Caring Too Much: Misapplying the False Claims Act to Target Overtreatment

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As the costs of health-care administration and delivery continue to grow, health-care fraud enforcement actions have increased in number and severity, and, with the recently upheld Patient Protection and Affordable Care Act adding more than $350 million over the next ten years to fight health-care fraud, they will likely continue to do so. Continuing a strategy it has used for decades, the federal government is relying mainly on the False Claims Act (FCA), an age-old statute with blunt penalties, to levy remarkable fines against providers in an ever-expanding net of enforcement. But recent examples indicate that the government is applying the FCA to scenarios in which its application seems unwarranted. Namely, the government is now increasingly wielding the FCA against "overtreatment"—defined as cases in which a provider has allegedly provided "too much" care in an inefficient, overly expensive, or unnecessary way—presumably to address the looming fiscal crisis. Exemplified by the Department of Justice's ongoing implantable cardioverter defibrillator investigation, the federal government is seeking to regulate overtreatment through application of its powerful anti-fraud statute.

Even though health-care waste and abuse undeniably plague American health care, this Article argues that the government's solution of applying the FCA against providers who engage in overtreatment is doctrinally unsatisfying and practically destructive. The overreliance on "data mining," a desire to freeze vague and developing practice standards, and the FCA's overwhelming penalties that precipitate immediate settlement make up the key components of this overtreatment enforcement model. This results in cascading settlements, allowing the government to unilaterally change developing medical practice standards with little clinical input or judicial review in what can be called "backdoor rationing." Further, these anti-fraud initiatives often impact the wrong providers and can stifle innovation.

This analysis provides an in-depth critique of this new development in health-care fraud enforcement in an effort to decouple conventional health-care fraud cases from overtreatment investigations. Ideally, this piece will start the conversation toward an improved and more legitimate enforcement framework. At bottom, it illustrates the doctrinal and practical problems that will likely continue to exist at the complex intersection of medical necessity, health-care financing, and fraud—even as the administration of America's health care undergoes radical change.

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I. INTRODUCTION

In America in 2013, being tough on health-care fraud is in vogue. CNBC airs *Health Care Hustle*, a one-hour documentary that tracks white-collar criminals in Puerto Rico and South Beach who defraud Medicare and Medicaid by falsifying medical records, follows a crooked pharmacist in the middle of the country, who—unbeknownst to his bosses—forges prescriptions and keeps the profits, and visits officers of the U.S. government's special taskforce while its members prepare for their next raid by practicing at a firing range.[1] President Obama's Department of Justice (DOJ) publishes press releases praising its successful pharmaceutical settlements[2] and arrests of fraudsters[3] as it protects

[1] *See* Scott Cohn, *Health Care Hustle*, CNBC INVESTIGATIONS, INC. (May 2, 2012), http://www.cnbc.com/id/46824701/.

[2] *See, e.g.*, Press Release, U.S. Dep't of Justice, Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-Label Promotion of Depakote (May 7, 2012), *available at* http://www.justice.gov/opa/pr/2012/May/12-civ-585.html (publicizing a guilty plea by Abbott Laboratories Inc. for off-label marketing).

[3] *See, e.g.*, Press Release, U.S. Dep't of Health & Human Servs., Medicare Fraud Strike Force Charges 107 Individuals for Approximately $452 Million in False Billing (May 2, 2012), *available at* http://www.hhs.gov/news/press/2012pres/05/20120502b.html

taxpayers. Even citizens are now on the front lines of the war on health-care fraud: CBS News' website tells Americans how to report, prevent, and learn more about fraud affecting the federal health-care programs of Medicare and Medicaid.[4]

All of the attention is warranted, and the government's intense focus on health-care fraud has made a difference in protecting American taxpayers.[5] Indeed, it is clear that health-care fraud is an undeniable drain on the system and accounts for a good percentage of overall health-care expenditures; in fact, some estimate that health-care fraud is costing America as much as $100 billion annually.[6] By addressing fraud that is undoubtedly rampant, the government seeks to offset ever-ballooning health-care costs.[7] This includes examples in which an individual games the system by prescribing drugs or devices to a fictional beneficiary, a pharmaceutical company knowingly violates the FDA marketing laws in order to increase profits, or a career criminal opens a faux medical device company to siphon money from Medicare or Medicaid. This Article refers to these scenarios as "conventional" health-care fraud; other authors have referred to similar examples as "traditional" fraud.[8]

But there is a larger problem affecting American health care. It is the problem that I—and others including author Shannon Brownlee—refer to as

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(documenting Medicare Fraud Strike Force investigations that resulted in charges against 107 people in a "nationwide takedown").

[4] *See* Melissa McNamara, *Preventing Health Care Fraud*, CBS NEWS (Jan. 8, 2010, 9:33 AM), http://www.cbsnews.com/2100-500823_162-2067346.html (offering tips on the definition of health care fraud, reporting procedures, and suggestions for prevention).

[5] The numbers of health care fraud cases opened under President Obama have skyrocketed. *See* Bernice Yeung, *S. Calif. Lab, Radiology Company Accused of Health Care Fraud*, CAL. WATCH (June 18, 2012), http://californiawatch.org/dailyreport/s-calif-lab-radiology-company-accused-health-care-fraud-16517. In 2001, DOJ opened 211 FCA cases, in 2008, the number rose to 291, and in 2011, it was 454. *Id.*

[6] *See* Parija Kavilanz, *Health Care: A 'Goldmine' for Fraudsters*, CNNMONEY (Jan. 13, 2010, 3:07 PM), http://money.cnn.com/2010/01/13/news/economy/health_care_fraud/; Merrill Matthews, *Medicare and Medicaid Fraud Is Costing Taxpayers Billions*, FORBES (May 31, 2012, 3:08 PM), http://www.forbes.com/sites/merrillmatthews/2012/05/31/medicare-and-medicaid-fraud-is-costing-taxpayers-billions/2/ (noting that "others, including U.S. Attorney General Eric Holder, suggest that there is an estimated $60 to $90 billion in fraud in Medicare and a similar amount for Medicaid"); Michael Winter, *Feds Charge 107 with Defrauding Medicare of $452M*, USA TODAY (May 2, 2012, 11:00 PM), http://content.usatoday.com/communities/ondeadline/post/2012/05/feds-charge-107-with-defrauding-medicare-of-450-million/1# (noting that "Medicare fraud costs taxpayers an estimated $60 billion to $90 billion each year").

[7] Nevertheless, in fiscal years 2009 and 2010, health care spending slowed, growing more slowly than it has in fifty years, with early signs from fiscal year 2011 pointing the same way. *See* Ricardo Alonso-Zaldivar, *A Welcome Let-up in Health Costs That May Not Last*, YAHOO! NEWS (June 18, 2012), http://news.yahoo.com/welcome-let-health-costs-may-not-last-065238757--finance.html.

[8] *See, e.g.*, Joan H. Krause, *"Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1372 (2002).

overtreatment.[9] Overtreatment is best illustrated by scenarios in which a provider allegedly administers inefficient, comparatively too expensive, or unnecessary care to a patient. This may include performing an inpatient surgery when it arguably should have been performed on an outpatient basis,[10] ordering a CT scan instead of trusting clinical judgment when the physician thinks, but is not sure, that the patient does *not* have appendicitis,[11] or prescribing brand-name drugs for a patient's high cholesterol instead of the trusted generic because of the doctor's belief that the generic is not as effective.[12] Ironically, even though many Americans demand *more* care from their doctors, the practice of overtreatment is harmful to patients.[13]

Wasteful care is a major concern. In a recent survey, physicians noted that $6.8 billion dollars are wasted annually on twelve commonly used, but unnecessary, clinical tests.[14] The American College of Physicians has placed the overall estimate of overtreatment far higher—estimating that as much as $250 billion is wasted annually on all excessive testing and treatment.[15] Still others have estimated that as much as $700 billion—fully one-third of all health-care expenditures in this country—is wasted on unnecessary or unneeded medical services.[16] The Institute of Medicine puts its estimate at $765 billion—$210 billion due to unnecessary services, $130 billion due to inefficiently

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[9] SHANNON BROWNLEE, OVERTREATED: WHY TOO MUCH MEDICINE IS MAKING US SICKER AND POORER 6 (2007).

[10] *See* discussion *infra* Part VI.A.

[11] *See* BROWNLEE, *supra* note 9, at 150–53 (describing how the availability of clinical imaging contributes to unnecessary tests).

[12] *See* Michelle Andrews, *Doctors Estimate $6.8 Billion in Unnecessary Medical Tests*, WASH. POST (Oct. 31, 2011), http://www.washingtonpost.com/national/health-science/doctors-estimate-68-billion-in-unnecessary-medical-tests/2011/10/28/gIQANpEXZM_story.html.

[13] *See* BROWNLEE, *supra* note 9, at 152 (noting that "a CT scan . . . is only one piece of information—and a potentially misleading one at that—which can fail to add much to a careful clinical exam"); *see also* Maxwell J. Mehlman, *Dishonest Medical Mistakes*, 59 VAND. L. REV. 1137, 1138 n.4 (2006) ("Patients also can be harmed when doctors provide too much care."); Kieke G.H. Okma, *Health Care Systems in Transition: An International Perspective*, 25 J. HEALTH POL. POL'Y & L. 1178, 1182 (2000) ("[G]ood access to health care is essential, but too much intervention can be harmful and costly.").

[14] Andrews, *supra* note 12 ("The activity most frequently performed without need was a complete blood cell count at a routine physical exam. In 56[%] of routine physicals, doctors inappropriately ordered such tests, accounting for $32.7 million in unnecessary costs.").

[15] Press Release, MedSolutions, MedSolutions Responds to Choosing Wisely Campaign, Which Highlights Unnecessary Tests and Procedures (Apr. 5, 2012), *available at* http://www.reuters.com/article/2012/04/05/idUS162843+05-Apr-2012+BW20120405.

[16] BROWNLEE, *supra* note 9, at 5 ("We spend between one fifth and one third of our health care dollars, . . . between five hundred and seven hundred billion dollars . . . , on care that does nothing to improve our health."); *see also id.* at 37 (noting that as much as 30% of "medical care that is paid for by Medicare as well as private insurers is useless, unneeded, a waste—a figure that has been arrived at independently by other researchers").

delivered services, $105 billion due to inflated prices, and (only) $75 billion due to conventional health-care fraud.[17] Whatever the actual number, much of the overtreatment is characterized by different "tests, procedures, and drugs" whose utility is largely dependent on the doctor's discretion.[18] As a result, there are no guidelines against their use in certain situations because "there are no hard-and-fast rules about when to use them."[19]

The unsettling numbers have prompted providers to act. Spurred by Howard Brody's provocative challenge to each subspecialty society to find "that specialty's 'Top Five' list"—five of that specialty's commonly used procedures that are often clinically unnecessary and are highly expensive[20]—nine specialty societies provided a list of forty-five tests and procedures that should be curbed.[21] Compiled "after months of analyses and reviews of the medical literature by expert committees,"[22] these lists include stress tests during yearly checkups for asymptomatic cardiac patients, antibiotics for most sinus infections, universal and routine chest x-rays before surgery, two or more colonoscopies within ten years of each other, and x-rays for non-serious low back pain.[23]

Different from the doctor-driven effort, the federal government—mainly through its attorneys at DOJ—has sought to curtail overtreatment through investigations, threatened enforcement actions, and settlements with providers.[24] Specifically, the agencies tasked with overseeing the federal health-care programs—Health and Human Services (HHS), the Office of Inspector

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[17] *The Cost of Health Care: How Much Is Waste?*, INST. MED. 1, http://iom.edu/Reports/2011/~/media/Files/widget/VSRT/healthcare-waste.swf (noting that, between 1999 and 2009, the average U.S. salary increased 38%, while health care premiums increased 131%).

[18] *See* BROWNLEE, *supra* note 9, at 60.

[19] *Id.*

[20] Howard Brody, *Medicine's Ethical Responsibility for Health Care Reform—The Top Five List*, 362 NEW ENG. J. MED., Jan. 28, 2010, at 284 (positing that each subspecialty should come up with the specialty's "Top Five" list, which "would consist of five diagnostic tests or treatments that are very commonly ordered by members of that specialty, that are among the most expensive services provided, and that have been shown by the current available evidence not to provide any meaningful benefit to at least some major categories of patients for whom they are commonly ordered").

[21] Roni Caryn Rabin, *Doctor Panels Recommend Fewer Tests for Patients*, N.Y. TIMES, Apr. 4, 2012, at A10 (additionally, "[e]ight other specialty boards are preparing to follow suit with additional lists of procedures their members should perform far less often").

[22] Editorial, *Do You Need That Test?: Doctors' Groups Make Pioneering Lists of Unnecessary Tests and Treatments*, N.Y. TIMES, Apr. 9, 2012, http://www.nytimes.com/2012/04/09/opinion/do-you-really-need-that-medical-test.html.

[23] Brian Vastag, *Doctors Groups Call for End to Unnecessary Procedures*, WASH. POST (Apr. 4, 2012, 12:32 PM), http://www.washingtonpost.com/blogs/the-checkup/post/doctors-groups-call-for-end-to-unnecessary-procedures/2012/04/03/gIQAvrDptS_blog.html. Other unnecessary tests included CT scans—both for appendicitis in children and for patients who have experienced recent fainting. *Do You Need That Test?*, *supra* note 22.

[24] *See* discussion *infra* Parts V, VI.B.2 and accompanying notes.

General (OIG), and the enforcement mechanisms at DOJ—are increasingly using the tools traditionally reserved for the worst of the health-care fraudsters against providers who have plainly administered too much care.[25] As a result, doctors who "do too much" may now be the target of civil False Claims Act[26] (FCA) investigations,[27] a practice that is likely to continue due to the undeniably good return on investment for the government.[28]

But daunting problems accompany this approach. Besides being a temporary, piecemeal solution to the structural problems of overtreatment, three components of this strategy combine to raise questions about its overall legitimacy. First, in overtreatment enforcement actions, DOJ overly relies on a process called "data mining," in which it searches for "outlier" providers and statistical anomalies.[29] Doctors who administer procedures differently from the majority quickly catch the attention of the government attorneys. Second, through these cases, DOJ is attempting to set medical practice standards for often new, highly complex, and contested areas of practice—areas of practice in which the standard is still developing—with little or no clinical input.[30] The line between what is "fraudulent" and what is medically appropriate is difficult to discern, especially because it is unsettled or in flux. Third, DOJ relies upon this powerful weapon to compel quick settlements, no matter whether any actual wrongdoing occurred. Because of the overwhelming statutory penalties built into the FCA and other threatened administrative penalties that can "exclude" providers from participation in the federal health-care programs,[31] no provider is willing to take the risk of fighting the allegations to trial.

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[25] *See id.*

[26] 31 U.S.C. § 3729(a) (2006).

[27] Richard Doan argues that the scienter standard within the FCA is "eroding" due to government overuse. Richard Doan, *The False Claims Act and the Eroding Scienter in Healthcare Fraud Litigation*, 20 ANNALS HEALTH L. 49, 50 (2011). The treatment of the new cases of overtreatment provide perhaps the most radical example of how the FCA has been stretched to apply to many activities that may not be fairly characterized as "fraudulent."

[28] Although most peg the return on investment at $7-to-$1, some note that the government may make as much as $15 for each $1 it spends on anti-fraud enforcement efforts. *See* Katie Thomas & Michael S. Schmidt, *Drug Firm Guilty in Criminal Case, Glaxo Agrees To Pay $3 Billion in Fraud Settlement*, N.Y. TIMES, July 3, 2012, http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html?; *see also* Doan, *supra* note 27, at 58–59 ("These gains serve to encourage the expansion of enforcement actions as well as the scope of anti-fraud laws.").

[29] *See* Robert Radick, *Claims Data and Health Care Fraud: The Controversy Continues*, FORBES (Sept. 25, 2012, 11:50 AM), http://www.forbes.com/sites/insider/2012/09/25/claims-data-and-health-care-fraud-the-controversy-continues/ ("Data mining techniques and investigations that stem from billing anomalies have been the bread and butter of the federal government's Medicare Fraud Strike Force.").

[30] *See* discussion *infra* Part VI.B and accompanying notes.

[31] *See* 42 U.S.C. § 1320a-7 (2010) (delineating the requirements of both mandatory and permissive exclusions from the federal health care programs).

As a result, the problems created by the "coercive" FCA settlements articulated by Professor Joan Krause—specifically, that resulting FCA settlements comprise "an amorphous collection of quasi-legal guidance with no precedential value" and "an unofficial body of law comprised of legally untested theories of falsity and fraud"[32]—are exacerbated in the overtreatment context. Further, these three components—which are prominent features of DOJ's current overtreatment enforcement model—freeze the clinical practice standard, stifle innovation, and ultimately change providers' behavior without sufficiently consulting current clinical standards.

In this Article, I will examine America's overtreatment challenge while evaluating its newest solution of increasing the application of the FCA. To accomplish this task, Part II will present the problem by examining the American health-care system by the numbers, focusing particularly on its problem of compounding costs as a result of overtreatment. Part III will introduce the FCA, a potent weapon for any U.S. attorney fighting health-care fraud, and a weapon that the Obama administration has leaned on quite heavily in achieving headline-grabbing settlements with, and verdicts against, various health-care providers and companies. Part IV will review the modern application of the FCA to a relatively new class of cases, the "quality of care" cases. Part V will introduce and detail DOJ's ongoing implantable cardioverter defibrillator (ICD) investigation, a case study reflecting the current enforcement model. Finally, in Part VI, the application of the FCA to overtreatment will be critiqued, highlighting major problems associated with achieving enforcement in this way.

II. THE CURRENT PROGNOSIS

A. *The Crisis*

It has been a common refrain in 21st-century America: American health care—and in particular, government-paid-for health care (Medicaid and Medicare)—is broken.[33] As it creeps ever closer, Medicare insolvency is now

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[32] 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, 205–06 (2001).

[33] *See* Leslie Meltzer Henry & Maxwell L. Stearns, *Commerce Games and the Individual Mandate*, 100 GEO. L.J. 1117, 1123 (2012) ("During the 2008 Presidential primaries, candidates from both ends of the political spectrum agreed on one thing: The American health care system was broken and demanded urgent reform."); Andrew Koppelman, *Bad News for Mail Robbers: The Obvious Constitutionality of Health Care Reform*, 121 YALE L.J. ONLINE 1, 24 (Apr. 26, 2011), http://yalelawjournal.org/the-yale-law-journal-pocket-part/constitutional-law/bad-news-for-mail-robbers:-the-obvious-constitutionality-of-health-care-reform/ (noting that Congress "took on the spectacularly broken American system of health care delivery" through passage of the Affordable Care Act in 2010); Jonathan Mann, *Obama's Deadly Enemy Within*, CNN (May 15, 2009), http://articles.cnn.com/2009-05-15/politics/pm.obama.healthcare_1_healthcare-health-

twelve years away.[34] The nation's leaders constantly warn of the surely coming doom. "Leaving Medicare and Social Security on auto pilot and allowing them to continue to grow beyond their means is no longer an option," Senator Orrin Hatch (R-UT) said recently.[35] Senator Tom Coburn's (R-OK) 2011 op-ed in the *New York Post* was entitled, "Reform or Go Broke: Medicaid, Medicare Must Change."[36] The nation's leaders on the other side of the aisle agree, albeit in less pessimistic terms. "We can make Medicare solvent again. We don't have to gut it to make it last," Vice President Joseph Biden said early last year.[37] Of course, the refrain has been virtually unchanged for two decades: "[t]his health care system of ours is badly broken, and it is time to fix it," then-President Clinton declared in 1993.[38]

Nevertheless, not only are the federal health-care programs speeding toward bankruptcy, but the quality of U.S. health care is mediocre, the headlines say. "Healthcare in the United States is the most expensive in the world," newspapers scream, "but it's not the best."[39] A May 2012 piece in the *Atlantic* asks "What's the Matter with Health Care and Education?"[40] The article continues, "[i]t is well-known that when the total cost of the American health care system is divided by the size of our population, we have one of the most expensive health care systems in the world."[41] And when it comes to quality, "[t]he outcomes for the average client are just average in an international context, and the outcomes for those clients with scarce financial resources are comparable to the health outcomes for the citizens of third world countries," the

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insurance-system-obama-s-administration ("Our healthcare system is broken," President Obama noted four months after taking office.).

[34] *See* Noam N. Levey, *Social Security Is Slipping Closer to Insolvency*, L.A. TIMES (Apr. 24, 2012), http://articles.latimes.com/2012/apr/24/nation/la-na-medicare-report-20120424 ("Medicare, which will provide health insurance to more than 50 million elderly and disabled Americans this year, is expected to start operating in the red in its largest fund in 2024 . . . .").

[35] *Id.*

[36] Tom Coburn, *Reform or Go Broke: Medicaid, Medicare Must Change*, N.Y. POST (Apr. 6, 2011, 12:33 AM), http://www.nypost.com/p/news/opinion/opedcolumnists/reform_or_go_broke_AxZmLn5iEzaEZohOJPB23J.

[37] Curt Anderson, *Biden: GOP Changes Threaten Medicare for Millions*, CNS NEWS (Mar. 23, 2012), http://cnsnews.com/news/article/biden-gop-changes-threaten-medicare-millions.

[38] Catherine Rampell, *Bill Clinton on Health Care, 1993*, N.Y. TIMES, (Sept. 9, 2009, 6:59 PM), http://economix.blogs.nytimes.com/2009/09/09/bill-clinton-on-health-care-1993/.

[39] Tiffany Hsu, *U.S. Healthcare Costs the Most but Isn't the Best: Report*, L.A. TIMES (May 3, 2012, 12:41 PM), http://www.latimes.com/business/money/la-fi-mo-healthcare-costs-20120503,0,6063895.story.

[40] Marc Tucker, *American Dinosaurs: What's the Matter with Health Care and Education*, ATLANTIC (May 7, 2012, 10:21 AM), http://www.the atlantic.com/business/archive/2012/05/american-dinosaurs-whats-the-matter-with-health-care-and-education/256807/.

[41] *Id.*

article notes.[42] In 2011, HHS Secretary Kathleen Sebelius frankly noted that "[w]e pay 2 ½ times what anybody else pays in the world, and our care outcomes look like we're in a developing country."[43]

Unfortunately, much of the gloomy rhetoric is well-supported by data. A 2011 study by the Organisation for Economic Co-operation and Development (OECD)[44] concluded that the United States "spends two-and-a-half times more than the OECD average health expenditure per person," including "twice as much as France," amounting to 17.4% of its GDP in 2009.[45] This is "by far the highest share in the OECD."[46] This number is only expected to rise—in six years, health-care spending may increase to about 20% of America's GDP; by 2040, it is forecast to hit 34%.[47] According to the OECD, two factors contribute to the crisis: (1) health-care costs "substantially higher" in America than other countries, and (2) the United States provides *more* health care to its citizenry.[48] Most disappointingly, America's additional care does not result in better health. The study found life expectancy in the United States to be "below the OECD average" (78.2 years in the United States to 79.5 years as the OECD average).[49] America was also below average in "infant mortality and potential years of life lost."[50] The United States is particularly deficient in providing quality primary care, which results in frequent and expensive hospital admissions.[51]

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[42] *Id.*

[43] Sarah Kliff, *Kathleen Sebelius: Health Care Outcomes in U.S. Like 'a Developing Country'*, POLITICO (Mar. 31, 2011, 4:47 PM), http://www.politico.com/news/stories/0311/52339.html.

[44] OECD, or the Organisation for Economic Co-operation and Development, is made up of the following thirty-four countries: Australia, Austria, Belgium, Canada, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, and United States. *See* ORG. FOR ECON. CO-OPERATION & DEV., HEALTH AT A GLANCE 2011: OECD INDICATORS 20 (2011), *available at* http://www.oecd.org/els/health-systems/49105858.pdf.

[45] ORG. FOR ECON. CO-OPERATION & DEV., HEALTH AT A GLANCE 2011: OECD INDICATORS, WHY IS HEALTH SPENDING IN THE UNITED STATES SO HIGH? 1 (2011) [hereinafter U.S. HEALTH AT A GLANCE], *available at* http://www.oecd.org/unitedstates/49084355.pdf.

[46] ORG. FOR ECON. CO-OPERATION & DEV., HEALTH AT A GLANCE 2011: OECD INDICATORS, KEY FINDINGS: UNITED STATES (2011), *available at* http://www.oecd.org/dataoecd/12/58/49084319.pdf.

[47] *See* Peter J. Kalis & Judy Hlafcsak, *Healthcare Reform: Let's Act Locally*, 50 DUQ. L. REV. 253, 257 (2012) ("By 2018, healthcare spending is projected to rise to nearly $4.3 trillion, which is approximately 20% of GDP. This percentage is projected to reach 34% by 2040, if costs continue to grow at historic rates.").

[48] *See* U.S. HEALTH AT A GLANCE, *supra* note 45, at 4.

[49] *Id.* at 6.

[50] *Id.*

[51] *See id.* ("The United States performs well in some subsystems such as cancer care and treating acute conditions in hospitals, but does not perform well in primary care and in preventing costly hospital admissions for chronic conditions."); *see also* BROWNLEE, *supra*

The OECD study found that even though the United States has fewer practicing physicians, doctor consultations, hospital beds, hospital discharges, and average hospital stays than the OECD per capita average,[52] the United States "does do a lot of interventions," "has a lot of expensive diagnostic equipment, which it uses a lot," and "does a lot of elective surgery—the sort of activities where it is not always clear-cut about whether a particular intervention is necessary or not."[53] To this end, the United States performs double the rate of MRI exams (ranking second of thirty-four), nearly double the number of tonsillectomies (second), and more than double the number of coronary angioplasties (third), than the OECD average.[54]

Results of recent studies of physicians have echoed and furthered the OECD findings. According to a study published in the Archives of Internal Medicine, twelve commonly used and unnecessary treatments totaled $6.8 billion in 2009.[55] The unnecessary expense has two main sources: (1) prescription drugs and (2) services and care. More than 85% of the $6.8 billion figure was drug-related, blamed on physicians "ordering brand-name statins before trying patients on a generic drug first."[56] This represented $5.8 billion of the nearly $7 billion total.[57] In a second study of primary care physicians published in the Archives of Internal Medicine that relied on a national survey, 42% of doctors replied that their patients "were receiving too much medical care."[58] Twenty-eight percent responded that they were "ordering more tests and making more referrals to specialists than they would 'ideally like to be.'"[59]

Newer numbers from the American College of Physicians put the overall cost of excessive testing far higher—from between $200 to $250 billion per year.[60] This would constitute 7–9% of the overall $2.7 trillion health-care

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note 9, at 65 (noting that lack of primary care creates "barely controlled chaos of multiple caretakers," that "doesn't work well when there is no single individual, in particular no generalist, who's in charge of coordinating a patient's care").

[52] *See* U.S. HEALTH AT A GLANCE, *supra* note 45, at 5 (noting that the United States only has 2.4 physicians, 3.1 hospital beds, and 130.9 discharges per 1,000 population and its average hospital stay is 4.9 days).

[53] *Id.*

[54] *Id.*

[55] *See* Andrews, *supra* note 12 (documenting physician survey).

[56] *Id.*

[57] *See id.*

[58] Karen Kaplan, *Some Doctors Blame Themselves for Rising Healthcare Costs*, L.A. TIMES (Sept. 27, 2011), http://articles.latimes.com/2011/sep/27/news/la-heb-doctors-aggressive-medicine-20110927.

[59] *Id.*

[60] *See* Debra Sherman, *Stemming the Tide of Overtreatment in U.S. Healthcare*, REUTERS (Feb. 16, 2012, 3:55 PM), http://www.reuters.com/article/2012/02/16/us-overtreatment-idUSTRE81F0UF20120216 (Dr. Steven Weinberger of the American College of Physicians attributes the causes of the waste to "imaging studies, CT scans for lung disease, overuse of routine electrocardiograms and other cardiac tests such as stress testing.").

budget in 2011.[61] Others put the total cost of waste still higher—MIT health-care economist Dr. Jonathan Gruber estimates that about $800 billion—or one-third of the overall health-care budget—is wasted on unnecessary care.[62] By way of example, in order to effectively screen for and prevent colorectal cancer, the CDC recommends one of three tests—a colonoscopy every ten years, a flexible sigmoidoscopy every five years, or a stool test annually.[63] Even though the stool test costs $10 and the colonoscopy costs $3,000, the colonoscopy is the test most frequently used.[64] An examination into why American providers order more tests and administer more care—a phenomenon which undeniably affects the cost of health care and the viability of federal health-care programs in this country—follows.

B. *Why "More?"*

This phenomenon—that American providers administer more care than any other OECD country—may be best attributed to four interrelated factors: (1) the financial incentives that exist for providers to do more, and the absence of cost pressures that would influence patient behavior; (2) the inefficient and uncoordinated structure of the delivery of American health care; (3) the effect of technology and supply on the practice of medicine; and (4) the demands of patients themselves, which can lead to the practice of defensive medicine.

1. *Financial Incentives*

First, and most importantly, incentives exist on both sides of the hospital bed that contribute to overtreatment. As Professor David Orentlicher has recently noted, "structural features . . . foster the high prices and high volumes that characterize American health care."[65] Patients "have too great an incentive to seek care" due to the fact that insurance will cover and obscure much of the cost of a health-care procedure:[66] This is known as "moral hazard."[67] Because

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[61] *See National Health Expenditures 2011 Highlights*, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf (last visited Apr. 20, 2013) (noting that Medicare spending in 2011 was $554.3 billion, and Medicaid spending totaled $407.7 billion).

[62] *See* Sherman, *supra* note 60 (Gruber blames "unnecessary diagnostic tests, procedures and extra days in the hospital" for his nearly $800 billion total in health care waste).

[63] *See id.*

[64] *See id.*

[65] David Orentlicher, *Cost Containment and the Patient Protection and Affordable Care Act*, 6 FLA. INT'L U. L. REV. 67, 71 (2010).

[66] *Id.*

[67] *See* Charles P. Litchfield, Note, *Taxing Youth: Health Care Reform Writes a Costly Prescription That Leaves the Young and Healthy Paying the Bill*, 85 S. CAL. L. REV. 353,

consumer-patients have little conception of the cost other than the copay for which they are responsible, there is no incentive to limit consumption or shop for the best cost.[68] In fact, not only are patient-consumers unaware of and uninterested in the cost of medical procedures, but others have pointed out that having insurance actually encourages detrimental behavior. Indeed, "insurance both caus[es] people to overuse medical care and [causes] them to take risks they might have avoided had they been uninsured."[69]

Additionally, physicians are not incentivized to make cost-effective treatment decisions. Physicians and other providers who enjoy a fee-for-service reimbursement method "are paid more for doing more."[70] Doctors with higher utilization of tests and procedures enjoy greater reimbursement.[71] As Professor Orentlicher notes, inversely, "[w]hen physicians are paid a salary, they are less likely to order lab tests, request radiologic scans or perform surgeries."[72]

As a result, as Brownlee points out, the system fails to reward hospitals and physicians "for keeping patients safe[,] . . . coordinating their care[, or] for retaining the right mix of specialists and primary care physicians."[73] Instead, "physicians and hospitals are paid, by and large, to do more, and distortions in what gets reimbursed most richly have ensured that the simplest, most effective care often falls through the cracks in favor of more-invasive, complicated treatment."[74] Americans continue to pay for expensive acute care, instead of inexpensive preventative care.[75]

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361 (2012) (noting that insurance coverage gives individuals a "decreased incentive to avoid losses that are covered . . . [creating] the problem of moral hazard").

[68] *See* Orentlicher, *supra* note 65, at 71.

[69] Allison K. Hoffman, *Three Models of Health Insurance: The Conceptual Pluralism of the Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1873, 1892 (2011); *see also* Litchfield, *supra* note 67, at 361–62 ("Generally, moral hazard refers to the natural human inclination to engage in immoral, risky, or inappropriate behavior because there is ultimately no negative consequence. Theoretically, moral hazard manifests in health insurance in two ways: (1) benefits that cover certain preventable hearth risks decrease the incentive to avoid such risks; and (2) excessive benefits encourage overutilization and expensive care choices because people generally will try to get the most value out of their insurance benefits, even if it means choosing a less efficient treatment option." (citations omitted)).

[70] Orentlicher, *supra* note 65, at 71.

[71] *See* Kalis & Hlafcsak, *supra* note 47, at 258 ("Perhaps most notably, our payment system rewards medical utilization—we pay for procedures and tests. . . . Physicians only remain in business if they are treating and testing patients.").

[72] Orentlicher, *supra* note 65, at 72.

[73] BROWNLEE, *supra* note 9, at 70.

[74] *Id.*

[75] *See id.*; Kalis & Hlafcsak, *supra* note 47, at 258 ("We pay for acute episodic care, rather than paying for outcomes, prevention, and wellness.").

2. *Fragmentation*

Second, the American health-care system is not well-configured for optimum efficiency. Rather, it is fragmented, with a lack of communication and collaboration among providers.[76] In a recent survey, 40% of physicians reported that "they didn't get to spend enough time with their patients to figure out what is really wrong with them, so they ordered tests and consultations to provide some of the answers."[77] Instead of collaboration, there is suspicion among providers: 61% of the primary care physicians believed subspecialists provided too much care, and 62% noted that subspecialists "would cut back on testing in the absence of a financial incentive."[78]

According to economist Alain Enthoven, such "systemic fragmentation is difficult to dislodge" because it is "steeped in the history and culture of medicine and is embedded population-wide in the current system—operationally, financially, and in the clinic."[79] By "revering physician autonomy and infallibility," medical training focuses on "individual rather than team performance."[80] As a result, "physicians tend to practice as individuals."[81] The aging populace and technological advances—which result in a need for increased numbers of specialists—have also contributed to the crisis. As Dr. Enthoven notes,

> The accelerating advances and complexity of modern healthcare have driven greater specialization and a "silo approach" to healthcare consistent with the described isolationist history and professional culture. Yet, in recent years, increasingly prevalent chronic, often comorbid conditions ([e.g.,] diabetes, heart failure, depression) require that patients receive care from multiple providers in multiple settings. Although intensified specialization sought to generate greater interdependence among clinicians and the need for cross-silo coordination, greater specialization has exacerbated fragmentation by increasing the number of narrowly trained specialists.[82]

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[76] *See* Kalis & Hlafcsak, *supra* note 47, at 259.

[77] Kaplan, *supra* note 58.

[78] *Id.*

[79] Alain C. Enthoven, *Integrated Delivery Systems: The Cure for Fragmentation*, 15 AM. J. MANAG. CARE S284, S284 (2009), *available at* http://www.ajmc.com/publications/supplement/2009/a264_09dec_hlthpolicycvrone/a264_09dec_enthovens284to290/1 (last visited Aug. 3, 2012).

[80] *Id.*

[81] *Id.*; *see also* BROWNLEE, *supra* note 9, at 9 ("We've never structured the delivery system to ensure that patients get all of the treatments and procedures they need and aren't subjected to care they don't.").

[82] Enthoven, *supra* note 79, at S285.

The shortage of primary care physicians (the United States is expected to experience a 63,000 shortage of primary care physicians in 2015)[83] results in a lack of coordination of care. Instead, "[o]ne doctor often doesn't know that another physician has already ordered a battery of tests, or that they have both prescribed two different drugs that do the same thing."[84]

3. *Technology and Supply-Driven Demand*

Perhaps surprisingly, America's state-of-the-art equipment and its technological breakthroughs also contribute to health-care waste. This cause comprises two highly related factors. First, technological advances—of which the United States enjoys many—drive up the prices of services, and second, when hospitals and clinics acquire new machinery and cutting-edge equipment, utilization of the more expensive services, predictably, rises.

Unlike many other industries,[85] technological innovation in health care actually drives prices *higher*—resulting in "technology-driven cost inflation."[86] There are a number of reasons for this phenomenon—from patients' lack of control and information to patients' and physicians' lack of price sensitivity, to—for life-saving or life-prolonging procedures—a feeling that most Americans would not be comfortable with a health-care system that universally limits all procedures to only those with a demonstrated ability to pay.[87] Particularly in health care, low prices "may even create the perception of low quality," which eliminates "the normal market incentive for health-care suppliers to create innovative low-cost treatments."[88]

Second, the availability of tests and equipment often directly results in overutilization.[89] Brownlee notes that "hospitals in cities and towns across the

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[83] *See* Patience Haggin, *Doctor Shortage?*, TIME, Aug. 13, 2012, at 26 (noting that "residency training has been frozen" and "interest in becoming a primary-care physician has plummeted; the field's grueling hours and relatively low pay have given it a 'second-class status'"); *see also* Brody, *supra* note 20, at 285 (noting that the primary care shortage can be blamed at least in part on "the income gap between that field and others").

[84] BROWNLEE, *supra* note 9, at 9.

[85] *See* DIANA FARRELL ET AL., MCKINSEY&CO. GLOBAL INST, ACCOUNTING FOR THE COST OF US HEALTH CARE: A NEW LOOK AT WHY AMERICANS SPEND MORE 29 (2008), *available at* http://www.mckinsey.com/insights/mgi/research/americas/accounting_for_the_cost_of_us_health_care (consumer electronics is given as a prime example).

[86] *Id.*

[87] *See id.* at 102.

[88] *Id.*

[89] Increased overutilization may also result in *worse care*. This is evident in examples in which the physician orders imaging tests in all cases of suspected infection instead of relying on clinical judgment in all cases except the ones in which he or she is unsure. Given the error rate of imaging—and the propensities for false negatives—the physician relying on imaging tests for all patients is going to incorrectly classify a group of individuals as needing intervention when they do not. *See* BROWNLEE, *supra* note 9, at 153.

country are engaged in a medical-technology arms race"[90] in which each health system seeks the newest equipment. "When hospitals buy faster machines . . . it lowers the barrier for physicians to order yet another unnecessary test, setting up a vicious cycle."[91]

There is further evidence that supply is driving demand in health care. While examining cardiology procedures, researchers found "an almost-perfect correlation between the availability of catheterization labs in a region and the propensity for patients to be given angioplasty or bypass surgery."[92] Relatedly, researchers have also shown that providers' decision to admit patients is (often unknowingly) tied to whether there are hospital beds available. As a result, providers admit "patients who are less ill and [let] them stay longer when there is a place for them."[93] Researchers have found that in hospitals with fewer available beds, fewer Medicare admission rates have resulted.[94] This suggests that the more expensive equipment, the more clinics, even the more hospital beds in a given health center, the more overtreatment is likely to result.

4. *Defensive Medicine and Demanding Patients*

Finally, although a contested cause of increased expense,[95] some argue that the practice of "defensive medicine"—in which additional tests are ordered to protect the wary physician from a medical malpractice lawsuit should the patient's health decline—causes unnecessary care. On the heels of its study, Mattias Rumpf, the OECD's Chief Media Officer for the United States and Canada, noted that in countries "where there is a greater stress on controlling costs, and different tort law rules, there are fewer such interventions" than in the United States.[96] Still, correlation does not prove causation, and many peg the cost of defensive medicine as quite low—from a comparatively meager $13 billion[97] to no more than about $50 billion annually.[98]

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[90] *Id.* at 163.

[91] *Id.*

[92] *Id.* at 108.

[93] *Id.* at 113.

[94] *See id.* at 112–13.

[95] *See* Orentlicher, *supra* note 65, at 72 ("For example, the legal costs from medical malpractice are less than [1%] of total health care costs, and defensive medicine also represents a very small part of the health care budget.").

[96] Sarah Clune & Jason Kane, *Why Does Health Care Cost So Much in the United States?*, PBS NEWSHOUR (Nov. 25, 2011, 10:32 AM), http://www.pbs.org/newshour/rundown/2011/11/why-does-healthcare-cost-so-much.html.

[97] Rene Letourneau, *Defensive Medicine Costs Billions*, HEALTHCARE FIN. NEWS, Nov. 2011, at 23 (noting that Professor J. William Thomas of the Muskie School of Public Policy in Portland, Maine argues that the "Jackson Healthcare estimates of defensive medicine costs are significantly higher than those based on current research").

[98] *See* Micah L. Berman, *Foreword: Improving Patient Safety and Providing Fair Compensation*, 46 NEW ENG. L. REV. 409, 410 (2012), (citing Michelle M. Mello et al., *National Costs of the Medical Liability System*, 29 HEALTH AFF. 1569, 1569 (2010))

Nevertheless, doctors *themselves* seem to think defensive medicine plays a major role in causing overtreatment, resulting in inflated costs. The nationwide survey of primary care physicians found that 76% of doctors said "fear of malpractice lawsuits prompted them to practice more aggressive medicine."[99] A 2005 Journal of American Medical Association (JAMA) study of specialists practicing in "high-liability specialties" found that 93% "reported practicing defensive medicine"—a particular cause of which was "assurance behavior."[100] Further, a study published in the Archives of Internal Medicine (AIM) in 2010 found that 91% of physicians believe that defensive medicine exists, resulting in the administration of "more tests and procedures than necessary."[101] Dr. Tara Bishop, one of the co-authors of the AIM study, was quoted as saying that "[a]bout $60 billion is spent annually on defensive medicine and many physicians feel they are vulnerable to malpractice lawsuits even when they practice competently within the standard of care."[102]

According to physicians, overtreatment is particularly prevalent in America's radiology departments: emergency room physicians order tests that are not needed, and radiologists "run patients through scanners even when they know they shouldn't because other physicians asked for the test."[103] According to Brownlee, "the two reasons doctors give most often for why they do so much excess imaging are patient demand and worries about malpractice suits."[104] Other numbers reflect this: in the JAMA study, 59% of the survey's respondents said "they often ordered more diagnostic tests than were medically indicated."[105] Physicians reported relying on technology to "pacify demanding patients, bolster their own self-confidence, or create a trail of evidence that they had confirmed or excluded particular disease entities."[106] Interestingly, overtreatment causes *even more overtreatment* by changing the standard of care.

(estimating, while acknowledging that empirical evidence was limited, that "the total cost of defensive medicine was less than [2%] of overall healthcare costs"); Julie Rovner, *Costs of Defensive Medicine May Be Overstated*, NPR HEALTH BLOG (Sept. 7, 2010, 4:45 PM), http://www.npr.org/blogs/health/2010/09/07/129706676/defensive-medicine-not-as-much-as-the-doctor-ordered-after-all (noting that Mello's total was about 80% of $55.6 billion per year—which totals about $44.5 billion).

[99] Kaplan, *supra* note 58.

[100] David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2609 (June 1, 2005), *available at* http://jama.jamanetwork.com/article.aspx?articleid=200994.

[101] Press Release, Mount Sinai, Vast Majority of Physical Practice 'Defensive Medicine' According to Physicians Survey (June 28, 2010), *available at* http://mountsinai.org/about-us/newsroom/press-releases/vast-majority-of-physicians-practice'"defensive-medicine"-according-to-new-physician-survey, *reprinted in Vast Majority of Physicians Practice 'Defensive Medicine', According to Physician Survey*, SCIENCEDAILY (July 1, 2010), http://www.sciencedaily.com/releases/2010/06/100629094155.htm.

[102] *Id.*

[103] BROWNLEE, *supra* note 9, at 154.

[104] *Id.*

[105] Studdert et al., *supra* note 100, at 2612.

[106] *Id.* at 2616.

The JAMA study found that the "more physicians order tests or perform diagnostic procedures with low predictive values or provide aggressive treatment for low-risk conditions, the more likely such practices are to become the legal standard of care."[107]

America's often-demanding patients—taking what they have heard about a particular procedure or drug from television advertisements or trusted neighbors—contribute to this phenomenon. According to Brownlee:

> Doctors say that when a patient demands a test, they often comply—even when they know the test is not warranted. It's easier to acquiesce than to explain why a CT scan won't necessarily help diagnose appendicitis, or why the doctor is certain that the patient's ankle is sprained, not broken, and doesn't need to be X-rayed, or why an MRI won't change the fact that the first remedy for mild back pain is ice, over-the-counter pain medication, and normal activity. As one emergency physician who is a pediatric specialist tells me, he'd rather send a child to radiology than fight with the kid's parents, who will only think he's incompetent because they *know* their child needs a scan.[108]

C. *Recovering Money Through the Fraud Statutes*

As America's health-care costs have grown, the federal government has reacted with an ever-increasing focus on conventional health-care fraud[109]—even though it constitutes only a portion of overall health-care expenditures.[110] Nevertheless, it is popular and cost-effective, and DOJ and HHS have developed innovative ways to find and penalize a number of participants in the health-care administration and delivery industries.[111] Likely because it is so cost-effective and politically attractive, the government first began sweeping in providers and participants who engaged in behavior that contributed to the mediocre (substandard) care that many Americans receive, and now is targeting those who provide too much care to patients by government standards.

Months after taking his new job, Attorney General Holder noted that "every year [America loses] tens of billions of dollars in Medicare and Medicaid funds

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[107] *Id.*

[108] BROWNLEE, *supra* note 9, at 157–58.

[109] *See* Yeung, *supra* note 5. Both the number of cases and total settlement amounts have risen dramatically since President Obama's inauguration. *Id.*

[110] Conventional fraud constitutes only about 10% of the total estimated cost of unnecessary care. *See The Cost of Health Care*, *supra* note 17.

[111] *See* Kelly Kennedy, *Fight Against Health Care Fraud Recovers $4.1B*, USA TODAY (Feb. 14, 2012, 8:48 PM), http://www.usatoday.com/news/washington/story/2012-02-14/sebelius-holder-announce-health-care-fraud-money/53097474/1; *see also Anatomy of a Fraud Bust: From Investigation to Conviction: Hearing Before the S. Comm. on Fin.*, 112th Cong. 3 (2012) [hereinafter *Anatomy of a Fraud Bust*] (testimony of Daniel R. Levinson, Inspector General, U.S. Dep't of Health and Human Servs.), *available at* http://oig.hhs.gov/testimony/docs/2012/levinson_ testimony_04242012.pdf.

to fraud."[112] To address the problem, in May 2009, the administration announced the HEAT initiative—the "Heath Care Fraud Prevention and Enforcement Action Team"—as a joint taskforce between the Justice Department and the Department of Health and Human Services.[113] Holder went on to note that the new initiative bolstered the fight against fraud "by launching a new effort with increased tools, resources and a sustained focus by senior-level leadership."[114] HEAT sought to increase efficiency and information exchange between the two agencies, and Holder noted that the team would "continue to combine and leverage the resources of both Departments, including the FBI and the Office of Inspector General at HHS, to prevent and prosecute fraud."[115] Holder took his lead from President Obama; the President has spoken out against the scourge of health-care fraud, noting that "[t]he health care system has billions of dollars that should go to patient care, and they're lost each and every year to fraud and abuse and massive subsidies that line the pockets of the insurance company executives."[116]

The increased focus and hard work has resulted in several prosecutions and recoveries. In 2010, the government's efforts led to over $4 billion in health-care fraud recoveries.[117] In 2011, the government collected $4.1 billion as a result of its health-care anti-fraud efforts, including $2.4 billion in recoveries under the FCA alone.[118] Continuing the trend, in 2012, the government recovered $4.2 billion from health-care fraud prosecutions and settlements.[119] Further, in 2011, the HEAT taskforce's work "sent 175 people to prison,"[120] and the total number of individuals charged with health-care fraud was 1430 in 2011—up from 797 in 2008.[121]

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[112] Eric Holder, U.S. Att'y Gen., Attorney General Holder on New Medicare Fraud Initiative at a Press Conference with HHS Secretary Sebelius, JUST. NEWS (May 20, 2009), http://www.justice.gov/ag/speeches/2009/ag-speech-090520.html.

[113] *See id.*

[114] *Id.*

[115] *Id.*

[116] Helene Cooper & Robert Pear, *Obama Gets Tough on Health Care Fraud*, N.Y. TIMES (Mar. 10, 2010), http://www.nytimes.com/2010/03/11/health/policy/11health.html.

[117] *See* Kelly Kennedy, *Health Care Fraud Prosecutions on Pace to Rise 85%*, USA TODAY (Aug. 29, 2011, 9:24 PM), http://www.usatoday.com/news/washington/story/2011-08-29/Health-care-fraud-prosecutions-on-pace-to-rise-85/50180282/1. In fact, in Fiscal Year 2010, according to DOJ, *all* False Claims Act recoveries totaled $3 billion—with health care related False Claims Act recoveries totaling $2.5 billion, or 83%, of the total. *See* Press Release, U.S. Dep't of Justice, Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010), *available at* http://www.justice.gov/opa/pr/2010/November/10-civ-1335.html.

[118] *See* Kennedy, *supra* note 111.

[119] *See* Chad Terhune, *Report: U.S. Recovered $4.2 Billion from Healthcare Fraud in 2012*, L.A. TIMES, (Feb. 11, 2013), http://articles.latimes.com/2013/feb/11/business/la-fi-mo-healthcare-fraud-20130211.

[120] *See* Kennedy, *supra* note 111.

[121] *See* Press Release, U.S. Dep't of Health and Human Servs., HHS, Dep't of Justice Highlight Obama Administration Efforts, Health Reform Tools to Combat Medicare Fraud,

The government continues to pour resources into fighting health-care fraud. In February 2012, Secretary Sebelius noted that an additional $300 million would be budgeted to pay for new and expanded HEAT teams nationwide.[122] It was an uncontroversial investment: for every dollar the U.S. government spent preventing and prosecuting fraud between 2009 and 2011, it recovered $7.20.[123] Additionally, the recently upheld[124] Patient Protection and Affordable Care Act (Affordable Care Act, ACA)[125] includes an increase in funding of $350 million over ten years to "ramp up anti-fraud efforts, including increasing scrutiny of claims before they've been paid, investments in sophisticated data analytics, and an increased number of law enforcement agents and others to fight fraud in the health-care system."[126]

Finally, in the summer of 2012, President Obama announced a new partnership between the federal government and major insurance companies.[127] Called the National Fraud Prevention Partnership (Partnership), federal officials (including individuals from the Federal Bureau of Investigation), two major trade organizations for the industry,[128] and private insurers "will pool claims data and look for suspicious billing patterns and aberrations."[129] The Partnership will provide the opportunity for a "trusted third party"[130]—hired by

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(Apr. 4, 2012), *available at* http://www.hhs.gov/news/press/2012pres/04/20120404a.html. Total prosecutions jumped nearly 69% from FY 2010 to FY 2011. *See* Syracuse Univ., *Record Number of Federal Criminal Health Care Fraud Prosecutions Filed in FY 2011*, TRAC REPS. (Dec. 14, 2011), http://trac.syr.edu/tracreports/crim/270/.

[122] *See* Kennedy, *supra* note 111.

[123] *See id.* This is up from $5.10 per dollar recovered between 1997 and 2008, according to the article. *See Anatomy of a Fraud Bust*, *supra* note 111, at 7 ("This strategy has resulted in significant accomplishments, including achieving a return on investment of more than $7 to $1 over the past 3 years.").

[124] *See* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012) (upholding the Affordable Care Act's penalty provision under Congress' near-plenary tax and spending power, but declaring unconstitutionally coercive the enforcement mechanism with respect to the required expansion of Medicaid).

[125] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

[126] *New Tools to Fight Fraud, Strengthen Federal and Private Health Programs, and Protect Consumer and Taxpayer Dollars*, HEALTHCARE (Mar. 15, 2012), http://www.healthcare.gov/news/factsheets/2011/03/fraud03152011a.html.

[127] *See* Robert Pear, *Obama and Insurers Join to Cut Health Care Fraud*, N.Y. TIMES July 25, 2012, at A18 (noting that "federal investigators and insurers will pool claims data and look for suspicious billing patterns and aberrations.").

[128] According to the New York Times, the two trade organizations expected to join the Partnership are America's Health Insurance Plans and the Blue Cross and Blue Shield Association. *See id.*

[129] *Id.*

[130] T.R. Goldman, *Health Policy Brief*, HEALTH AFF. (July 31, 2012), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=72 (noting that some have been critical of third-party contractors on which the government relies to investigate potential fraud allegations). However, some third-party contractors have been criticized for their often aggressive work:

the federal government—to look at claims data from the federal health-care programs as well as private insurance in an effort to detect anomalies,[131] which will undoubtedly result in additional investigations.

III. THE FALSE CLAIMS ACT: A HISTORICAL SUMMARY

The federal government's most potent weapon[132] against health-care fraud has had a long and eventful lifespan. Created during the American Civil War in an effort to prevent individuals from selling defective equipment to Union soldiers,[133] the modern FCA came into being in 1986, following Congressional amendments that increased penalties, sweetened whistleblower incentives and protections, and broadened the scope of punishable offenses.[134] Since 1986, the government has recovered more than $27 billion under this strengthened FCA.[135] The Fraud Enforcement and Recovery Act of 2009,[136] the Dodd-Frank Wall Street Reform and Consumer Protection Act[137] and the Affordable Care Act have further expanded offenses and strengthened whistleblower protections within the Act.[138]

> Some providers complain that overzealous contractors, motivated to find problems by their contingent fee arrangement with CMS, focus on technical mistakes rather than outright wrongdoing. There have also been complaints that contractors are too quick to determine that paid claims are improper, necessitating the spending of thousands of dollars in expensive provider appeals that can take up to two years to resolve. In response to these concerns, CMS is auditing the work of its contractors for accuracy and has also required the contractors to increase the medical credentials of their staff to improve the credibility of their actions.

Id.

[131] *See* Pear, *supra* note 127, at A18.

[132] In 2011, the civil False Claims Act brought in $2.4 billion of the $4.1 billion *total* in health care fraud recoveries and settlements. *See* Kennedy, *supra* note 111.

[133] *See* Krause, *supra* note 32, at 129–30 (detailing the history of the FCA).

[134] *See* CHRISTINA W. FLEPS, HEALTH CARE FRAUD AND ABUSE COMPLIANCE MANUAL § 2:38 (Supp. 2012).

[135] *See id.* § 2:39.

[136] *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (codified as amended at 18 U.S.C. § 27 (2009)) (amending False Claims Act provisions at 31 U.S.C. § 3729 (2006) and other sections of the United States Code).

[137] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1079A, 124 Stat. 1376, 2079 (2010) (amending False Claims Act provisions at 31 U.S.C. § 3730(h) (2006) and other sections of the United States Code).

[138] FLEPS, *supra* note 134, § 2:38. Perhaps the ACA's biggest change to FCA enforcement linked the Anti-Kickback Statute to the FCA. *See* 42 U.S.C.A. § 1320a-7b(g) (West 2013) ("In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31."). This change explicitly recognized that a violation of the Anti-Kickback Statute could constitute a predicate claim for an FCA violation. *See id.*

In addition to other provisions, the FCA imposes liability on "any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or any individual who "(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or one who

> knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.[139]

"Knowingly," in this context, means that an individual "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information."[140] The FCA *mandates* a minimum penalty of $5,500 and a maximum penalty of $11,000 for each claim "plus three times the amount of damages which the Government sustains because of the act of that person."[141]

What makes the FCA unique—and especially potent—is its *qui tam*[142] provision, which allows private persons to bring actions on behalf of the government.[143] Once the private individual has filed a claim, the government can intervene and proceed with the action as the plaintiff.[144] If the government intervenes, however, the private plaintiff is still entitled to between 15 and 25% of the recovery.[145] Finally, the statute allows the government to issue civil

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[139] 31 U.S.C. § 3729(a) (2006).

[140] 31 U.S.C. § 3729(b) (2006). Gross negligence "plus" is required to demonstrate the requisite intent. *See* United States *ex rel.* Burlbaw v. Orenduff, 548 F.3d 931, 945 n.12 (10th Cir. 2008) ("An aggravated form of gross negligence (i.e. reckless disregard) will satisfy the scienter requirement for an FCA violation."); United States v. Krizek, 111 F.3d 934, 942 (D.C. Cir. 1997) (upholding the scienter requirement of gross negligence "plus" and noting that "as the statute explicitly states that specific intent is not required, it is logical to conclude that reckless disregard in this context is not a 'lesser form of intent,' . . . but an extreme version of ordinary negligence" (citation omitted)); Crane Helicopter Servs., Inc. v. United States, 45 Fed. Cl. 410, 433 n.26 (1999) ("[U]nder the False Claims Act, reckless disregard may be considered the equivalent of 'aggravated form of gross negligence,' or gross negligence-plus.'" (citations omitted)).

[141] 31 U.S.C.A. § 3729(a)(1) (West 2013). The statute actually requires the minimum penalty to be $5,000 per claim and the maximum penalty as $10,000 per claim, but these amounts were adjusted for inflation in 1999. *See* 28 C.F.R. § 85.3(9)(2012).

[142] "Qui tam is an abbreviation for the maxim qui tam pro domino rege quam pro se ipso in hac parte sequitur, or 'who pursues this action does so on the behalf of our Lord the King as well as on his own behalf.'" BOUVIER LAW DICTIONARY 1183 (Stephen M. Sheppard ed., 2011).

[143] 31 U.S.C. § 3730(b)(1) (2006).

[144] *Id.* § 3730(b)(2).

[145] *Id.* § 3730(d)(1).

investigative demands, which are powerful tools forcing private litigants to produce documents or provide testimony.[146]

The FCA has figured particularly prominently in modern health-care recoveries. Called "a significant deterrence against fraud,"[147] "merciless,"[148] "potent,"[149] and a "weapon of choice in combating fraud and abuse in healthcare today,"[150] the FCA is an old tool that has been stretched to apply to America's modern patchwork that constitutes the health-care industry. As such, the application of the FCA to health-care fraud is a (relatively) new and somewhat uncomfortable phenomenon.[151] The fit between the FCA's stark, brutal statutory penalties and modern health care's complex web of actors and their decisions—often whose culpability levels are unclear—is not perfect, but the government enjoys application of the old fraud statute to an industry in which fraud is allegedly "everywhere."[152] Further, the federal government has encouraged states to enact their own anti-fraud statutes based on the federal FCA as part of the Deficit Reduction Act of 2005.[153] As a result, many states have enthusiastically and increasingly sought to apply their own "state false claims acts" in recent cases.[154]

Recently, FCA actions have resulted in major penalties, particularly against the life sciences industry. In 2012, a verdict against pharmaceutical giant

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[146] *Id.* § 3733(a)(1).

[147] Timothy Stoltzfus Jost, *Optimizing* Qui Tam *Litigation and Minimizing Fraud and Abuse: A Comment on Christopher Alexion's* Open the Door, Not the Floodgates, 69 WASH. & LEE L. REV. 419, 421 (2012). Jost also notes that the total settlements and judgment amounts received as a result of the False Claims Act between 1987 and 2008 are $21.6 billion. *See id.* at 421 n.10.

[148] Doan, *supra* note 27, at 60.

[149] *Id.*

[150] 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, 39 (2008).

[151] DOJ was criticized for its handling of a well-covered case in the late 1990s involving a Washington, D.C. psychiatrist, George Krizek. *See* Thomas L. Greaney & Joan H. Krause, United States v. Krizek*: Rough Justice Under the Civil False Claims Act*, *in* HEALTH LAW & BIOETHICS: CASES IN CONTEXT 187–96 (Sandra H. Johnson et al. eds., 2009). Use of the False Claims Act in the case demonstrated its shortcomings—including its bluntness to govern a complex reimbursement system. *See id.* at 203–04.

[152] *See* Catherine Arnst, *10 Ways to Cut Health-Care Costs*, BUSINESSWEEK (Nov. 12, 2009), http://www.businessweek.com/magazine/content/09_47/b4156034717852.htm ("'Everywhere we look, we see evidence of fraud,' says Lewis Morris, chief counsel for the Office of the Inspector General at the U.S. Health & Human Services Dept.").

[153] *See Incentivising State False Claims Acts*, NAT'L CONF. ST. LEGISLATURES, http://www.ncsl.org/issues-research/health/clarifying-requirements-for-a-state-false-claims-a.aspx (last visited Aug. 2, 2012).

[154] *See, e.g.*, Katie Thomas, *J.&J. Fined $1.2 Billion in Drug Case*, N.Y. TIMES, Apr. 11, 2012, http://www.nytimes.com/2012/04/12/business/drug-giant-is-fined-1-2-billion-in-arkansas.html; *see also* Zack Buck, *Rigid, Severe Penalties of FCAs On Full Display*, HEALTH REFORM WATCH (Apr. 15, 2012), http://www.healthreformwatch.com/2012/04/15/rigid-severe-penalties-of-fcas-on-full-display/.

Johnson & Johnson by an Arkansas court resulted in an award amount of $1.2 *billion* under the Arkansas False Claims Act,[155] a finding that sent shockwaves through the health-care industry. Bolstered by the potential liability mandated by the FCA (or state iterations of it) that faces a defendant should it try its hand at trial, pharmaceuticals' settlement amounts continue to break stratospheric records—from Pfizer's $2.3 billion in 2009,[156] to GlaxoSmithKline's $3 billion in 2011,[157] to Abbott's $1.6 billion in 2012.[158]

According to Inspector General Daniel Levinson, the growing[159] number of health-care fraud investigations typically follows the same pattern. The investigation begins with "analyz[ing] and evaluat[ing] Medicare claims data."[160] This includes "analyz[ing] Medicare billing data to look for billing anomalies" and "conduct[ing] time analysis reports."[161] After amassing other

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[155] *See* Thomas, *supra* note 154 (noting that the fine imposed on Johnson & Johnson "ranked among the largest on record for a state fraud case involving a drug company").

[156] *See* Gardiner Harris, *Pfizer Pays $2.3 Billion to Settle Marketing Case*, N.Y. TIMES Sept. 2, 2009, http://www.nytimes.com/2009/09/03/business/03health.html ("It was the largest health care fraud settlement and the largest criminal fine of any kind ever.").

[157] Duff Wilson, *Glaxo Settles Cases with U.S. for $3 Billion*, N.Y. TIMES, Nov. 3, 2011, at B1 ("The settlement would be the largest yet in a wave of federal cases against pharmaceutical companies accused of illegal marketing, surpassing the previous record of $2.3 billion paid by Pfizer in 2009.").

[158] Peter Loftus & Brent Kendall, *Abbott to Pay $1.6 Billion*, WALL ST. J., May 7, 2012, http://online.wsj.com/article/SB10001424052702304451104577390182002017146.html ("The Justice Department said it was the second-largest payment by a drug company to settle an investigation, after Pfizer, Inc.'s $2.3 billion settlement in 2009. It is the latest in a series of settlements by major drug makers whose marketing practices have been investigated by the government in recent years.").

[159] Even though the growing settlement amounts and jury verdicts show no sign of slowing in the health care context, other industries may be experiencing a fraying of the FCA. To this end, a federal court in Virginia recently found that the penalties required by the FCA constituted an excessive penalty under the Eighth Amendment in *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, Nos. 1:02cv1168 (AJT/TRJ), 1:07cv1198, 2012 WL 488256, at *11 (E.D. Va. Feb. 14, 2012). The party contracting with the government—the agreement related to transporting goods owned by U.S. military members—had certified that it had not engaged in any price collusion when in fact it had. *See id.* at *1, *3. The court found that the companies did defraud the government, but that the government was not financially harmed because the colluded prices were fair and reasonable. Because the government had not been financially harmed, the court found the statutorily mandated damages amount—$5500 per violation, multiplied by 9,136 invoices, totaling over $50 million—to be unconstitutionally excessive. *See id.* at *3–4, *7, *11. Due to the FCA's strict requirements, the court concluded that it lacked discretion to set a different statutory penalty and did not award *any damages* to the relators, nor to the government. *See id.* at *13.

Indeed, courts have not employed similar analyses to the *Bunk* court when the defendants have been health care providers or pharmaceutical companies. Still, if *Bunk* is any indication, more courts may begin to look more carefully at the FCA's immense liability, including, perhaps, in the health care context.

[160] *See Anatomy of a Fraud Bust*, *supra* note 111, at 3.

[161] *Id.*

evidence—including information gained by interviewing witnesses, consulting banking information, and contacting medical records and billing departments, the indictments (under the criminal fraud statutes) and further investigations typically follow.[162] Once charges are brought, agents complete a number of follow-up tasks to see if other actors are involved in the fraud, as well as constructing safeguards to prevent others from accomplishing the same scheme.[163] Levinson underscored the importance of the advanced technology to the investigators, mentioning that "specialized training and advanced data analytics have changed the way [the government] investigate[s] cases."[164]

IV. PENALIZING DEFICIENT CARE

The government's reliance on the FCA as an enforcement tool against the health-care industry has continued to increase. Until the late 1990s, health-care fraud cases (which were spearheaded by FCA allegations) typically "involved a claim for a service that was either (1) not provided, (2) not necessary, or (3) had been 'upcoded' to bill for a higher level of service than was actually provided."[165] At that point, "the underlying quality of the service being provided was irrelevant to the reimbursement."[166]

But in the late 1990s, this would change; U.S Attorney offices began developing—and courts began allowing—novel ways in which the old statute could be applied to the modern American health-care system.[167] In the recent era, the government has boldly sought to apply the FCA to two different (and in some ways, opposite) types of harms it has identified in the American health-care system regarding administered clinical care. The government's focus has turned to these two "wrongs" recently—seeking to penalize both (1) care that is

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[162] *See id.*

[163] *See id.* at 3–4, 7.

[164] *Id.* at 7.

[165] Devin S. Schindler, *Pay for Performance, Quality of Care and the Revitalization of the False Claims Act*, 19 HEALTH MATRIX 387, 396 (2009).

[166] *Id.*

[167] *See* Publication of OIG Special Fraud Alert: Fraud and Abuse in Nursing Home Arrangements with Hospices, 63 Fed. Reg. 20,415 (Apr. 24, 1998); Joan H. Krause, *A Conceptual Model of Health Care Enforcement*, 12 J.L. & POL'Y 55, 62–63 (2003) ("In addition to pursuing allegations of fraud against individual providers, the government developed proactive initiatives targeting particular sectors of the health care industry for intensive scrutiny. . . . By the late 1990s, nursing homes increasingly found themselves under scrutiny for fraud based on alleged quality-of-care deficiencies." (footnote omitted)); *see also* Brennan & Paddock, *supra* note 150, at 43; Joan H. Krause, *Healthcare Fraud and Quality of Care: A Patient-Centered Approach*, 37 J. HEALTH L. 161, 163–64 (2004) ("[P]rosecutors . . . have sought to extend this powerful law to encompass broader categories of improper activities" and "[r]ecent cases have sought to style regulatory noncompliance, rather than billing misrepresentations, as actionable falsity or fraud.").

substandard, and (2) care that is unnecessary—garnering, where solicited, a tepid response from the judiciary.[168]

A well-documented example of the government's stretching of the FCA to address undesirable practice patterns that may not be seen as conventional fraudulent behavior is its application in so-called "quality of care" cases.[169] Based upon the argument that the government is defrauded whenever it pays for grossly deficient health services, this new theory of liability provided the connection between bad care and fraud. Specifically, the government has employed two different theories—worthless service and false certification—to extend the FCA's application to cases where providers' services were substandard.[170]

One of the theories, the worthless services theory, quickly emerged as a viable strain of FCA liability in the nursing home and long-term care facility context.[171] The theory imposes FCA liability where the care administered is so bad that it is *worthless*; by reimbursing the provider, the government is effectively paying for *nothing*, and as a result, it is harmed. The theory is said to have emerged in 1996, when the U.S. Attorney's Office for the Eastern District of Pennsylvania brought a FCA lawsuit against Tucker House, an inner-city long-term care facility, alleging "'grossly inadequate' nutritional services and wound care services."[172] Specifically, the government argued that a violation of

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[168] Judges have noted the difficulties. *See, e.g.*, United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1152 (W.D. Mo. 2000) ("At the outset, the Court notes that the parties and many of the articles and cases which the Court has read in the course of its research have discussed the policy considerations of the Government's recent trend of utilizing the FCA as a check on health care providers. While at certain times a court is required to consider policy questions, it is generally the function of the courts to interpret the law as written. In this case there may be broad negative implications for the health care industry by the continued prosecution of providers under the FCA. But it is not the place of this Court to exempt an entire industry from FCA liability simply because it may be hurt by such suits. If the claims submitted by the Government comport with the requirements of claims submitted under the FCA, then the suit is proper. If this outcome is unsavory to the Defendant or its industry as a whole then the change is to made [sic] in the political arena via Congress or the Executive Branch. This Court will interpret the plain meaning and logical interpretation of the FCA as it applies to this case, and not entertain wide speculation as to the effect of any particular decision.").

[169] *See* Krause, *supra* note 8, at 1399–1406 (documenting the various types of quality-of-care fraud).

[170] *See, e.g.*, United States *ex rel.* Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001) (granting leave to amend following dismissal due to applying worthless services theory); United States *ex rel.* Bailey v. Ector Co. Hosp., 386 F. Supp. 2d 759 (W.D. Tex. 2004) (addressing and recognizing both strains of liability, but granting dismissal); United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs., Inc., 945 F. Supp. 1485, 1487–89 (W.D. Okla. 1996) (applying false certification theory).

[171] *See* Schindler, *supra* note 165, at 396–97; *see also* United States *ex rel.* Swan v. Covenant Care Inc., 279 F. Supp. 2d 1212, 1212 (E.D. Cal. 2002) (denying worthless services claim but recognizing it as a viable strain of liability).

[172] Brennan & Paddock, *supra* note 150, at 43; *see also* Krause, supra note 8, at 1403.

the FCA occurred because the facility offered services that were clearly inadequate.[173] The lawsuit had stemmed from the emergency hospitalization of one of its patients in which providers noticed that the patient "was suffering from 26 ulcers, a gangrenous leg and a series of other serious complications."[174] The parties eventually entered into a settlement agreement, and Tucker House agreed to pay $25,000 to settle the novel FCA allegations.[175] The new theory was applied by the same office in a subsequent investigation of three more nursing homes which resulted in settlements totaling $500,000.[176]

Beyond serving as a tool that precipitates settlements for DOJ, at least one circuit court has recognized the worthless services theory as a statutorily grounded and well-supported legal theory. Albeit while dismissing the plaintiff's FCA complaint for other reasons without prejudice,[177] the court noted that "knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under [the FCA]."[178] Even though other courts have required heightened showings by plaintiffs to satisfy the worthless services theory strain of liability,[179] it remains both a tool for the government and a threat to all health-care providers. As a result, "facilities which consistently fail to meet whatever standard of care the [f]ederal government currently considers appropriate, are at risk of both malpractice claims . . . and of being charged with either civil or criminal billing fraud."[180]

The other theory of liability—false certification—can arise in similar scenarios. False certification theory[181] works to apply FCA liability to services rendered that failed to be "medically indicated and necessary for the health" of the Medicaid or Medicare beneficiary.[182] Should the provider sign off on this

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[173] *See* Schindler, *supra* note 165, at 396–97.

[174] *Id.* The amount of Tucker House's settlement—compared with more recent settlements—seems quite low.

[175] Brennan & Paddock, *supra* note 150, at 43.

[176] *See* Schindler, *supra* note 165, at 397.

[177] *See* United States *ex rel.* Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053–54 (9th Cir. 2001).

[178] *Id.* at 1053.

[179] *See* United States *ex rel.* Bailey v. Ector Co. Hosp., 386 F. Supp. 2d 759, 766 (W.D. Tex. 2004) (holding that because "the record [did] not show the Defendants' services were so deficient as to be worthless," the quality-of-care claim should be dismissed); United States *ex rel.* Swan v. Covenant Care Inc., 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) ("Because Swan does not allege that Covenant Care's neglect of its patients was so severe that, for all practical purposes, the patients were receiving no room and board services or routine care at all, her FCA claim does not fit within the worthless services category.").

[180] Schindler, *supra* note 165, at 400.

[181] Scholars have made insightful arguments against recognition of false certification theory—namely, when predicated on a violation of the Anti-Kickback Statute. *See, e.g.*, 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 (1999).

[182] *Health Insurance Claim Form 1500*, CENTERS FOR MEDICARE & MEDICAID SERVICES (Aug. 2005), http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//CMS1500805.pdf.

type of care and submit the bill for reimbursement, he or she is subjected to liability because it cannot be said that the care complied with all applicable statutes and regulations—chiefly, in quality-of-care cases, because it did not meet the standard of care.

In an early iteration of the false certification theory, the Western District of Oklahoma allowed an FCA lawsuit to proceed where plaintiffs relied on an implied false certification theory after the defendant facility allegedly "knew that it was not providing to its patients appropriate quality of care and a safe and secure environment."[183] Specifically, the patients allegedly suffered physical injury and sexual abuse because of "understaffed shifts, lack of monitoring equipment, and inappropriate housing assignments."[184] Rejecting the defendant's assertion that the government failed to identify any "statute or rule that imposes an objective standard of safety or quality of care as a billing requirement," the court found that rules governing Medicaid "clearly require health-care providers to meet quality of care standards," allowing the FCA claim to proceed "against a provider of substandard health-care services under appropriate circumstances."[185] Based upon this argument, and subject to what constitutes "appropriate circumstances," the FCA would always apply to cases of substandard care.

In another early quality-of-care case, the Western District of Missouri refused to dismiss FCA claims based on substandard care on the basis of implied false certification theory.[186] The court noted that the "health care provider can be held to have impliedly certified that it will comply with the relevant standard of care as set forth in the regulations and statutes if that standard of care lies at the core of the parties' agreement."[187] More clearly, the dispute focused not on *how* the defendant provided certain health-care services, "but *whether* the [d]efendant did these things at all."[188] By drawing this distinction, the court recognized a real—but limited—strain of liability based on implied certification and refused to dismiss the government's FCA claim against NHC Healthcare Corporation.

Still, neither the worthless services theory nor the false certification theory is universally recognized; one circuit court has explicitly narrowed the false certification theory,[189] and another has jettisoned other court-made categories

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[183] United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs., 945 F. Supp. 1485, 1487 (W.D. Okla. 1996).

[184] *Id.* at 1488.

[185] *Id.*

[186] *See* United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1155 (W.D. Mo. 2000).

[187] *Id.*

[188] *Id.*

[189] *See* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001).

for analyzing FCA cases altogether.[190] In *Mikes v. Straus*, a *qui tam* relator brought an FCA claim against her former employer, alleging that because the providers with whom she worked failed to calibrate spirometer machines,[191] the test results were unreliable.[192] By using the machines and then billing federal health-care programs for reimbursement, the clinic had violated the FCA, the relator alleged.

The Second Circuit found that certifying the "medical necessity" of the tests (what the providers had to certify in order to get reimbursement from the government) did not "impart a qualitative element mandating a particular standard of medical care" and that the term "ordinarily indicates the level—not the quality—of the service."[193] The court's critique of the theory went deeper. Differentiating its approach from the approach applied to false certification cases, the *Mikes* court noted that its approach "to the phrase 'medically necessary'" would apply "to *ex ante* coverage decisions but not *ex post* critiques of how providers executed a procedure."[194] The court concluded that—through the certification—the provider only certified that the procedure was performed and that the "procedure was medically necessary," but said nothing of the quality of the procedure and whether or not it met the applicable standard of care.[195] As the Second Circuit clearly indicated, the various quality-of-care theories are not universally recognized by all courts.

Following in the footsteps of the quality-of-care cases, a new type of liability—fraud liability based on overtreatment—has recently emerged. However, unlike the quality-of-care theories, this theory has been shielded from any meaningful judicial review. A review of the overtreatment enforcement model is finally provided below.

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[190] *See* United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 385 (1st Cir. 2011) (refusing to classify case as a "certification" case and noting that the court-made categories "obscure and distort" the FCA).

[191] Spirometry—a "common office test"—is used to diagnose asthma, chronic obstructive pulmonary disease (COPD), and other respiratory conditions. *Spirometry*, MAYO CLINIC (July 9, 2011), http://www.mayoclinic.com/health/spirometry/MY00413/. It measures the quantity of air and speed at which one can exhale during respiration. *See id.*

[192] *See Mikes*, 274 F.3d at 692–93.

[193] *Id.* at 698.

[194] *Id.*

[195] *See* Schindler, *supra* note 165, at 403; *see also Mikes*, 274 F.3d at 699–700 ("[T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment—and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach. Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that 'the regulation of health and safety matters is primarily, and historically, a matter of local concern.'").

V. PENALIZING OVERTREATMENT AND THE ICD INVESTIGATION

Different from fraud investigations that seek to ensure *more* or *better* care (as in the quality-of-care cases mentioned above), the government has recently begun to go after overtreatment in an effort to achieve *less* care.[196] In these investigations, the government claims that the defendant has committed fraud by administering care and services that are beyond what is medically necessary.[197] Using present investigations as a guide, this type of case can be commenced when the government notices anomalies in a particular provider's billing, focusing on "wasteful services" for which Medicaid or Medicare has been billed.[198] DOJ flags and notifies the provider or facility, alleging that the FCA has been violated. Afraid of the high penalties associated with the FCA, providers and facilities acquiesce in the face of the government's allegations and settle the charges by paying a large fine.[199] DOJ hails the settlement as protecting American patients and taxpayers from fraud.[200] Then investigators look at more hospitals' and providers' bills, and the story repeats itself. This new wave of liability—which relies on the threat of FCA liability to penalize overtreatment—is perhaps best exemplified by an ongoing initiative undertaken

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[196] *See infra* notes 202–23 and accompanying text. The exemplar initiatives presented in this piece seek to achieve the goal of reining in expense, limiting time in the hospital, or limiting the provision of certain procedures.

[197] *See, e.g.*, Liz Kowalczyk, *Hospital's Medicare Billing Examined*, BOSTON.COM (Feb. 6, 2012), http://www.boston.com/news/local/massachusetts/articles/2012/02/06/federal_investigators_subpoena_six_years_of_medicare_records_from_beth_israel_deaconess/ (describing an example of attorneys reviewing billing records to determine whether or not the procedures were medically necessary and appropriate).

[198] *See id.* This pattern follows the steps outlined by Mr. Levinson in his 2012 testimony before Congress. *See Anatomy of a Fraud Bust*, *supra* note 111.

[199] Interestingly, during the kyphoplasty initiative, which will be used as an example of an overtreatment investigation, the government has not pressed providers to enter into a Corporate Integrity Agreement (CIA) in conjunction with settlement. *See* Faegre Baker Daniels LLP, *Where is the CIA?—Recent Pharmaceutical and Hospital False Claims Act Settlements Raise the Question of Whether a Presumption Against Corporate Integrity Agreements Exists for Certain Categories of Conduct*, BEYOND HEALTHCARE REFORM (Feb. 14, 2012), http://beyondhealthcarereform.com/where-is-the-cia/ (opining that the kyphoplasty settlements did not come with CIAs due to a lack of monitoring resources and the type of conduct that occurred).

[200] *See, e.g.*, Press Release, U.S. Dep't of Justice, Fourteen Hospitals to Pay U.S. More Than $12 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (Feb. 7, 2012), *available at* http://www.justice.gov/opa/pr/2012/February/12-civ-173.html (quoting Assistant Attorney General for the Civil Division Tony West as saying, "Patients want reassurance that their health care provider is making treatment decisions based on the patient's best interests, not an interest in maximizing profits . . . . By recovering taxpayer dollars lost to improper billing, this settlement will help support the vital health care programs we depend on.").

by DOJ: the investigation into the medical appropriateness of using implantable cardioverter defibrillators (ICDs).[201]

Although it has not yet reached full resolution, DOJ has undertaken a groundbreaking nationwide "patient-by-patient" investigation of the placement of ICDs over a seven-year period in the United States.[202] ICDs are described as "small device[s] . . . placed in the chest or abdomen" that are used to "help treat irregular heartbeats" by using "electrical pulses or shocks to help control life-threatening arrhythmias."[203] These expensive devices—ICDs cost Medicare $40,000 each[204]—are intended for those who are at the highest risk of sudden cardiac arrest.[205] Scientific reports published in early 2011[206] concluded that a significant percentage of patients—more than 20% of those receiving the ICDs between 2005 and 2010—did not meet established Medicare guidelines for the procedures.[207] As a result, the procedure caught the eye of the government attorneys and regulators, who are concerned about the medical appropriateness and necessity of ICDs that were implanted outside of the bounds of the Medicare guidelines.

Specifically, DOJ appears focused on the particulars of the Medicare National Coverage Determination (NCD)[208]—with the granular timing requirements within the NCD that determine when the ICD is clearly "medically necessary" becoming the focal point of the investigation. To this

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[201] *See What Is an Implantable Cardioverter Defibrillator?*, NAT'L HEART, LUNG, & BLOOD INST. (Nov. 9, 2011), http://www.nhlbi.nih.gov/health/health-topics/topics/icd/ (noting that an ICD "is a small device that's placed in the chest or abdomen . . . . to help treat irregular heartbeats called arrhythmias . . . . [by using] electrical pulses or shocks to help control life-threatening arrhythmias, especially those that can cause sudden cardiac arrest").

[202] Joe Carlson, *Cardiac Arrests: Hospitals Anxious They Could Face Hefty False Claims Penalties in Implanted Cardiac Defibrillator Cases*, MODERN HEALTHCARE, Jul. 23, 2012, at 6, 6, *available at* http://www.modernhealthcare.com/article/20120721/MAGAZINE/307219994.

[203] *What Is An Implantable Cardioverter Defibrillator?*, *supra* note 201.

[204] *See* Carlson, *supra* note 202, at 6.

[205] *See id.*

[206] *See id.*; Sana M. Al-Khatib et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 JAMA 43, 43–49 (2011).

[207] *See* Carlson, *supra* note 202; *see also* Sabriya Rice & Miriam Falco, *Study: Many Defibrillator Implants Went to Marginal Candidates*, CNN (Jan. 5, 2011, 2:25 AM), http://www.cnn.com/2011/HEALTH/01/04/defibrillator.implants.study/index.html (noting that "[m]ore than 20% of patients who received an implantable cardioverter-defibrillator . . . were not good candidates to receive the device").

[208] According to CMS, National Coverage Determinations "are made through an evidence-based process, with opportunities for public participation." *Medicare Coverage Determination Process*, CENTERS FOR MEDICARE & MEDICAID SERVICES (Mar. 5, 2012), http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html?redirect=/DeterminationProcess. NCDs clarify which "items and services . . . are reasonable and necessary for the diagnosis or treatment of an illness or injury," and thus eligible for coverage under Medicare. *Id.*

point, Medicare does not cover ICDs implanted within forty days of a heart attack or ninety days of an angioplasty or bypass surgery.[209] But as providers and lawyers have noted, the guidelines are rigid,[210] and do not reflect clinical reality.[211] For example, many candidates who recently had a heart attack, angioplasty, or a bypass surgery still remain appropriate candidates for an ICD if they have elevated risk of sudden death from cardiac arrest—and some are patients particularly in need of the procedure.[212]

Whether and to what extent the FCA will be used by DOJ in an effort to achieve settlement for the alleged overtreatment—a "first-of-its-kind legal strategy of enforcing . . . [an NCD]"—has not yet been determined.[213] Interestingly, "[h]ospital lawyers [who are being investigated] say the [DOJ] is looking to enforce Medicare's coverage rules through the lens of the [FCA] . . . which is not how reviews of medical-necessity have been conducted."[214] Still, it seems that if hospitals "billed in violation of the [Medicare ICD] timing requirement," the government will be "seek[ing] some sort of payment."[215]

What makes the investigation particularly tricky is each patient's individualized presentation. DOJ will likely take the position that "medical necessity in this area is not always black and white"—and will seek creative

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[209] *See* Carlson, *supra* note 202, at 7.

[210] *See, e.g.*, Nina Youngstrom, *DOJ Appears Open to Idea that Medical Necessity, NCD Don't Always Overlap*, HEALTH BUS. DAILY (July 5, 2011), http://aishealth.com/archive/ rmc062711-01 ("[Minneapolis attorney David] Glaser and other experts, including physician Tom McCarter, chief clinical officer of Executive Health Resources in Philadelphia, say that ICDs should be more open to interpretation. Sometimes ICDs are medically necessary even if they don't fit inside the tidy box of the covered indications. A classic example is former vice president Dick Cheney . . . who has an ICD implant [and] became fodder for the Medicare ICD coverage debate even though at the time he was covered by the Federal Employees Health Benefits Program rather than Medicare. Despite serious, highly publicized heart problems, Cheney still would not have been a candidate for Medicare-covered ICD surgery . . . . '[Cheney] didn't actually qualify . . . because his ejection fraction was 40%,' said physician Arthur Moss, who represented the Guidant Corporation, a device maker. The NCD requires ejection fractions of less than or equal to 35%. (Ejection fraction refers to how well the left side of the heart is pumping blood.).").

[211] *See* Carlson, *supra* note 202, at 7.

[212] *See id.*

[213] *See id.* Indeed, "[i]nitially, DOJ took the position that noncompliant billing for ICD implantation is within the realm of the [FCA]." Larry Husten, *Guest Post: Feds Turn Corner in ICD Investigation; Hospital Liability Divided into Categories*, FORBES (Aug. 7, 2012), http://www.forbes.com/sites/larryhusten/2012/08/07/guest-post-feds-turn-corner-in-icd-investigation-hospital-liability-divided-into-categories/. But now "the government is considering whether to apply the [FCA] in some instances." Carlson, *supra* note 202, at 16.

[214] Carlson, *supra* note 202, at 6.

[215] Husten, *supra* note 213.

penalties based on each hospital's individual facts.[216] However, the fact that an ICD was implanted outside of Medicare guidance does not make the procedure medically inappropriate. As attorney David Glaser notes, "DOJ and Medicare auditors should be asking hospitals whether the decision to implant the ICD in the patient is reasonable and necessary, rather than whether the implants met the letter of the NCD."[217]

As part of the investigation, DOJ has reviewed ICDs performed at a number of hospitals nationwide, including the world-renowned Cleveland Clinic. In its review of the Cleveland Clinic, its module flagged, as potentially inappropriate, 264, or 4.4%, of all ICDs done within its doors.[218] Dr. Bruce Lindsay, who heads "the cardiac pacing and electro-physiology section for the system . . . personally examined every one of the . . . cases the Justice Department questioned."[219] In Lindsay's opinion, all 264 patients were appropriate recipients of an ICD, but he found twelve "in which the timing of the implants appeared to fall outside of the rules laid down by the CMS [Centers for Medicare and Medicaid Services] for when patients can receive the devices."[220] His review shows how clinical judgment may diverge from bureaucratic guidelines in this instance—or at least it demonstrates that clinical judgment may not be at consensus. What is undisputable is the fact that some doctors placed ICDs outside of the guidelines based upon their clinical judgment, and would do it again.[221]

Nevertheless, as of the fall of 2012, a "breakthrough" in the investigation had occurred.[222] Specifically, "DOJ now has a blueprint for determining hospital liability," and the investigation will likely result in settlements in the near future.[223] The ICD investigation provides a clear example of DOJ's new enforcement strategy against overtreatment—where anti-fraud tools are increasingly being applied—and serves as a vehicle for which to study the unsettling consequences that come with such a strategy.

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[216] *Id.*; *see also* Ara Beth Gershengorn et al., *United States: DOJ Takes New Tack on Hospital Recoupments: Implantable Cardiac Defibrillators*, MONDAQ (Sept. 7, 2012), http://www.mondaq.com/unitedstates/x/195336/trials+appeals+compensation/DOJ+Takes+New+Tack+On+Hospital+Recoupments+Implantable+Cardiac+Defibrillators (noting that guidance released in the fall of 2012 indicates that DOJ "will evaluate each hospital's situation individually" and will apply a "damages multiplier" based upon four factors).

[217] Youngstrom, *supra* note 210.

[218] *See* Carlson, *supra* note 202, at 7.

[219] *Id.*

[220] *Id.*

[221] *Id.*

[222] *See* Husten, *supra* note 213; *see also* Gershengorn et al., *supra* note 216 (documenting DOJ's model to individually determine provider hospital liability based on different individualized factors).

[223] Husten, *supra* note 213.

VI. CONCERNING ENFORCEMENT

Presumably, the government has begun to recover funds for overtreatment cases through fraud investigations and settlements because they offer a good return on enforcement expenditures, provide positive publicity, and easily achieve settlement. However, for both doctrinal and policy-based reasons, the FCA's application to overtreatment cases—catching the providers who performed and implanted ICDs beyond the bounds of Medicare standards, for example—is troubling. In general, the strategy constitutes a minimal, piecemeal approach that will never actually address the root causes of overtreatment discussed above.

Additionally, DOJ's enforcement model in overtreatment cases presents an expansion of FCA liability that is reliant on three interrelated and concerning characteristics. First, data mining—characterized as the practice of scouring hospital bills using sophisticated data review technology—is wielded by the government as proof that fraud must have occurred, and incentivizes quick settlement without allowing sufficient review of the particular procedure's clinical appropriateness. Second, in overtreatment cases, the government is willing to enforce a practice standard within areas in which the standard is likely still developing within clinical practice—with drastic effects. As a result, the merits of the investigation revolve around the vague, underdeveloped definition of "medical appropriateness," and settlements freeze the practice standard that exists at the time. Finally, the exorbitant statutory penalties that result from the application of the FCA forces providers to settle allegations even if the providers did not actually commit any wrongdoing. The risk to providers of an adverse finding at trial—even if that risk is exceedingly minimal—is simply too great for doctors and hospitals to take. Below an in-depth review of these three factors—complete with enforcement examples—is undertaken.

A. *DOJ's Data-Mining Tactics*

As seen in the ICD investigation, DOJ is increasingly using data mining—in which investigators look for clusters of billing anomalies—to regulate the practice of medicine. In May 2012, following the "largest one-day takedown ever by the government's Medicare fraud task force," HHS Secretary Sebelius said the use of data review would be intensified.[224] "Now, we're analyzing patterns and trends and claims data, instead of just going claim by claim," she

[224] Scott Cohn, *Feds Announce Biggest-Ever Medicare Fraud, Totaling $450 Million*, NBC NEWS (May 2, 2012), http://usnews.nbcnews.com/_news/2012/05/02/11504338-feds-announce-biggest-ever-medicare-fraud-totaling-450-million?lite. Interestingly, some note that the federal government has been rather slow to implement technologies that private insurance has used to ferret out fraud for years. Estimates vary, but it has been estimated that "private insurers lose perhaps 1 to 1.5 percent in fraud," while "Medicare and Medicaid may be closer to 10 to 15 percent." Matthews, *supra* note 6.

said.[225] Inspector General Daniel Levinson—in his testimony to Congress—confirmed the importance of billing records, noting that "medical record reviews" and "analysis of financial and billing data," coupled with other intelligence, often helps agents identify conspirators engaged in a fraudulent scheme.[226]

Granted, on one hand, the practice tool of data mining is a welcome development; through it, government investigators can easily catch a fraudulent scheme in progress. Additionally, it often provides an important inception point for an FCA investigation—when investigators notice an anomaly in the data, resources can justifiably be spent in further investigating those providers. The danger, of course, comes in relying exclusively on data mining. Once the government has the data that a hospital is an "outlier," and sends a letter of investigation, defendants are increasingly incentivized (for reasons explored, *infra* Part VI.C) to settle immediately. This transforms data mining from *a* helpful tool to *the* primary tool used to catch providers and achieve settlement. Allegations based solely on records data result in quick settlement, perhaps with little inquiry into why the hospital's records were outliers in the first place.

An apt example of the power of data mining can be found in the currently ongoing kyphoplasty investigation.[227] Originally initiated by a *qui tam* complaint filed in the Western District of New York,[228] the lawsuit resulted in a $75 million[229] settlement with medical device company Kyphon Inc. (Kyphon), now a part of Medtronic Spine LLC,[230] to settle allegations that the company's

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[225] Matthews, *supra* note 6.

[226] *Anatomy of a Fraud Bust*, *supra* note 111, at 4.

[227] According to the Mayo Clinic, a kyphoplasty is a procedure offered to patients with "compression fractures in the spine." *Vertebroplasty*, MAYO CLINIC, http://www.mayoclinic.org/vertebroplasty/kyphoplasty.html (last visited Apr. 11, 2013) Further, during the procedure:

> a patient undergoing kyphoplasty lies face down. The physician advances a thin tube into the fractured vertebra from an incision in the back. Through the tube, the physician drills a small hole through the hard, outer part of the bone and into its softer center. This provides a pathway for the physician to insert a special balloon into the interior of the vertebra, which is then inflated. This pushes apart the caps, or end plates, of the fractured vertebra, and restores the vertebra to its original shape as much as possible. The balloon is then deflated and removed, leaving a cavity that the physician fills with bone cement.

Id.

[228] *See* First Amended Complaint, United States *ex rel.* Bates v. Kyphon, Inc., No. 05-CV-6568 CJS(f) (W.D.N.Y. Jan. 5, 2006), 2006 WL 6272663 [hereinafter First Amended Complaint].

[229] *See* Press Release, U.S. Dep't of Justice, Medtronic Spine, Formerly Kyphon Inc., to Pay U.S. $75 Million to Resolve Allegations of Defrauding Medicare (May 22, 2008), *available at* http://www.justice.gov/opa/pr/ 2008/May/08-civ-455.html.

[230] Medtronic acquired Kyphon in 2007 for $3.9 billion. It is asserted that the fraudulent marketing scheme increased Kyphon's profits and stock price, ultimately resulting in Medtronic's purchase of the company. *See* Mary Williams Walsh, *Medtronic Settles a Civil*

marketing staff had devised a seven-year scheme to encourage hospitals to perform and bill Medicare for *inpatient* kyphoplasties "rather than less costly and more clinically appropriate *outpatient* kyphoplasty treatment."[231] The *qui tam* relators asserted that "in the vast majority of cases" one-night inpatient hospital stays were not medically necessary for patients receiving kyphoplasty.[232]

After the settlement with Kyphon, the office of the U.S. Attorney for the Western District of New York William J. Hochul started reviewing hospitals' billing records, searching for data that reflected overutilization of inpatient kyphoplasty.[233] The initiative has largely relied on data to find the targets of the investigation, and the "kyphoplasty initiative," as it has become known, has been highly successful for the government.[234] Investigations of individual hospitals have followed a similar pattern: when investigators come upon evidence of abnormally high clusters of inpatient kyphoplasties in a hospital, they send letters to the implicated facilities, "saying that by billing for an impatient stay following a kyphoplasty the hospital knowingly violated the [FCA] and is liable for treble damages and penalties."[235] Accompanying the contact is usually the government's "offer[] to compromise the hospital's liability if it agrees to 'cooperate.'"[236] Upon such cooperation, DOJ has offered to waive the traditional treble liability under the FCA—in favor of double damages.[237] After receiving the letters, hospitals have been undoubtedly willing to negotiate, and the investigations have resulted in an ever-growing number of settlements. Bolstered by waves in May 2009,[238] September 2009,[239] May

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Lawsuit on Allegations of Medicare Fraud, N.Y. TIMES, May 23, 2008, at C1. After sale to Medtronic, Kyphon's top fifteen executives reportedly received about $145 million in options and stock. *See id.*

[231] Press Release, U.S. Dep't of Justice, *supra* note 229.

[232] First Amended Complaint, *supra* note 228, at para. 102.

[233] *See* Kirk S. Davis, *The Increasing Complexity of Health Care Litigation*, ASPATORE, Sept. 2011, at *7, *available at* 2011 WL 4453329.

[234] *See* Steven W. Postal & Robyn Whipple Diaz, *DOJ's Kyphoplasty Initiative: AHA Urges Greater Oversight in the Wake of Continuing Settlement Announcements*, ABA HEALTH ESOURCE (May 10, 2011), http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1105_postal.html (describing and documenting the "kyphoplasty initiative").

[235] Davis, *supra* note 233, at *7.

[236] *Id.*

[237] *See* Letter from Richard J. Umbdenstock, President and C.E.O., Am. Hosp. Ass'n, to Eric Holder, Jr., Att'y Gen., and Kathleen Sebelius, Sec'y, Dep't of Health and Human Servs. (Sept. 7, 2010) [hereinafter September 7 Letter], *available at* www.aha.org/aha/letter/2010/100907-let-HEAT-FCA.pdf.

[238] *See* Press Release, U.S. Dep't of Justice, Minnesota Hospitals to Pay U.S. $2.28 Million to Settle False Claims Act Allegations (May 21, 2009), *available at* http://www.justice.gov/opa/pr/2009/May/09-civ-497.html.

[239] *See* Press Release, U.S. Dep't of Justice, Indiana and Alabama Hospitals to Pay U.S. Over $8 Million to Settle False Claims Act Allegations (Sept. 29, 2009), *available at* http://www.justice.gov/opa/pr/2009/September/09-civ-1030.html.

2010,[240] January 2011,[241] and February 2012,[242] as of the fall of 2012, the initiative had boasted settlements with 40 hospitals nationwide, and had netted more than $39 million.[243] Once settlements are achieved, the attorneys return to the data to find other outliers.

Like the Cleveland Clinic in the ICD enforcement example, Greenville Memorial Hospital in Greenville, South Carolina received a letter from DOJ as part of the kyphoplasty initiative. In response, Greenville Memorial conducted its own internal review, but found no evidence of any wrongdoing.[244] Still, the hospital settled for $1.1 million, because "'investigators told them they had the power to widen their fraud probe far beyond just the spinal-compression surgery if the hospital refused to settle the litigation.'"[245] Although the appropriateness of such a stance taken by DOJ attorneys is questionable,[246] the apparent threats coupled with the devastating penalties mandated by the FCA are proving highly effective in achieving settlement.[247]

Unsurprisingly, the industry's largest trade association, the American Hospital Association (AHA), has repeatedly and clearly objected to both the government's initiative and its tactics surrounding the kyphoplasty investigation. A September 2010 letter from AHA President Richard J. Umbdenstock to U.S. Attorney General Holder and HHS Secretary Sebelius portrayed the "kyphoplasty initiative as the most egregious example" of what it called "DOJ's overly-aggressive enforcement tactics."[248] Noting that the FCA was not meant to apply to "billing errors" or "non-culpable over-utilization,"[249] the AHA alleged that the initial DOJ letter to hospitals "force[d] providers into

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[240] *See* Press Release, U.S. Dep't of Justice, Nine Hospitals in Seven States to Pay U.S. More Than $9.4 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (May 17, 2010), *available at* http://www.justice.gov/opa/pr/2010/May/10-civ-578.html.

[241] *See* Press Release, U.S. Dep't of Justice, Seven Hospitals in Six States to Pay U.S. More Than $6.3 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (Jan. 4, 2011), *available at* http://www.justice.gov/opa/pr/2011/January/11-civ-006.html.

[242] *See* Press Release, U.S. Dep't of Justice, *supra* note 200.

[243] *See id.*

[244] *See* A. Brian Albritton, *Can They Do That? Government Threats to "Come Down and Look Around" to Force Settlement in* Qui Tam *Cases*, 24 HEALTH LAW. 16, 16 (2011).

[245] *Id.*

[246] *See id.* at 16–17 ("While civil government attorneys have broad authority, they cannot simply 'come down and look around' if a hospital does not give in to government settlement demands in a civil *qui tam* action. . . . Hence, a civil government attorney may be subject to discipline by the DOJ for violating a state's rules of professional conduct if he or she threatens to employ government process to 'look around' in areas which are outside the scope of the investigation and for which the attorney does not have cause to investigate.").

[247] *See* Doan, *supra* note 27, at 60 ("Critics have characterized the U.S. government's increased use of the FCA against the healthcare industry as a mechanism 'to bully' providers and to 'inflict a death blow on already struggling healthcare institutions.' . . . Regardless of one's perception, the reality is that the FCA, as employed against unsophisticated healthcare providers, is merciless in its enforcement." (footnotes omitted)).

[248] Postal and Whipple Diaz, *supra* note 234.

[249] September 7 Letter, *supra* note 237.

undertaking expensive and burdensome audits" and required their results to "be turned over to DOJ in order to appear cooperative."[250] Further, Umbdenstock argued that requiring an FCA settlement here was especially wasteful.[251] Finally, "[w]ithout greater oversight from your offices," Umbdenstock continued, "we are concerned that such settlements will be taken as vindication of a theory, and of tactics."[252]

Echoing the AHA, health-care attorneys have recently criticized DOJ for its tactics. Assailing the use of data mining in this way,[253] those in the industry have asserted that federal officials are scrutinizing overnight stays to determine "whether those admissions are medically necessary or if they are simply an unnecessary cost that enhances hospital revenue," a practice some argue is inappropriate for bureaucrats.[254]

Granted, data mining—when coupled with other investigative and information-gathering tactics—is an efficient and important tool. But when the investigation uses data to find outliers, and the information-gathering phase of the investigation is short-circuited in order to achieve quicker settlements, the time for clinical explanation for why the hospital was applying a different standard—a key and determining factor in whether or not fraud occurred—is arrested. The development of the practice standard in overtreatment cases is explored more deeply below.

B. *Freezing the Practice Standard*

Overtreatment cases—in fact, *all* health-care fraud cases—serve as a quick and (relatively) easy way for the federal government to either change or cement the applicable practice standard, which purportedly invades a sacred province typically reserved to physicians and other health-care providers.[255] In

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[250] Postal and Whipple Diaz, *supra* note 234.

[251] *See* September 7 Letter, *supra* note 237.

[252] *Id.*

[253] *See id.*

[254] Kowalczyk, *supra* note 197. "The government has gotten more aggressive in this area, but this is a medical call," a Seattle health care regulatory attorney was recently quoted as saying. *Id.* He continued, "It seems to me for the [U.S.] attorney to weigh in on whether my 80-year-old grandmother needed to be admitted to the hospital, he doesn't know what . . . he is talking about." *Id.*

Others have focused on the importance of independent medical judgment. One attorney highlighted the fact that it is important for the government to understand that the physician has to make an informed medical judgment at the time of admission based on the expected medical treatment and follow-up care. Just because the patient who received the procedure improved and is ready to be discharged—and it turned out to be a short stay—does not mean it was an inappropriate admission. *See id.*

[255] *See, e.g.*, Tine Hansen-Turton et al., *Nurse Practitioners in Primary Care*, 82 TEMP. L. REV. 1235, 1255 (2010) (noting that only nurses have the right to articulate the clinical standard for the nursing profession); Neil Vidmar, *The American Civil Jury for Auslander (Foreigners)*, 13 DUKE J. COMP. & INT'L L. 95, 100 (2003) ("[D]octors, hospitals, and their

overtreatment actions, by investigating and penalizing the provider's decision to administer more care, the government takes the decision out of the hands of the physicians and forces them to do less, not waiting for the likely change to, and development of, the prevailing medical standard.

As a result, the national evolution of this standard—in which physicians and other providers read medical literature and realize that certain procedures can be performed more efficiently or safely—is curtailed. Instead, DOJ uses its investigatory power to allege FCA violations, immediately causing all physicians and providers to either change or cement their behavior. Not only does the government get an opportunity to decide what the requisite standard should be, but it also avails itself of settlement funds from providers and hospitals in order to make up for the retroactively "incorrect" clinical decision made by doctors.

Just like in the quality-of-care context mentioned above, by opening these investigations and leveling these charges, the government is often taking away clinical judgment from health-care providers. But when the government brings allegations in overtreatment cases, it is doing something *very* different than the quality-of-care cases. Here, as shown by the ICD investigation, when the government alleges FCA violations because of overtreatment, DOJ is no longer seeking to ensure care of a *better quality*. Instead, here, the government is applying the fraud statute to cases to *limit* care in which the provider may not know that the care he or she (or it) is providing is too extensive or expensive. A successful initiative, from the government's perspective, will cause physicians and other providers to do *less*—to provide *less* care, *fewer* interventions, and *fewer* inpatient (instead of outpatient) procedures. This is the primary difference between quality-of-care cases and overtreatment cases, and this serves as what can be called "backdoor rationing."[256]

Indeed, in conventional fraud cases, government enforcement results in a change to the practice standard—and often results in limiting care—but does so in a different way. For example, if a group of doctors repeatedly orders unnecessary X-rays of patients' lower backs after patients present with generalized back pain as part of a concerted scheme to increase reimbursement payments, an anti-fraud enforcement action will undoubtedly result in fewer x-rays by those physicians. But ferreting out a group of providers who are offering a clearly unnecessary procedure with the requisite fraudulent intent is a wholly different exercise. A key distinction in overtreatment cases is that the procedure cannot be *universally* characterized as unnecessary without an

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medical insurance companies argue that only doctors are competent to understand the complex medical issues and to determine the appropriate standard of care.").

[256] It is worthwhile to keep in mind that the cases discussed here—the types of overtreatment cases in which the government brings FCA allegations—are cases in which the government, and not private insurance companies, seeks to address a harm. As a result, DOJ's enforcement strategy will likely have an undue effect on hospitals with larger Medicare populations.

examination of key individualized indicators—something that is truncated by DOJ investigations because of the reliance on data mining.

In the overtreatment enforcement model, DOJ finds "culpable" providers by searching for clusters of expensive, questionably medically necessary procedures, and threatens to use the biggest tool in its arsenal against those providers in an effort to change their future behavior at the risk of oversimplifying often highly complex clinical decisions. Compounding the effect is the fact that nearly all of the overtreatment enforcement actions feature procedures with *still-developing* standards of care.[257] Without a well-established standard, this type of enforcement is clearly at odds with allowing medical practice itself to determine which procedures are the most expensive, overused, and unnecessary.[258]

In addition to catching providers who administer new types of care to patients off guard, this enforcement has the effect of cutting off and freezing the development and determination of medical appropriateness of these cutting-edge procedures without clinical input. At this early point, a procedure's details could vary widely among different providers, and an overtreatment enforcement action may unfairly target a number of providers who have a strong and verifiable clinical defense. Worse, these impacted individuals are often the innovators; they are the providers who are pushing the applicable standard forward.

Using the ICD investigation as an example, a provider who places an ICD *within* forty days of a patient's heart attack—which would now be outside Medicare's payment regulations—may have a verifiable clinical reason for why that placement was medically appropriate. And, perhaps, years from now, largely due to that clinician's ICD placements, as well as ever-developing clinical knowledge, the recognized practice standard's outer limit for ICDs could shift to thirty days instead of forty. But an FCA investigation and settlement with a provider hospital would cut off this organic development of the standard. As seen in the ICD context, for many of DOJ "hits," providers allege they have a clinically sound explanation for the way they administered the procedure at issue. This may reflect that the prevailing clinical standard has changed or developed since the last time the government published Medicare guidelines.

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[257] For example, in the ICD investigation, there appears to be clinical debate over whether placement of ICDs in individuals too temporally close to a major cardiac event is appropriate or not. *See* Carlson, *supra* note 202, at 6. In the kyphoplasty initiative, the determination of when and how many kyphoplasties should be performed on an inpatient basis was also still being developed. *See* discussion *infra* Part VI.B.2. After all, the kyphoplasty procedure itself was brand new—only about 1,500 were performed in 2000; 48,000 were performed in 2004. *See* First Amended Complaint, *supra* note 228, at para. 94.

[258] *See supra* note 20 and accompanying text.

1. *Lessons of the "Drive-Through Delivery" Battle*

The peril of government-forced standard setting is poignantly made by the highly publicized and politicized battle revolving around "drive-through" deliveries in the mid-1990s.[259] As a result of this battle, the federal government *mandated* more coverage for treatment for mothers and their newborns. Codified by the Newborns' and Mothers' Health Protection Act of 1996 (Protection Act),[260] insurance companies are now required to cover "at least forty-eight hours of hospitalization following a normal vaginal delivery and ninety-six hours of hospitalization following a Cesarean section."[261] Medicaid is not subject to the same requirement under the law,[262] although some states have instituted similar requirements on their own.[263] Under the law, a provider may, "after consulting with the mother, . . . discharge the mother or newborn child earlier," but "[a] mother cannot be encouraged to accept less than the minimum protections available to her . . . and an attending provider cannot be induced to discharge a mother or newborn earlier than 48 or 96 hours after delivery."[264]

But the public's fervor in favor of passage may not have adequately taken into account the clinical advisability of the new policy. In fact, mandating a longer stay may only have a negligible effect—and maybe even a harmful one—on the health of the mother and newborn. Specifically, "no study has demonstrated *any* statistically significant increase in infant or maternal mortality after a rapid postpartum discharge."[265] Instead, a report on the Protection Act "implicitly criticize[d] the . . . Act for its focus on the number of hours of postpartum hospital care, instead of the needs of the mother and

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[259] The Newborns' and Mothers' Health Protection Act of 1996 gained broad support after highly publicized stories were covered by national media featuring newborns who died "following rapid postpartum discharges." David A. Hyman, *Drive-Through Deliveries: Is "Consumer-Protection" Just What the Doctor Ordered?*, 78 N.C. L. REV. 5, 19 (1999). And it was fueled by a backlash against health management organizations (HMOs), by the senators' personal stories, by passionate and supportive newspaper columns, and even by a speech from First Lady Hillary Rodham Clinton at the Democratic National Convention. *See id.* at 18–24. Simply, public passion and "common sense" pushed through the legislation. *Id.* at 21.

[260] *See* Newborns' and Mothers' Health Protection Act of 1996, Pub. L. No. 104-204, 110 Stat. 2935.

[261] Hyman, *supra* note 259, at 29.

[262] *See id.* at 30 ("[T]he Newborns' Act excludes Medicaid recipients from its protections.").

[263] *See AHCCCS Benefit Changes: Frequently Asked Questions*, ARIZ. HEALTH CARE COST CONTAINMENT SYS. (Mar. 15, 2013), http://www.azahcccs.gov/reporting/Downloads/Legislation/2011/BenefitChanges_FAQs.pdf.

[264] *Fact Sheet: Newborns' and Mothers' Health Protection Act*, U.S. DEP'T LABOR, http://www.dol.gov/ebsa/pdf/newborns.pdf (last visited Aug. 5, 2012).

[265] Hyman, *supra* note 259, at 45.

newborn and . . . the content and quality of the care they receive[d]."[266] According to Professor David Hyman, "there is little or no evidence on the benefit side of the ledger for postpartum stays of the specified length,"[267] while the Protection Act's mandated longer coverage—if taken advantage of by postpartum mothers—could cost as "high as $8 billion per year."[268]

Although the Protection Act was celebrated at passage,[269] its effects may actually be harmful to patients. The support for allowing longer stays in the hospital is particularly striking, given the realization of the dangers unnecessary stays in hospitals pose to patients. Most notably, hospital-acquired infections cause about 100,000 deaths a year, and the numbers for "post-operative bloodstream infections and catheter-associated urinary tract infections" are rising.[270] Although the ACA will penalize hospitals with the highest rates of infection starting in 2015, a recent government report called hospital-acquired infections a problem that "merited 'urgent attention.'"[271] In addition to infections, the Institute of Medicine in its famous 1999 report, *To Err Is Human*, estimated that between 44,000 and 98,000 die each year "as a result of medical errors that could have been prevented"—causing more deaths than "motor-vehicle wrecks, breast cancer, and AIDS."[272] In short, hospitals are frequently not the safest places for relatively healthy individuals to be.

Placing aside the politicized nature of the debate, perhaps Congress should have waited to evaluate the clinical advisability of lengthening hospital stays for mothers and newborns, because it may be likely that clinical judgment in this area was still developing. Instead, because of the hard-law solution, presumably outdated clinical judgment is now codified. The same phenomenon results from overtreatment enforcement strategies that seek to punish the outlier providers for procedures whose standards have not yet fully developed.

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[266] *Id.* at 60 (internal quotation marks omitted).

[267] *Id.* at 67.

[268] *Id.* at 69. Using his own estimate, Professor Hyman argues that the additional hospital stays "have a social cost somewhere between $900 million and $1.8 billion every year." *Id.* at 77.

[269] *See, e.g.*, Debra E. Kuper, *Newborns' and Mothers' Health Protection Act: Putting the Brakes on Drive-Through Deliveries*, 80 MARQ. L. REV. 667, 689 (1997) ("[T]he adoption of the Newborns' and Mothers' Health Protection Act of 1996 is an excellent first step in this still-developing area. New mothers can breathe a sigh of relief now that Congress has properly placed the focus of childbirth, not on an insurance company's bottom line, but on the health and safety of the mother and child.").

[270] *See* Kevin Sack, *Hospital Infection Problem Is Persistent, Study Reports*, N.Y. TIMES, Apr. 14, 2010, at A17 (documenting a study reported by the Agency for Healthcare Research and Quality).

[271] *Id.*

[272] INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1 (1999), *available at* http://www.iom.edu/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf. Notably, the errors were estimated to cost hospitals "between $17 billion and $29 billion per year." *Id.*

2. *Kyphoplasty and Medical-Necessity Ambiguity*

Another example of DOJ's overtreatment enforcement strategy that seeks to solidify a standard in flux can be found in the kyphoplasty initiative—some have worried that DOJ is working to "turn medical-necessity ambiguity into a false claims case."[273] Beyond prompting additional compliance measures, the government's kyphoplasty initiative has been particularly stinging to hospitals, because, according to them, no fraud occurred. Specifically, hospitals argue that they were completely justified in performing inpatient kyphoplasties because frequent federal government guidance at the time reflected that inpatient kyphoplasties were actually medically appropriate.[274]

To bolster their argument, the affected hospitals cite to (1) InterQual's[275] recommendation of inpatient admission for kyphoplasty between 2005 and 2008,[276] (2) CMS's statement in 2008 that it was considering kyphoplasty for an NCD and that "typically, vertebroplasties are performed in an outpatient setting, while kyphoplasty typically requires hospital admission,"[277] (3) the AHA's Coding Clinic's 2004 statement that "kyphoplasty is typically performed in an inpatient setting,"[278] and (4) Medicare auditors' repeated approval of inpatient kyphoplasties as medically necessary as clear indicators that hospitals that performed inpatient kyphoplasties were not committing fraud.[279] The fact that InterQual, a source that has "received implicit government endorsement,"[280] recommended that hospitals conduct kyphoplasties on an inpatient basis is especially informative. DOJ and OIG have relied on InterQual's admissions and medical necessity decisions in the past and have required that facilities use InterQual's expertise through Corporate Integrity Agreements (CIAs).[281] The numerous settlements have resolved allegations that the providers fraudulently overtreated kyphoplasty

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[273] *Feds Widen Investigation of Inpatient Spine Surgery; Site of Service Is Under Dispute*, 18 REP. ON MEDICARE COMPLIANCE, no. 23, June 29, 2009, at 1, 7 [hereinafter KYPHOPLASTY REPORT ON MEDICARE COMPLIANCE].

[274] *See id.*

[275] InterQual is a product line owned by McKesson Health Solutions. *See The Gold Standard in Evidence-Based Clinical Decision Support*, MCKESSON, http://www.mckesson.com/en_us/McKesson.com/Our%2BBusinesses/McKesson%2BHealth%2BSolutions/Solution%2BAreas/InterQual%2BDecision%2BSupport/InterQual%2BDecision%2BSupport.html (last visited Mar. 8, 2013). McKesson calls InterQual "the undisputed gold standard in evidence-based clinical decision support." *Id.* Founded more than thirty years ago, the guidance "can be applied in a range of clinical situations." *Id.*

[276] *See* KYPHOPLASTY REPORT ON MEDICARE COMPLIANCE, *supra* note 273, at 7.

[277] *Id.*

[278] *Id.*

[279] *See id.*

[280] *Id.*

[281] *See id.*

patients between 2000 and 2008[282]—presumably during a time when the kyphoplasty clinical standard was developing, given the conflicting guidance that was published into the middle of the decade.

Still, Robert Trusiak, the chief of the affirmative civil enforcement unit in U.S. Attorney Hochul's office,[283] denies that InterQual has any government endorsement, indicating that "[i]t may be considered for its evidentiary value, but will take a back seat to documentation indicating that a hospital's site-of service decisions 'were made for financial reasons.'"[284] Further, he notes that CMS' NCD notice was not a determination that kyphoplasties should be performed on an inpatient basis; in fact, he notes, "[k]yphoplasty does not appear on Medicare's inpatient-only list."[285] Mr. Trusiak also responded that

> the government will consider the fact that Medicare auditors approved kyphoplasty claims or lost denials on appeal "before deciding [FCA] liability," but again, the driving force in the investigation is whether admissions were reasonable and necessary and patients required the intensity of service "beyond the temporal limits of observation as reflected in the medical record."[286]

Nevertheless, the public will never know if the hospitals truly believed whether their clinical explanations were defensible because of the third factor that distinguishes and impacts overtreatment enforcement: the fact that these cases result in rapid settlements that are not subject to the judicial scrutiny that comes with a trial.

C. *The Consequences of "Settlement-Made Law"*

None of these overtreatment *investigations* ever turn into overtreatment *trials* due to the crushing liability of the FCA,[287] with major implications for the

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[282] *See, e.g.*, Press Release, U.S. Dep't of Justice, *supra* note 240 ("The settlements resolve allegations that the hospitals overcharged Medicare between 2000 and 2008 when performing kyphoplasty . . . .").

[283] *See* KYPHOPLASTY REPORT ON MEDICARE COMPLIANCE, *supra* note 273, at 1.

[284] *Id.* at 7.

[285] *Id.*

[286] *Id.*

[287] *See* Joan H. Krause, Skilling *and the Pursuit of Healthcare Fraud*, 66 U. MIAMI L. REV. 363, 388 (2012) ("As we have seen in other health care fraud contexts, most notably in cases brought under the FCA, the availability of severe penalties significantly increases the odds that defendants will settle rather than take their chances at trial."); Joan H. Krause, *Twenty-Five Years of Health Law Through the Lens of the False Claims Act*, 19 ANNALS HEALTH L. 13, 15 (2010) ("Faced with potential exposure in the tens or hundreds of millions of dollars, it is no wonder that most defendants choose to settle FCA allegations rather than testing their luck at trial."); Krause, *supra* note 8, at 1368 ("[C]ritics now argue that the Act's enormous penalties give health care providers virtually no choice but to settle cases that could not be proven in court, such as allegations based on good faith interpretations of ambiguous health care regulations."); John B. Reiss et al., *Your Business in Court 2007–08*,

legitimacy of DOJ's overtreatment enforcement strategy. As Chief Medical Officer of Rex Healthcare,[288] Dr. Linda Butler—one of the provider entities swept up in the kyphoplasty initiative—said:

> We don't feel like we did anything wrong. We were following rules at the time but *it was probably easier and cheaper to settle* than to fight the government on this. We were performing this procedure on elderly frail patients in their 70s and 80s who were in excruciating back pain and they had a lot of problems like cancer and cardiac issues. Some even spent the night in the ICU due to their frail state. During that time we were following the InterQual third-party billing recommendations to bill this as an inpatient procedure. In 2007 when it was deemed to be an outpatient procedure we began billing it as outpatient. When the government decided to retroactively penalize people who had billed it as inpatient before 2007 we were caught with that. We didn't think we did anything wrong. We think it is unfair, but it was probably better to settle.[289]

Given the FCA's blunt penalties, providers—especially smaller providers[290]—simply cannot risk legal exposure to the FCA at trial. Not only are the providers subject to liability and fines under the FCA, but should they be found liable, they are subject to exclusion from participation in the federal health-care programs[291]—often called the "death penalty" or "death sentence"

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63 FOOD & DRUG L.J. 753, 759 (2008) ("As usual, there are few cases that go to trial when allegations involve the federal FCA because of the draconian penalties that can result.").

[288] Rex Healthcare has multiple wellness center and clinic locations—and one major hospital—in the Research Triangle area in central North Carolina. *See Rex Healthcare Locations*, REX UNC HEALTH CARE, http://www.rexhealth.com/body.cfm?id=866&iirf_redirect=1 (last visited July 23, 2012).

[289] John Commins, *Rex Healthcare to Pay $1.9M to Settle Fraud Claims*, HEALTHLEADERS MEDIA (Apr. 5, 2011), http://www.healthleadersmedia.com/page-1/HEP-264523/Rex-Healthcare-to-Pay-19M-to-Settle-Fraud-Claims (emphasis added).

[290] This risk is particularly potent for smaller providers, as Richard Doan argues:

> Unlike large hospitals, community clinics (and comparable medical providers) do not have the hundreds of thousands, or millions of dollars, needed to adequately defend against FCA suits. They would be forced to quickly capitulate and settle, despite the absence of any meaningful evidence. The alternative, unfortunately, is to face the even stiffer penalties from a negative FCA judgment.

Doan, *supra* note 27, at 63 (footnote omitted).

[291] *See* DEP'T OF HEALTH & HUMAN SERVS., MEDICARE FRAUD & ABUSE: PREVENTION, DETECTION, AND REPORTING 5 (2012), *available at* http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf ("The Inspector General has the authority to exclude individuals and entities who have engaged in fraud or abuse from participation in Medicare, Medicaid, and other Federal health care programs, and . . . maintains a list of excluded parties . . . ."). According to CMS, "[e]xclusion means that, for a designated period, Medicare, Medicaid, and other Federal health care programs will not pay the provider for services performed or for services ordered by the excluded party." *Id.* at 4.

in the industry.[292] As a result, many hospitals and doctors who first receive notice that an investigation has been opened against them have a high willingness to settle. The utility that comes with having a trial—testing theories, examining evidence and intent, and most importantly, learning where the lines are in the gray areas of the law—never occurs. Further, as Professor Krause argues, this gives prosecutors an "unchecked" ability to write the law.[293]

That these cases never reach trial precipitates additional specific consequences in the overtreatment context. Because no defendants are willing to fight the allegations to trial, which would entail business-ending risks, the government is never put to its proofs—in showing fraudulent intent, combatting any provider defenses, or, indeed, any part of the new theory of liability DOJ is espousing. The result, according to Professor Krause, is "an unofficial body of law comprised of legally untested theories of falsity and fraud."[294]

First, as Professor Krause has argued when examining FCA enforcement generally, providers and hospitals are never given an opportunity to argue that they did not have the requisite fraudulent scienter[295]—and judges never make findings regarding the provider's intent.[296] This has been a concern shared by commentators in the field,[297] but applying the FCA in overtreatment cases *compounds* its effect because of the underlying vagueness of the medical appropriateness standard. Hospitals may be blindsided by the government's inquiry—uncomfortably falling under the government's suspicion and investigative focus—and then quickly want to settle the allegations while never truly believing any violation occurred.

Adversely, in conventional FCA cases, fraudulent intent is comparatively easy to demonstrate. This is particularly true in examples in which the provider either "upcodes" the medical bill before submitting it for reimbursement, or in cases in which the provider does not administer the procedure for which he bills. In those scenarios, the individual knows that the procedure for which he or

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[292] *See* Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control* Qui Tam *Litigation Under the Civil False Claims Act*, 76 U. CIN. L. REV. 1233, 1252 (2008) ("Exclusion or debarment can be the equivalent of the death penalty in the health care industry, where much of a provider's business typically is dependent on Medicare reimbursement."); Alex T. Paradiso, Note, *Prosecutorial Regulation of Off-Label Promotion: Sidestepping the Courts and Congress to Levy a Tax on Suspect "Big Pharma" Marketing*, 60 SYRACUSE L. REV. 161, 164 (2009) (calling exclusion from Medicare a "'corporate death sentence' for drug makers").

[293] Krause, *supra* note 8, at 1413 ("Without judicial scrutiny, there is a risk that prosecutors' lawmaking activities will proceed unchecked.").

[294] Krause, *supra* note 32, at 206.

[295] *See supra* note 140 (discussion of requisite intent under the FCA).

[296] *See* Krause, *supra* note 32, at 204 ("While issues of falsity, intent, and preemption receive careful (if not always consistent) treatment by the courts, no such review occurs in a settlement.").

[297] *See, e.g.*, Doan, *supra* note 27, at 74 (expressing concern that the Medicare and Medicaid regulations are so "voluminous" that "reckless disregard" under the FCA is easy to demonstrate).

she seeks reimbursement did not take place and a fraudulent intent is easily established. Assuming negligent or honest mistakes are excluded, by simply completing the act the provider has the requisite fraudulent intent.

The same is true within the quality-of-care context where the government opens an investigation against a provider where the provider *has to know* that he or she is providing substandard care—or the care is so substandard that, by definition, the provider must demonstrate at least "an aggravated form of gross negligence."[298] In quality-of-care cases, it is difficult to imagine a scenario where a provider could be unaware that the patient has been given such inadequate care; the care is so substandard that the health-care professional must know it is occurring. As a result, the provider must also be aware that bills he submits to the government reflect obviously substandard care. But neither is the case in the overtreatment context.

Second, because few trials exist, no provider avails him- or herself of any defense. Adding to the problem is the fact that DOJ intercedes after—sometimes years after[299]—the services at issue have been rendered and paid for. In practice, once the government attorneys find the data anomaly, make the determination that some aspect of the care administered was unnecessary, and open an investigation, the allegations, by their very nature, are serious enough to push the provider toward settlement. Different from conventional scenarios in which the FCA investigatory letter *begins* the investigation that eventually may result in a trial, here the case is sufficiently packaged when the first notice of investigation arrives.

Third, beyond not reviewing just the intent of the provider, a court does not have an opportunity to review *any part* of DOJ's newest theory of liability under the FCA, which, ultimately, stunts development of the FCA itself.[300] Specifically, aggressive new tactics are never reviewed, nor are DOJ's substantive allegations. For example, in quality-of-care cases that arose throughout the late 1990s and early 2000s, jurists—and in particular, the Second Circuit—were careful to cabin the ability of the federal government to penalize health-care providers and entities under the FCA.[301] To do so, the Second

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[298] United States *ex rel.* Burlbaw v. Orenduff, 548 F.3d 931, 945 n.12 (10th Cir. 2008); *see also supra* note 140.

[299] As seen in the kyphoplasty initiative, DOJ is alleging that health care fraud took place between 2000 and 2008—and has settled cases in 2009, 2010, 2011, and 2012. *See supra* notes 238–43.

[300] *See* Krause, *supra* note 32, at 205–06 ("To the extent that settlement removes many factual and legal issues from judicial scrutiny, it precludes a provider from arguing a range of issues that are crucial both to the development of FCA jurisprudence and to the underlying regulatory policy. As one commentator argues, 'many aspects of the law are never litigated and never face the winnowing effects of judicial scrutiny.' . . . So viewed, frequent settlements may be improper not only for their coercive effects on the industry, but also because they stifles [sic] the development of the law." (footnotes omitted)).

[301] *See* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001) ("Since the Act is restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's

Circuit limited the reach of the FCA by allowing enforcement of cases in which the advisability of a *whole* procedure was in question, and dismissed a prominent case in which a *characteristic* of the procedure was arguably substandard, as it did in *Mikes v. Straus*.[302] The court noted that it was especially careful to avoid turning medical regulations into predicates of fraud actions.[303]

In *Mikes*, as aforementioned, pulmonologist Patricia Mikes brought a *qui tam* suit against her employer, Pulmonary and Critical Care Associates.[304] She argued that her bosses failed to appropriately calibrate the spirometer in their office, making the yielded test results incorrect.[305] In a seemingly innovative argument, she alleged that because the testing machinery was not properly calibrated and the test results were incorrect, the medical office submitted claims to Medicare for false claims under the FCA when it billed for administering the test.[306] The court rejected her claims that the defendants engaged in false certification and that the tests were not medically necessary.[307] Upholding the district court's dismissal,[308] the Second Circuit was particularly concerned with preserving the appropriate bounds of the FCA, noting that "courts are not the best forum to resolve medical issues concerning levels of care."[309] To do differently would "promote federalization of medical malpractice," Judge Cardamone wrote.[310] Instead of courts determining appropriate standards of care, the court noted that "[s]tate, local or private medical agencies, boards and societies are better suited to monitor quality of care issues."[311]

But the government's overtreatment investigations ignore the limitation imposed by the Second Circuit in *Mikes*. Instead, in overtreatment cases, the government is unlimited in penalizing specific *characteristics* of the treatment. Seemingly beyond what the *Mikes* court would allow, in overtreatment investigations, the government does not focus on whether a health-care procedure or test is wasteful per se, but may instead look to wasteful *characteristics* of that test or procedure. As illustrated by the kyphoplasty initiative, the government investigates the *inpatient status* of the kyphoplasty, not whether the *entire kyphoplasty procedure* should have occurred in the first

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decision to pay. Accordingly, while the Act is 'intended to reach all types of fraud, without qualification, that might result in financial loss to the Government,' it does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." (citation omitted)).

[302] *See id.* at 687–88.

[303] *See id.* at 699–700.

[304] *Id.* at 692.

[305] *Id.* at 693.

[306] *See id.*

[307] *See Mikes*, 274 F.3d at 693.

[308] *See id.* at 706.

[309] *Id.* at 700.

[310] *Id.*

[311] *Id.*

place. Similarly, in the ICD investigations, the question is whether the timing of the placement of the ICD was appropriate—again, a component or *characteristic* of the procedure. In *Mikes*, at issue was not whether the spirometry tests should have been administered; instead, the discussion revolved around whether the machine was calibrated to output correct results.[312] This distinction was dispositive for Ms. Mikes' case, but is the central point of investigation in both the kyphoplasty and ICD investigations.[313]

Finally, future providers are shortchanged by overtreatment enforcement because the guidance they receive—and the frozen clinical standard to which they are subjected—results not from clinical decision-makers nor court-made precedent, but individual settlements. More investigations open,[314] more defendants settle, Congress and the President hail the work of the tireless taxpayer defenders, and the process restarts—all the while leaving legal commentators, compliance officers, and providers largely unclear on what behavior must be avoided in order to protect against the sharp penalties of the FCA. At bottom, as Professor Krause has argued, this may have damaging results on the relationship between providers and the federal health-care programs, especially during a time of change, when a lack of cooperation seems especially injurious.[315] Indeed, as she notes, "[w]ithout a limiting principle to restrain overuse of the FCA . . . there is a danger that the health care provider community will come to believe that the law is being applied in an unfair and inconsistent manner," which would "likely lead to further industry noncompliance, necessitating the use of even more coercive enforcement mechanisms."[316]

D. *The Cumulative Effect*

An over-reliance on data mining, an effort to enforce and cement dynamic standards of care based on medical appropriateness distanced from clinical

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[312] *See id.* at 699 ("This statutory design supports the conclusion that the medical necessity for a procedure and its quality are distinct considerations. Inasmuch as Mikes challenges only the quality of defendants' spirometry tests and not the decisions to order this procedure for patients, she fails to support her contention that the tests were not medically necessary.").

[313] In the ICD investigation, the key consideration appears to be the timing of the procedure. *See supra* notes 208–11 and accompanying text. The kyphoplasty investigation is focused exclusively on whether the procedure should have been done on an inpatient or outpatient basis, not whether the procedure should have ever been done. *See supra* notes 233–35 and accompanying text.

[314] *See* Yeung, *supra* note 5. In 2011, the number of new federal health care fraud prosecutions skyrocketed 68.9 % from 2010, which had previously set a record for the most new cases in a year. *See* Syracuse Univ., *Record Number of Federal Criminal Health Care Fraud Prosecutions Filed in FY 2011*, TRAC REPS. (Dec. 14, 2011), http://trac.syr.edu/tracreports/crim/270/.

[315] *See* Krause, *supra* note 32, at 127–28.

[316] *Id.*

practice, and highly damaging FCA penalties result in harmful consequences to America's quality of care. By going after overtreatment through the FCA, DOJ sacrifices a holistic approach that would instead target the root causes of overtreatment. Although on their own the factors produce effects that seem unfair and unclear to individual providers, the most damning effect of the overtreatment enforcement model could be that it stifles innovation among providers—actors that patients expect to be aggressive and creative problem solvers.

Of course, using the example of the ICD investigation, DOJ may catch some individuals who knowingly and wrongly placed ICDs in patients who were not the appropriate candidates. Studies that focused DOJ attention on the procedures in the first place reached this conclusion.[317] Similarly, in the kyphoplasty initiative, there may be settling hospitals that were influenced by Kyphon's marketing teams and performed more inpatient kyphoplasties as a result.[318] Providers who engage in non-clinically supportable treatment will have their behavior altered.

But there are other providers who may get caught in the overtreatment enforcement model. Above all, the group of providers who innocently administer what the government alleges is overtreatment is made up of individuals who either: (1) practice in an inefficient or outdated way, or (2) practice in an innovative, clinically advanced manner who are *ahead* of the developing medical standards. Neither set of providers should be subject to the FCA—a statute intended for actors who defraud the government.

The first set, those who practice in an inefficient or outdated way, need increased information and training in order to gain exposure to more advanced and efficient techniques. Perhaps they just need an impetus to update their outdated techniques—like the challenge from Dr. Brody, which has spurred clinical changes in numerous specialties.[319] For this group, application of the FCA would seem illegitimate and particularly draconian; sure, the government may achieve its goal of updating the physician's technique, but the physician did not knowingly submit a false claim to the government. Indeed, there are ways to change behavior that do not involve DOJ's investigatory powers.

The second set of individuals—those who practice in an innovative or clinically advanced manner—are also caught by DOJ's overtreatment enforcement model. This phenomenon is best exemplified by the ICD investigation. Assuming there are clinically defensible and medically appropriate ICD placements that do occur outside of the bounds of the Medicare regulations, the providers who place the ICDs outside of the guidelines comparatively constitute a more risk-averse and more clinically innovative group than the providers who do not place ICDs outside of the guidelines.[320]

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[317] *See* Carlson, *supra* note 202; Rice & Falco, *supra* note 207.

[318] *See supra* notes 227–47 and accompanying text.

[319] *See* Brody, *supra* note 20, at 284.

[320] *See* fig.1.

These may be the practitioners at the Cleveland Clinic; this is the group of individuals who actually push the clinical standard forward. DOJ overtreatment investigations stifle this development. Perhaps—as may be the case in the ICD context—the bureaucratic standard has not caught up to the quickly developing standard in the field.

Instead of impacting individuals who may be engaged in defrauding the government by intentionally practicing overtreatment, the DOJ overtreatment enforcement model has the possibility of sweeping up these other providers as well.

Figure 1: *The Impacts of Overtreatment Investigations*

→ PROVIDERS INCREASINGLY COMFORTABLE WITH RISK OF ADVERSE CARDIAC EVENT →		
	More Averse to Risk	**More Comfortable with Risk**
→ INCREASINGLY CLINICALLY INNOVATIVE PROVIDERS →	Providers placing ICDs outside of the Medicare guidelines **Caught in overtreatment investigation**	*May be caught in overtreatment investigation*
	May be caught in overtreatment investigation	Not likely to place an ICD in a patient outside of the Medicare guidelines **Not caught in overtreatment investigation**

Going beyond taking development of the clinical practice standards out of the hands of providers, these investigations create the real possibility of freezing the most innovative of providers and cementing a medical appropriateness standard that does not adequately reflect clinical realities.

Granted, there may be a claim to be made that physicians either should not place ICDs within forty days of a heart attack, or if they do, they should not bill for them—as the practice is in contravention of Medicare's NCD guidance. The same concern could be raised in the kyphoplasty initiative: physicians should not be admitting patients after the procedure, perhaps citing the risk of medical

error one faces while in the hospital.[321] And perhaps some of those arguments, in certain circumstances, are defensible.

But perhaps the enforcement answer should be a fact-specific, well-targeted, and clinically influenced regulation, not a 150-year-old statute. Usage of the FCA—an initially military-minded anti-fraud statute that now carries "death penalties" with it for health-care providers—that results in either (1) preventing innovative physicians from offering procedures for certain patients they believe best, or (2) forcing providers—who, after consulting clinical judgment, conclude the procedure is appropriate—to not seek reimbursement as to avoid any potential governmental investigation, adversely impacts health-care quality. Instead of treating overtreatment as a challenging but separate problem from conventional health-care fraud, the federal government has sought to link the two—with damaging consequences for the quality of American health care.

VII. CONCLUSION

As America continues to pay a comparatively astronomical cost for health care for its citizens, the law must play an important and coherent role in cutting costs, ensuring quality, and shaping behavior. An aggressive U.S. Attorney's office, catastrophic statutory penalties, and cutting-edge technologies and procedures create formidable challenges in the regulation and penalization of health-care overtreatment.

Even though DOJ has applied the powerful FCA to overtreatment cases without missing a beat, the consequences of such an enforcement model must be examined in a critical way. Seeking to curtail spiraling health-care costs is an endeavor that cannot be avoided sooner or later, but by applying the most powerful anti-fraud statute to overtreatment cases, DOJ is providing nothing but a piecemeal, person-by-person strategy without addressing any of the root causes of America's overtreatment problem.

In addition to focusing on small and specific areas of overtreatment, DOJ's actions smack of an illegitimate enforcement model—one in which the odds are unfairly stacked against providers. The overtreatment initiatives often impact and penalize the wrong providers, freeze clinical standards without judicial or clinical input, and ultimately stifle innovation and development of our understanding of medical appropriateness. Indeed, this marks a new and confusing era in health-care fraud enforcement—one in which enforcement initiatives multiply, all seeking to target the providers who merely care too much.

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[321] *See* INST. OF MED., *supra* note 272, at 1.