).

194. See 42 C.F.R. § 482.13(b) (2015).

195. *Id.*

196. Brennan & Paddock, *supra* note 186, at 48; see also *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1219-21 (10th Cir. 2008); *United States ex rel. Gross v. AIDS Research All.-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005); *Mikes v. Straus*, 274 F.3d 687, 701-02 (2d Cir. 2001).

197. Brennan & Paddock, *supra* note 186, at 48; see also Martin, *supra* note 183, at 244-45 (noting precedent in which relator’s claim was rejected because the applicable Medicare regulation did not expressly condition payment on compliance with its terms.). Further, courts’ decisions “often hinge on the distinction between conditions of payment and conditions of participation.” Katherine A. Lauer et al., *Violations of Payment/ Participation Conditions as Predicates for False Claims*, ABA (2011), <http://apps.americanbar.org/litigation/committees/criminal/email/winter2012/winter2012-0402-violations-conditions-payment-participation-predicates-false-claims.html>.

distinction between CoPs and conditions of payment can both form the basis of an FCA claim (assuming the violation is material and scienter is met), this distinction no longer appears to be dispositive.¹⁹⁸

The historical distinction between CoPs and conditions of payment is due largely to a determination that CoPs—as opposed to conditions of payment—are enforceable by an administrative remedy, which is exclusion from the Medicare program.¹⁹⁹ Alternatively, conditions of payment “are those which, if the government knew they were not being followed, might cause it to actually refuse payment.”²⁰⁰ Of course, the relative dearth of providers excluded from the Medicare program for providing overtreatment demonstrates the lack of utility of the current remedy. Prior to *Escobar*, practitioners had noted that allowing an FCA action based upon a CoP would widen applicability of the FCA well beyond its intended application.²⁰¹ Of course, the full effect of the recent *Escobar* case on this argument, at time of publication, is unknown, but appears to remove one of the major hurdles to this theory of liability.

2. Implied Certification

Second, in most federal circuits,²⁰² and very recently recognized by the Supreme Court in *Escobar*,²⁰³ federal prosecutors can argue that an FCA violation occurred under an implied certification theory.²⁰⁴ Within this theory, the prosecutor could allege that by virtue of submitting the bill for repayment, the provider was impliedly certifying

198. See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (noting that “[d]efendants can be liable for violating requirements even if they were not expressly designated as conditions of payment. Conversely, even when a requirement is expressly designated a condition of payment, not every violation of such a requirement gives rise to liability.”).

199. See *Conner*, 543 F.3d at 1219-21 (“It is therefore with good reason that the agencies of the federal government, rather than the courts, manage Medicare participation in the first instance in cooperation with the states and accreditation organizations.”).

200. *Id.* at 1220-21 (“There is thus no basis in either law or logic to adopt an express false certification theory that turns every violation of a Medicare regulation into the subject of an FCA qui tam suit.”).

201. See Lauer et al., *supra* note 197 (“Expanding the reach of the FCA by conflating conditions of payment with requirements that are actually conditions of participation is neither consistent with established case law nor good public policy. The mechanisms in place for enforcing conditions of participation have been thoughtfully and thoroughly developed by the agencies overseeing the myriad of federal health care programs. Permitting qui tam relators to bring actions purporting to enforce these regulations creates uncertainty among health care providers and will result in additional costly litigation.”).

202. See Martin, *supra* note 183, at 242 (noting that the Fifth, Seventh, and Eighth Circuits have not yet recognized implied certification theory). But, in early 2015, the Fourth Circuit recognized the implied certification theory for the first time. Ellyce Cooper & Collin Wedel, *Fourth Circuit Recognizes Implied Certification Theory*, SIDLEY AUSTIN LLP (Jan. 15, 2015), <http://fcablog.sidley.com/fourth-circuit-recognizes-implied-certification-theory/>.

203. See *Escobar*, 136 S. Ct. at 1995.

204. See Hawk, *supra* note 179, at 68.

compliance with all of the rules and regulations that govern the Medicare program.²⁰⁵ This theory's main distinction from express certification centers on the fact that the implied certification theory features an *implied* "statement" that is satisfied by the submission of the claim for reimbursement, and not an express attestation. No "affirmative declaration" is required.²⁰⁶

Implied certification theory is typically seen as the second-best certification theory—particularly because, before *Escobar*, the theory was not universally recognized in the federal courts.²⁰⁷ Under implied certification, it is irrelevant whether or not the form includes a certification that the care complied with all rules and regulations of the Medicare program; indeed, by the act of submitting the bill, the provider impliedly certifies compliance. Where express certification is unavailable to the federal prosecutors, implied certification theory takes its place. For the instant analysis, the provider who fails to secure sufficient informed consent but then seeks reimbursement for the administered medical service would allegedly be in violation of the implied certification theory under the FCA. By virtue of submitting the claim for reimbursement, the provider is impliedly certifying compliance with Medicare's rules; a provider who fails to secure adequate informed consent is violating those programmatic provisions.²⁰⁸

Nevertheless, starting with the often-cited *Mikes v. Straus*,²⁰⁹ and spreading to other circuits nationwide,²¹⁰ courts had been hesitant to allow FCA liability for implied certification. In the summer of 2016, however, the U.S. Supreme Court recognized the implied certification theory and clearly concluded that a CoP violation—and not just an express condition of payment—could provide the basis for an FCA claim based on implied certification in the context of a state Medicaid program, as long as the violation was material.²¹¹ As a result, a

205. See Joan H. Krause, "Promises to Keep": Health Care Providers and the Civil False Claims Act, 23 CARDOZO L. REV. 1363, 1396 (2002) ("Both the government and *qui tam* relators have argued that participation in Medicare and Medicaid entails an implied certification that the claimant will abide by all relevant program statutes, rules, and regulations.").

206. See Martin, *supra* note 183, at 240.

207. See *id.* at 241 (noting that the Fifth, Seventh and Eighth Circuits have not recognized implied certification); Cooper & Wedel, *supra* note 202 (noting that the Fourth Circuit recognized implied certification in 2015).

208. See 42 C.F.R. § 482.13(a), (b)(2) (2015) (noting informed consent provisions under Medicare program).

209. *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001).

210. See Martin, *supra* note 183, at 242.

211. See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1993-94 (2016).

condition of payment violation is not automatically material under the FCA, and a violation of a CoP within Medicare seemingly *could* be material, forming the basis for an FCA claim.²¹²

Although the complete ramifications of the *Escobar* case are not yet known, it appears that, in some ways, it tracks the federal circuit court decisions in the First, D.C., and Federal Circuits, and not the tougher *Mikes* test.²¹³ These circuits have allowed for broader application of the implied certification theory, and under *Escobar*, it appears that the implied certification theory has been clearly entrenched in FCA jurisprudence.²¹⁴ Whether that opens the door to an implied certification claim based on a lack of informed consent—and how potentially widely it does so—remains an open question at the time of this writing.

3. *Worthless Services*

Third, the DOJ can attempt to tie the FCA to the failure to secure adequate informed consent by the “worthless services” theory.²¹⁵ Under this theory, the government alleges that care administered to the Medicare beneficiary was so deficient that paying for the service amounts to paying for *nothing*.²¹⁶ And, by getting paid for administering the worthless service, the provider is recovering an ill-gotten gain from the federal government; consequently, that provider is defrauding the federal government under the FCA. For services that fail to improve the health of the patient and, in fact, subject the patient to a number of increased health risks, the worthless services theory makes intuitive sense.

For the instant analysis, the worthless services theory may align easily with the claims that are based on a lack of informed consent. For nonbeneficial health services for which the patient was not provided with sufficient treatment alternatives, the procedure that ultimately takes place is undoubtedly worthless. It would not be a stretch to allege they were clinically worthless and, consequently, legally

212. *Id.*

213. See Martin, *supra* note 183, at 247.

214. See, e.g., United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 379-80 (1st Cir. 2011) (noting that implied certification still depends upon a showing that the violation would have been material to the government’s decision to pay).

215. See, e.g., *Extendicare Health Services Inc. Agrees to Pay \$38 Million to Settle False Claims Act Allegations Relating to the Provision of Substandard Nursing Care and Medically Unnecessary Rehabilitation Therapy*, DEP’T OF JUST. (Oct. 10, 2014), <http://www.justice.gov/opa/pr/extendicare-health-services-inc-agrees-pay-38-million-settle-false-claims-act-allegations> (noting the government allegations that the defendant “billed Medicare and Medicaid for materially substandard nursing services that were so deficient that they were *effectively worthless* and billed Medicare for medically unreasonable and unnecessary rehabilitation therapy services”) (emphasis added).

216. See United States *ex rel.* Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1050-54 (9th Cir. 2001) (recognizing the worthless services theory and allowing the plaintiff to amend complaint after defendant allegedly falsified control sample test results).

worthless under the FCA. Still, in order to successfully allege that the provider billed for worthless services, the services must be so deficient that billing for them resembles billing for no care at all.²¹⁷ Care that provides the basis for an informed consent-based liability case may not likely be classified as worthless, especially because, in those cases, there is no allegation that the care's quality *itself* was woefully deficient. Instead, these patients were treated—but were administered care that they would not have chosen. This legal harm seems more complex than the more straightforward worthless services theory, at least as it is currently recognized.

4. *Fraud Based on Medical Necessity*

Finally, for cases in which the consent at issue was not completely informed, the federal government—through the DOJ—could argue that when the provider seeks reimbursement for that service, he should not be entitled to payment; indeed, Medicare, the argument goes, should only pay for medically necessary services. And—importantly—a service that is administered without adequate informed consent is medical care that cannot be called medically necessary.²¹⁸ For the instant analysis, this argument can be deemed the “medical necessity” argument, and—lacking the legal barriers that may limit the other theories mentioned above—this allegation may be the likeliest of the four to succeed.

Specifically, this theory represents “express certification” in typical FCA parlance, because when the claim is submitted to the federal government, the provider attests to the fact that all care was reasonable and necessary—in accordance with Medicare's statutory requirement that all care be “reasonable and necessary.”²¹⁹ Ultimately, when the provider submits a bill for the service that was neither reasonable nor necessary, the provider is allegedly making a false statement to the federal government.²²⁰ This argument would be a novel one; in this

217. See *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001) (“In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.”).

218. In a previous work, I suggested a new construct of health care fraud regulation in overtreatment cases—particularly with an eye toward improving the accuracy and defensibility of medical necessity-based fraud regulation. In it, I argued that instead of linking the determination of fraud to whether or not the care at issue was medically necessary, federal prosecutors should be able to target individual providers simply by virtue of those providers exceeding a normal range of administered care as compared to other providers. For more arguments as to why this enforcement mechanism would be more accurate and defensible, see Buck, *Caring Too Much*, *supra* note 23, and Buck, *Enforcement Overdose*, *supra* note 23.

219. See 42 U.S.C.A. § 1395y(a)(1)(A) (West 2015).

220. The False Claims Act prevents the “knowing[]” presentation of a false claim to the federal government. 31 U.S.C. § 3729(a)(1)(A) (2012). Interestingly, in 2007, Wennberg and his colleagues suggested a new definition of medical necessity; instead of using medical necessity as a species of decision made by the physician or payer, they argued that it should be

context, it has never been successful—and rarely been employed.²²¹ This is likely due to the fact that medical necessity has historically been conceived of as dependent on the determination of one of two actors in the care delivery chain: (1) providers²²² and (2) payers (particularly the Medicare program itself).²²³

Whether or not the patient has evinced clear and complete informed consent has historically been irrelevant to the question of whether or not a procedure was medically necessary, creating the anomalous situation that care lacking in informed consent may not only be classified as medically necessary for purposes of Medicare reimbursement, but that the two values—informed consent and medical necessity—may inexplicably diverge.²²⁴ Most importantly, this theory would infuse medical necessity with a second requirement. Beyond the provider's determination, a procedure can only be medically necessary following complete and robust informed consent, inclusive of a number of disclosures. Under this new paradigm, medical care that is not appropriately consented to by the patient is care that is lacking in medical necessity—and, consequently, fraudulent.

This argument would steer clear of the broad prohibition and concern illustrated by the *Mikes* case, most notably because in its dismissal of Patricia Mikes' allegations, the Second Circuit was clear to note that “‘medical necessity’ as used in the certification did not translate

“based on the patient's preference, established through high-quality shared decision making.” Wennberg et al., *supra* note 32, at 1569. Indeed, a newly conceptualized definition of medical necessity would prove quite revolutionary for these fraud-based theories. Absent a formal change here, however, the argument can still be made that care lacking in informed consent is not medically necessary. See SNELL, *supra* note 174; Pope, *supra* note 33, at 278 (noting that unwanted medical treatment is not medically necessary, as “[w]hen a competent and informed patient or surrogate expressly declines treatment, such treatment cannot be considered ‘medically necessary’”) (citation omitted).

221. See, e.g., *Gross v. AIDS Research All.-Chi.*, No. 01C8182, 2003 WL 22508153, at *3 (N.D. Ill. Nov. 3, 2003) (granting a motion to dismiss after relator was not specific enough with allegations, but one allegation centered on a failure to obtain informed consent for a clinical study); *United States ex rel. Hartwig v. Medtronic, Inc.*, No. 3:11CV413-CWR-LRA, 2014 WL 1324339, at *12 (S.D. Miss. Mar. 31, 2014) (dismissing claims based on a lack of informed consent because “payment of Medicare claims does not require informed consent”).

222. See Nan D. Hunter, *Managed Process, Due Care: Structures of Accountability in Health Care*, 6 YALE J. HEALTH POL'Y L. & ETHICS 93, 103 (2006) (documenting the history of care providers' control over the medical necessity determination and then the “provider-dominated institutions [that] reviewed determinations of medical necessity made by providers”).

223. See Lester J. Perling, *Medicare's Medical Necessity Criteria: A Mystery in the Making*, HEALTH L., Oct. 2008, at 30, 32 (calling Medicare's coverage and medical necessity determinations “vague” and threatening to “providers' and suppliers' ability to practice and earn income”).

224. See generally D. Don Welch, Essay, *Walking in Their Shoes: Paying Respect to Incompetent Patients*, 42 VAND. L. REV. 1617, 1627 (1989) (admonishing that “[w]hen we think about treatment of incompetent patients without their consent, we should not think in terms of medical necessity overriding the value of informed consent”).

to a quality guarantee.”²²⁵ In *Mikes*, the certification—which indicated that a medically necessary and reimbursable procedure was administered²²⁶—was a significantly different type of certification than the proposed certification for care that lacks informed consent. The Second Circuit made clear that “[t]he fact that the ‘quality’ of the tests might not have met the applicable standard of care . . . was irrelevant under the FCA.”²²⁷ For the instant proposal, if care is lacking in complete informed consent, the certification that the care was medically necessary would clearly be a false submission; a failure to achieve sufficient informed consent is not just a quality failure, it is a bedrock requirement before treatment may commence.²²⁸

B. Practical Impacts

In many ways, this proposal signals a paradigm shift in the investigation and prosecution of health care fraud based on medical necessity. Up to this point, enforcement has been the province of the federal prosecutor (and sometimes a relator under the FCA). The enforcement framework has featured a government-based standard and a provider seeking to defend herself, often arguing over the grayly-shaded concept of medical necessity.

The enforcement mechanism has not yet availed itself of this separate and potentially viable legal alternative: that when patients are overtreated, they are subject to harm—and when they are administered care that is unnecessary or unwanted, there must be an allegation that the informed consent evinced by the patient—a vital and required showing before treatment may begin—was deficient. Freeing federal prosecutors to pursue this second avenue of liability makes the government reimbursement standard—often subject to criticism due to its arguable accuracy²²⁹—potentially irrelevant.

To demonstrate the attractiveness of this new theory, it is worthwhile to provide a concrete example. As is the case for many medical necessity-based investigations, this illustration focuses on fraud-based settlements recently announced by the DOJ as well as newspaper investigations commenced following allegedly unnecessary cardiac stents and services.²³⁰ These cases provide apt examples of where the

225. Devin S. Schindler, *Pay for Performance, Quality of Care and the Revitalization of the False Claims Act*, 19 HEALTH MATRIX: J.L.-MED. 387, 403 (2009).

226. *Id.*

227. *Id.*

228. See Parmet, *supra* note 106, at 173.

229. See Buck, *supra* note 24, at 1288 (discussing the critique that Medicare reimbursement determinations are often inaccurate and distorted).

230. See Reed Abelson & Julie Creswell, *Hospital Chain Inquiry Cited Unnecessary Cardiac Work*, N.Y. TIMES (Aug. 6, 2012), <http://www.nytimes.com/2012/08/07/business/>

protections of informed consent can provide a powerful platform from which to bring an FCA case for a federal prosecutor. These cases would feature an argument that, with evidence of being subject to unnecessary and nonbeneficial care, something about the informed consent that was achieved was deficient, giving the DOJ a second potential pathway to liability.

Hampered by an unaddressed knowledge deficit, many of the patients treated at King's Daughters,²³¹ the North Ohio Heart Center,²³² Saint Joseph Hospital London,²³³ or any of the Hospital Corporation of America ("HCA") hospitals under review,²³⁴ may not have known that the stents and other cardiac procedures they received were allegedly unnecessary. For example, these patients at both King's Daughters and Saint Joseph would not have known that these entities were performing cardiac procedures on patients who allegedly "did not need them,"²³⁵ nor would these patients know that the amount of stent placements in a suburb of Cleveland was allegedly many multiples higher than the national average.²³⁶ For HCA's Bayonet Point Hospital patients, the simple fact that allegedly "as many as 43 percent of the 355 angioplasty cases . . . were outside reasonable and expected medical practice"²³⁷—or that Bayonet Point allegedly administered angioplasty to patients whose blockages ranged from 33% to 53%, when typ-

hospital-chain-internal-reports-found-dubious-cardiac-work.html?pagewanted=all&r=0; *EMH Regional Medical Center and North Ohio Heart Center to Pay \$4.4 Million to Resolve False Claims Act Allegations*, DEP'T JUST. (Jan. 4, 2013), <http://www.justice.gov/usao/ohn/news/2013/04janemh.html> [hereinafter *EMH Regional Medical Center*]; *King's Daughters Medical Center to Pay Nearly \$41 Million to Resolve Allegations of False Billing for Unnecessary Cardiac Procedures and Kickbacks*, DEP'T JUST. (May 28, 2014), <http://www.justice.gov/opa/pr/king-s-daughters-medical-center-pay-nearly-41-million-resolve-allegations-false-billing> [hereinafter *King's Daughters Medical Center*]; *Saint Joseph London Hospital to Pay \$16.5 Million to Settle False Claims Act Allegations of Unnecessary Heart Procedures*, DEP'T JUST. (Jan. 28, 2014), <http://www.justice.gov/usao/kye/news/2014/2014-01-28-sjhlondon.html> [hereinafter *Saint Joseph London Hospital*].

231. See *King's Daughters Medical Center*, *supra* note 230.

232. See *EMH Regional Medical Center*, *supra* note 230.

233. See *Saint Joseph London Hospital*, *supra* note 230.

234. See Abelson & Creswell, *supra* note 230; see also Maria Armental, *HCA Discloses Suit Alleging Unnecessary Procedures, False Billing Claims*, WALL ST. J. (Feb. 26, 2015, 8:26 PM), <http://www.wsj.com/articles/hca-discloses-suit-alleging-unnecessary-procedures-false-billing-claims-1425000382> (noting that HCA has recently disclosed a lawsuit has been filed based upon the medical necessity of its cardiology procedures and that the "federal investigation continues").

235. *King's Daughters Medical Center*, *supra* note 230; *Saint Joseph London Hospital*, *supra* note 230.

236. See Abelson, *supra* note 44.

237. Abelson & Creswell, *supra* note 230.

ically cardiologists “do not operate on any blockage less than 70 percent”²³⁸—would seem to be important facts that may have been unknown by patients.

On top of this, patients likely lacked information that stent placements were no better than cheaper, less invasive therapies in preventing heart attacks in patients with stable coronary artery disease.²³⁹ Indeed, it is fair to assume that beyond the chest pains, the patients entering these institutions may have entered into the clinic without extensive knowledge as to what treatment was most clinically appropriate for their condition. As to the investigation where concrete facts exist—evidence of allegedly unnecessary procedures—an allegation of FCA liability based on deficient informed consent is not only intuitive, but seemingly demanded.²⁴⁰

Specifically, it seems reasonable to assume that a percentage of those patients—how many exactly remains unknown—would *not* have consented to undergoing a stent implantation or other cardiac procedure had they been aware of the comparative information referenced above. Had the patients either known that these entities were allegedly performing unnecessary cardiac procedures, or had the patients simply had access to comparative data (particularly that one of the institutions allegedly placed stents at four times the national rate²⁴¹), then the consent those patients granted may not have been as clearly forthcoming. As a result, the consent the providers allegedly received in cases like these had to be at least partly deficient—had they provided reasonable alternatives, including the option of doing nothing, then a discernable subset of patients surely would have declined the procedures. Aside from the allegation that these cardiac procedures were unnecessary, the prosecutors could argue that the patients did not receive enough information to make an informed decision.

In fact, for those patients, the provider’s disclosure may have been insufficient; for many clinically borderline cases, it may be that the provider failed to present all treatment alternatives—including, of course, the option of *doing nothing*. And had these hospitals been forced to (1) divulge information to prospective patients that included statistics on the comparative rate of stent placement,

238. *Id.*

239. See Anahad O’Connor, *Heart Stents Still Overused, Experts Say*, N.Y. TIMES (Aug. 15, 2013, 6:00 AM), http://well.blogs.nytimes.com/2013/08/15/heart-stents-continue-to-be-overused/?_r=0.

240. Abelson & Creswell, *supra* note 230.

241. See Abelson, *supra* note 44.

(2) present the reasonable alternative of adopting a “wait and see” approach, or (3) encourage them to get a second opinion, these patients may not have elected to undergo the surgery.²⁴²

Imagine that the doctrine of informed consent—here loosely termed “extended” informed consent—required the provider to disclose information that stents or other interventions may *not* be as effective as initially thought. This could include comparative data—like evidence focused on the North Ohio Heart Center (“NOHC”) and that it allegedly outpaced the Ohio and national averages of stent placement by multiples.²⁴³ Under an extended informed consent duty, the physician would be required to disclose this information to the prospective patient—or risk a DOJ investigation.

It is plausible—perhaps probable—that a number of those patients, when informed that cardiologists at NOHC allegedly exceeded the national stent placement average,²⁴⁴ would decline intervention or, perhaps, seek a second opinion from another provider. Of those who sought a second opinion, it would be fair to assume that a number of these patients may end up not undergoing a stent placement after being told of the potential risks, alternatives, and nonbeneficial clinical nature that accompanies stent placement.²⁴⁵ That many stents are overused—and that, for many patients, placing a stent allegedly came with more risks than simply doing nothing—may have been a convincing argument for the typical American patient.²⁴⁶

And although the taxpayers who footed the bill for these allegedly unnecessary stent placements were harmed, the key achievement of these arguments would be the deterrent value they secure; providers

242. Part of the unknowable problem here is how many patients—even with the information at their disposal—would still have elected for the surgery. However, given the information gleaned from studies focused on patients at the end of life, it is reasonable to assume that, when fully informed, a number of patients may not elect to undergo therapies. See *supra* notes 134-50 and accompanying text; see also Eisler & Hansen, *supra* note 13 (“A 1997 study in the *Journal of the American College of Surgeons* looked at 5,601 patients recommended for surgery and found that second opinions found no need for the operation in 9% of the cases. Among those who got the countervailing second opinion, 62% opted not to have the operation.”).

243. See Abelson, *supra* note 44.

244. The providers at NOHC not only exceeded the national average by four times, but exceeded the state average by three times. See *id.*

245. See Eisler & Hansen, *supra* note 13.

246. See Abelson, *supra* note 44.

in the future, when faced with burgeoning fraud-based arguments for failures to achieve extended informed consent, will be more cognizant of what they must disclose to the prospective patient.

C. *Challenges Associated with Proof*

Besides the potential legal challenges that face the informed consent-based regulatory regime, this theory would also need to overcome two practical challenges. This includes demonstrating important assumptions that (1) patients truly desire less care, and (2) that reasonable alternatives—including the possibility of doing nothing—are both knowable and known by providers. Assuming both of these factors are met, the application of this new theory seems quite beneficial. Again, the problems associated with proof regarding whether informed consent was achieved are not the focus of this analysis.

First, this legal argument relies on an assumption that fully informed patients—that is, patients told of comparative utilization data, treatment patterns, as well as alternative therapies and, in many instances, the viable option of doing *nothing*—will choose *less* care. For the federal government to allege that overtreatment administered is due to a failure of informed consent, and then allege that the failure of informed consent has actually translated the care at issue into fraudulent care, the government needs to be able to demonstrate that the lack of informed consent actually led to the administration of the care. Had the alternate occurred—that is, would the patient have still chosen the nonbeneficial care even when presented with all the disclosures required under the new extended informed consent requirements, then the theory of liability loses all of its power.²⁴⁷ And there

247. These scenarios should be at least anomalous, if not exceptionally rare. Whether or not patients can avail themselves of a nonbeneficial procedure raises a host of important questions beyond the scope of this analysis.

may be a reason to fear that even patients presented with additional and helpful information may not access the information to make more rational health care choices.²⁴⁸

However, for cases like those featuring the allegedly unnecessary cardiac procedures summarized above,²⁴⁹ allegations of deficient informed consent seem eminently supportable; without adequate information regarding the lack of medical necessity of a certain procedure, the patient cannot possibly evince adequate informed consent. Where a hospital's physician is performing angioplasties for which 76% of the procedures, after an outside review, may indicate "unwarranted cardiac catheterizations and . . . needless[] . . . multiple procedures,"²⁵⁰ this assumption—that patients do not want to be subjected to unnecessary cardiac procedures—seems unequivocally reasonable—and, perhaps, legally protectable. At the least, taxpayers should not be paying for these allegedly unnecessary stents—again, not necessarily because they did or did not comply with Medicare's reimbursement standards, but because the patients who were operated on did not adequately consent to the procedures.

A second assumption that this legal strain is dependent upon is the assumption that this data is knowable and known by providers. Indeed, for providers to be required to disclose clinically reasonable alternatives—particularly, to be aware of the overtreatment for which each provider himself is responsible—increased data sharing must occur.²⁵¹ Again, for the most egregious cases, this data is not easy for patients to attain; as early as 2004, an internal memorandum at HCA allegedly highlighted

248. To this point, even when made available to them, American patients do not review cost and quality data. See CATALYST FOR PAYMENT REFORM, THE STATE OF THE ART OF PRICE TRANSPARENCY TOOLS AND SOLUTIONS 5 (2013), <http://www.catalyzepaymentreform.org/images/documents/stateoftheart.pdf>. According to PricewaterhouseCoopers, "31 percent of U.S. consumers reported reading online reviews of doctors." *Id.* A separate study found that where 98% of health insurance plans provide a cost calculator tool, only 2% of patients use them. *Id.* Beyond the concerns associated with a failure to pay attention to the costs of a given procedure, however, patients may not pay attention to the risks and lack of benefits associated with a procedure. The "better safe than sorry" patient may not actually care about the potential health risks—and simple nuisance—that come with unnecessary medical services.

249. See *supra* note 230 and accompanying text.

250. Abelson & Creswell, *supra* note 230.

251. See Buck, *supra* note 24, at 1283-89 (noting the importance of increased data sharing to providers for new enforcement techniques under the FCA).

the fact that a substantial percentage of angioplasty procedures performed at Bayonet Point were not supported by foregoing medical practice standards.²⁵² But the hospital did not disclose this fact to patients.²⁵³

As a general matter, placing the burden on the profession itself—that is, requiring it to be aware of the amount each provider is exceeding the general clinical standard—may not be a costly or negative development. In a modern health care delivery system that features so much unnecessary care, perhaps it is time for the providers to have general practice patterns impacted. At the very least, these data should influence the amount of information they disclose to a patient who is considering a health procedure.

VI. CONCLUSION

While the current legal pathway may be unclear, a theory of liability under the FCA based upon a lack of informed consent could serve as an important and plausible legal construct in the fight against overtreatment. Over the years, a number of solutions have been attempted to limit or reduce the incentives that are cemented into the reimbursement structure, but American patients still undergo a stunning amount of unnecessary services and are subject to a startling amount of overtreatment each year. The distaste of this reality is made all the more surprising when surveys demonstrate that the majority of Americans do not *want* these services, to say nothing of the financial consequences and risk of harm involved.

This analysis lays the groundwork for an informed consent-based claim under the FCA, recognizing the potential current challenges that would exist in bringing one forward. However, the proposal has an intuitive attractiveness to it, largely because it seeks to align the universally supported ideal of robust informed consent with the financial necessity of limiting overtreatment. Indeed, this solution does not depend on government-determined medical necessity conclusions, a federal prosecutor's conception of good medical care, or a third-party payer or HMO's desire to increase profits. Basing an enforcement mechanism on informed consent—the ultimate patient-protective doctrine—is attractive because it places the American patient at the center of its application while seeking to do two important things: to protect both that patient from unwanted medical care and to protect the American taxpayer from the costly problem of overtreatment.

252. See Abelson & Creswell, *supra* note 230.

253. See *id.*