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**ENFORCEMENT OVERDOSE: HEALTH CARE FRAUD  
REGULATION IN AN ERA OF  
OVERCRIMINALIZATION AND OVERTREATMENT**

ISAAC D. BUCK\*

ABSTRACT

*In an effort to address the growing problem of “overtreatment” in American health care, the federal government has turned to its 150-year-old statute, the civil False Claims Act (“FCA”) to prosecute providers who do too much. Lacking many of the traditional hallmarks of conventional health care fraud scenarios, this new enforcement framework features cases in which the government alleges that a provider is administering health care that is inefficient, too costly, or unnecessary. As I have argued before, in addition to ensnaring “innocent” providers, this regulatory regime allows the federal government to both (1) freeze practice standards by arresting their natural evolution and (2) unilaterally limit care by engaging in what can be called “backdoor rationing.” In addition to largely shutting out the medical community during these initiatives, this chosen enforcement framework’s failures are compounded by the fact that the real causes of overtreatment—deep, structural challenges—are left largely unaddressed by the government’s investigations.*

*This Article builds upon my previous scholarship by firmly situating the regulation of overtreatment within the robust scholarship of enforcement literature. After examining overcriminalization and overenforcement, this analysis argues that unique factors characterizing the enforcement of overtreatment—the existence of a widely applicable and powerful statute in the FCA, political pressure, and fi-*

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\* Assistant Professor, Mercer University School of Law; JD, University of Pennsylvania Law School; Master of Bioethics, University of Pennsylvania; Bachelor of Arts, Miami University (Ohio). Thanks, as always, to Michelle, Audrey, and Lucy.

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*nancial reward to increase the number of health care fraud investigations—and comparatively easy resolution of allegations that result in lucrative settlement without litigation put the enforcement framework at risk for overuse. And like other regimes susceptible to overenforcement or overcriminalization, the regulation of overtreatment is highly reliant on prosecutorial discretion in determining both the targets of and penalties for alleged overtreatment violations.*

*A framework susceptible to disorder ensues. Such a regime risks provider buy-in, resulting in increased tension between the medical profession and the prosecutors tasked with regulating it. Most starkly, whether the enforcement framework actually nets the “worst” actors or not remains an unanswered question. By identifying the FCA’s enforcement mechanisms most at risk to overuse, this piece seeks to recalibrate the federal government’s chosen strategy to regulate health care fraud, injecting much-needed consistency to improve what scholars have called the chaotic, unfair, and disordered framework that currently characterizes health care fraud enforcement.*

## INTRODUCTION

The Department of Justice’s (“DOJ”) overtreatment enforcement strategy—characterized by pursuing and prosecuting providers who provide care that is allegedly unnecessary, inefficient, or too expensive—naturally coincides with a time of unprecedented challenge and change for health care administration in this country. Most notably, although politically battered<sup>1</sup> and judicially reshaped,<sup>2</sup> the Patient

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1. By the summer of 2013, Republicans in the House of Representatives had voted forty times to repeal either part of, or all of, the Patient Protection and Affordable Care Act of 2010 (“ACA”). See Sam Baker, *Week Ahead: ObamaCare Repeal Vote No. 40 Looms in House*, THE HILL (July 29, 2013), <http://thehill.com/blogs/healthwatch/health-reform-implementation/313967-week-ahead-obamacare-repeal-vote-no-40-looms-in-house>. Further, the public continues to be skeptical of the law. As of June of 2013, only thirty-seven percent of respondents of an NBC News/Wall Street Journal poll thought the ACA was “considered a good idea,” while forty-nine percent thought the ACA was “a bad idea.” See Tal Kopan, *Poll Finds Low Support for Obama-care*, POLITICO (June 6, 2013), <http://www.politico.com/story/2013/06/obamacare-poll-92322.html> (noting that “Obamacare is more unpopular than ever”). A year before, in July 2012, forty percent of respondents to the same poll said the ACA was a good idea, whereas forty-four percent answered that it was a bad idea. See Mark Murray, *Health Care Law’s Unpopularity Reaches New Highs*, NBC NEWS (June 5, 2013), [http://firstread.nbcnews.com/\\_news/2013/06/06/18781204-health-care-laws-unpopularity-reaches-new-highs?lite](http://firstread.nbcnews.com/_news/2013/06/06/18781204-health-care-laws-unpopularity-reaches-new-highs?lite).

Protection and Affordable Care Act of 2010 (“ACA”) limps toward full implementation with varying degrees of state support<sup>3</sup> while suffering from constant attacks from the political right<sup>4</sup> and self-imposed implementation spasms.<sup>5</sup> Just as newsworthy, however, are the multifaceted cost crises plaguing health care administration and delivery in the United States—crises that, in effect, precipitated the passage of the ACA. Although slowing,<sup>6</sup> health care expenditures continue to

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2. See Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2608 (2012) (upholding the law as rooted in Congress’s taxing and spending power but eliminating the Medicaid expansion requirement in the law).

3. By late May of 2013, only seventeen states had decided to implement their own state-based insurance exchange; an additional seven had decided to implement some sort of partnership with the federal government. *State Decisions for Creating Health Insurance Marketplaces*, THE HENRY J. KAISER FAMILY FOUND. (May 28, 2013), <http://kff.org/health-reform/state-indicator/health-insurance-exchanges/#map>.

By March of 2014, twenty-seven states (including the District of Columbia) had decided to expand their Medicaid programs, while twenty-four states—largely centered in the South—had decided to decline expanding their Medicaid programs. “Open debate” existed in five states. See *The Coverage Gap: Uninsured Poor Adults in States That Do Not Expand Medicaid*, THE HENRY J. KAISER FAMILY FOUND. (May 31, 2014), <http://kff.org/medicaid/issue-brief/analyzing-the-impact-of-state-medicaid-expansion-decisions/>. As of Aug. 28, 2013, another source noted that twenty-seven states and the District of Columbia were moving toward expansion. *Medicaid Expansion Map*, AMERICAN HEALTH LINE (Aug. 28, 2014), <http://www.americanhealthline.com/Analysis-and-Insight/Infographics/Medicaid-Expansion-Map>.

4. House Republicans voted to repeal forty times by the summer of 2013. See *supra* note 1 and accompanying text. Late in July of 2013, Senate Republicans were “coalescing around a proposal to block any government funding resolution that includes money for the implementation of the 2010 Affordable Care Act.” Alexander Bolton, *Government Shutdown Looms over Obama Care*, THE HILL (July 23, 2013), <http://thehill.com/homenews/administration/312727-shutdown-looms-over-obamacare>.

5. See Robert Pear, et al., *From the Start, Signs of Trouble at Health Portal*, N.Y. TIMES (Oct. 12, 2013), [http://www.nytimes.com/2013/10/13/us/politics/from-the-start-signs-of-trouble-at-health-portal.html?\\_r=0](http://www.nytimes.com/2013/10/13/us/politics/from-the-start-signs-of-trouble-at-health-portal.html?_r=0) (“For the past 12 days, a system costing more than \$400 million and billed as a one-stop click-and-go hub for citizens seeking health insurance has thwarted the efforts of millions to simply log in.”); see also Jonathan Allen, *Official Who Led HealthCare.gov Rollout Steps Down*, POLITICO (Dec. 30, 2013), <http://www.politico.com/story/2013/12/healthcaregov-rollout-official-steps-down-101607.html> (describing the ACA website rollout as “botched”).

6. Kelly Kennedy, *White House Touts Slow Increase in Health Care Costs*, USA TODAY (July 29, 2013), [www.usatoday.com/story/news/politics/2013/07/29/administration-lowered-premiums-white-house/2596453/](http://www.usatoday.com/story/news/politics/2013/07/29/administration-lowered-premiums-white-house/2596453/) (noting that a May of 2013 Congressional Budget Office report “showed a \$618 billion drop in projected Medicare and Medicaid spending over the next decade” and a recent Department of Health and Human Services report showed that employer-based insurance premiums rose only three percent from 2011 to 2012—“the lowest increase since 1996”); see Chris Fleming, *New Health Affairs Issue: Will the Health Care Spending Growth Slowdown Last?*, HEALTH AFFAIRS BLOG (May 6, 2013), <http://healthaffairs.org/blog/2013/05/06/new-health-affairs-issue-will-the-health-care-spending-growth-slowdown-last/> (noting that a “record slowdown in growth” occurred between 2007 and 2011); Kenneth Kaufman & Mark Grube, *The Slowing of Health Care Spend-*

rise,<sup>7</sup> and the ultimate impact of the ACA's wholesale changes remains largely unknown.<sup>8</sup>

Distinct from the access-securing focus of the ACA, one of the major root causes of the cost crisis in American health care is what I and author Shannon Brownlee have referred to as *overtreatment*.<sup>9</sup> Defined as inefficient, unnecessary, or overused medical procedures and services, overtreatment occurs as a result of America's structural inefficiencies and upside-down incentives that encourage health care professionals to constantly provide more—and more expensive—health care.<sup>10</sup>

In addition to a legislative solution in the ACA, the federal government has responded to the problem of health care expenditure growth with a renewed focus on prosecuting and preventing health care fraud, in which it—through federal prosecutors at the DOJ—seeks liability for individual providers and hospitals under intent-based civil fraud statutes like the federal civil False Claims Act (“FCA”).<sup>11</sup> The DOJ has now sought to apply the FCA to cases of overtreatment, asserting that, in many cases, the provision of more or more expensive services by itself constitutes health care fraud.

Using available federal statutes to prosecute those who unjustly siphon money from federal health care programs appears to be a rational way to put money back into the Medicare trust fund, even if the data show that only a fraction of total health care waste in the system

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*ing: Have We Turned a Corner?*, HEALTH AFFAIRS BLOG (Aug. 9, 2013), [http://healthaffairs.org/blog/2013/08/09/the-slowng-of-health-care-spending-have-we-turned-a-corner/?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=the-slowng-of-health-care-spending-have-we-turned-a-corner](http://healthaffairs.org/blog/2013/08/09/the-slowng-of-health-care-spending-have-we-turned-a-corner/?utm_source=rss&utm_medium=rss&utm_campaign=the-slowng-of-health-care-spending-have-we-turned-a-corner) (noting that in 2011, overall health care spending increased 3.9%, down from a high of 11% in 1990 and even 7.6% in 2007).

7. See Eduardo Porter, *A World of Rising Health Care Costs*, N.Y. TIMES ECONOMIX (June 27, 2013), <http://economix.blogs.nytimes.com/2013/06/27/a-world-of-rising-health-care-costs/>.

8. See Thomas Daschle & Bill Frist, *Technology and the Changing Business of Health Care*, HEALTH AFFAIRS BLOG (Aug. 14, 2013), <http://healthaffairs.org/blog/2013/08/14/technology-and-the-changing-business-of-health-care/> (noting the ACA's goal of cost-cutting through a focus on quality-based reimbursement, accountable care organizations, and patient-centered medical homes).

9. See SHANNON BROWNLEE, *OVERTREATED: WHY TOO MUCH MEDICINE IS MAKING US SICKER AND POORER* (2007); Isaac D. Buck, *Caring Too Much: Misapplying the False Claims Act to Target Overtreatment*, 74 OHIO ST. L.J. 463, 465–66 (2013).

10. See *supra* note 9.

11. As an example, in 2011, health care fraud prosecutions rose to 1,235, a rise of 69% from 2010 (when there were 731 prosecutions). See *Record Number of Federal Criminal Health Care Fraud Prosecutions Filed in FY 2011*, TRAC REPORTS (Dec. 14, 2011), <http://trac.syr.edu/tracreports/crim/270/>.

is a result of health care fraud.<sup>12</sup> Granted, every little bit helps, and with fraud prevention and prosecution constituting a lucrative<sup>13</sup> and universally politically popular investment for the federal government in an era of tight budgets and partisan gridlock,<sup>14</sup> this tougher stance on fraud and abuse shows no signs of abating.

But even if the federal government's chosen course of action is rational, lucrative, and politically popular, it should not escape in-depth legal and policy-based review. Penalizing overtreatment through application of the FCA has become common, but legal scholarly critique of the phenomenon has not occurred in earnest. In a previous piece,<sup>15</sup> I highlighted potential practical concerns with the federal government's approach—specifically, that pursuing providers engaged in overtreatment in this way may over-capture those providers administering clinically beneficial care. Results of this over-capture could be detrimental to quality of care and may stoke provider distrust of the law, pushing all providers into damagingly believing the regulatory framework is unpredictable, unguided, and unrestrained.<sup>16</sup>

But beyond the practical impact overtreatment enforcement initiatives may have on clinical care,<sup>17</sup> this Article advances the analysis by examining the overtreatment enforcement framework's particular susceptibility to overenforcement. By filling a gap in current scholarship, this piece seeks to place the regulation of overtreatment within

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12. See *infra* note 86–87 and accompanying text; see also PIERRE L. YONG & LEIGHANNE OLSEN, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY 51–52 (2010).

13. See Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay \$3 Billion in Fraud Settlement*, N.Y. TIMES (July 2, 2012), <http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html>? (“The Justice Department contends the prosecutions are well worth the effort—reaping more than \$15 in recoveries for every \$1 it spends, by one estimate”). Other estimates are lower. See Press Release, U.S. Dep’t of Health & Human Servs., Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud (Feb. 26, 2014), <http://www.hhs.gov/news/press/2014pres/02/20140226a.html> (noting that “for every dollar spent on health care-related fraud and abuse investigations through this and other programs in the last three years, the government recovered \$8.10”).

14. See Paul J. Larkin, Jr., *Public Choice Theory and Overcriminalization*, 36 HARV. J.L. & PUB. POL’Y 715, 731–32 (2013) (explaining that being tougher on crime “costs legislators nothing and garners them political capital”).

15. See Buck, *supra* note 9.

16. See Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 210 (2001).

17. See Buck, *supra* note 9.

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the rich literature of overcriminalization and overenforcement in an effort to identify the stark challenges that may accompany the DOJ's settlement-driven approach.

Unique factors—such as the uncommon breadth of the FCA, its ease of applicability, and the lucrative investment for the government—make fraud enforcement actions attractive for federal prosecutors. And because *proving* a health care fraud case at trial is inherently difficult, prosecutors rely nearly exclusively on achieving settlement with targeted providers. Without the purifier of trial, and with no real limiting force, the result is a regulatory strategy that is susceptible to being overused and over-applied. This precipitates an enforcement framework that not only over-captures individual providers, but fails to appropriately differentiate providers whose misconduct and individual level of culpability varies.

This Article will proceed in five parts. Part I will examine the literature on overenforcement and overcriminalization in an effort to provide doctrinal footing for a meaningful review. In particular, Part One will identify the concerns associated with “random enforcement” and “definitional spillover.” Part II will summarize the modern overtreatment enforcement regime, complete with a presentation of the nationwide investigation that best illustrates the DOJ's enforcement strategy. Part III will examine the FCA, the DOJ's primary tool in enforcing overtreatment, with a particular focus on the parts of the law that allow for potentially disordering inconsistencies in its application. Part IV will highlight specific application-based challenges within the settlement-based regulatory framework that make it susceptible to overenforcement and disarray. Finally, in Part V, the article will begin the conversation toward an improved framework focused on the inclusion of clinical expertise within the legal regime.

Ultimately, this Article seeks to recalibrate the enforcement mechanism in an effort to alleviate the medical and legal tension that currently characterizes health care fraud regulation. At bottom, it attempts to bring the two equally-important, but often conflicted, regimes of law and medicine into harmony during this critical time for health care administration and delivery in the United States.

## I. REGULATORY FEVERISHNESS

The tenets of overenforcement and the related doctrine of overcriminalization can provide key insights and cautionary warnings for those tasked with regulating health fraud. Even though a number of writers have focused their scholarship on overcriminalization in re-

cent years<sup>18</sup>—in particular analyzing whether the criminal sanction is appropriate in certain contexts—the instant analysis seeks to avoid focusing on the moral effects of an ever-expanding modern criminal law. Indeed, the FCA—the DOJ’s chosen tool for regulating over-treatment—is a civil statute, and many of the protections that are afforded criminal defendants do not translate to the civil context. Nevertheless, overcriminalization theory is helpful to the analysis for its doctrinal value and will be consulted where relevant. In addition to examining the causes and consequences of overenforcement and overcriminalization, this analysis will present the challenges of “random” enforcement.

*A. Overenforcement and Overcriminalization*

Generally, overenforcement has been a focus of scholars in disparate areas of the law, from securities regulation,<sup>19</sup> to criminal copyright laws,<sup>20</sup> to antitrust,<sup>21</sup> to law enforcement officers’ regulation of protestors.<sup>22</sup> Professor Dayna Bowen Matthew has noted a particularly applicable point that the qui tam provisions<sup>23</sup> in the FCA can lead to overenforcement of the statute in the pharmaceutical fraud context.<sup>24</sup> She notes that “[t]he availability of private enforcers creates significant opportunities for public prosecutors to overenforce.”<sup>25</sup>

Overenforcement has been defined as occurring “when the violator of a legal rule suffers excessive harm—or more harm than is necessary for optimal deterrence—from the actual implementation of

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18. See, e.g., Stuart P. Green, *Why It’s a Crime to Tear the Tag off a Mattress: Overcriminalization and the Moral Content of Regulatory Offenses*, 46 EMORY L.J. 1533 (1997); Erik Luna, *The Overcriminalization Phenomenon*, 54 AM. U. L. REV. 703 (2005).

19. See James J. Park, *Rule 10B-5 and the Rise of the Unjust Enrichment Principle*, 60 DUKE L.J. 345, 409 (2010); Amanda M. Rose, *Reforming Securities Litigation Reform: Restructuring the Relationship Between Public and Private Enforcement of Rule 10b-5*, 108 COLUM. L. REV. 1301 (2008).

20. See Geraldine Szott Moohr, *Defining Overcriminalization Through Cost-Benefit Analysis: The Example of Criminal Copyright Laws*, 54 AM. U. L. REV. 783, 785 (2005) (defining overcriminalization as “when the costs of treating conduct as a crime exceed the benefits of the new criminal law”).

21. See Warren F. Schwartz, *An Overview of the Economics of Antitrust Enforcement*, 68 GEO. L.J. 1075 (1980).

22. See Alafair Burke, *Policing, Protestors, and Discretion*, 40 FORDHAM URB. L.J. 999, 1002 (2013).

23. See 31 U.S.C. § 3730(b)(1) (2012).

24. For analysis of how the qui tam provisions of the FCA cause overenforcement, see Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281 (2007).

25. *Id.* at 282.

that rule.”<sup>26</sup> Granted, “any enforcement system mistakenly treats some nonviolators as violators and subjects them to sanctions,”<sup>27</sup> but “excessive sanctions produce overenforcement—a level of enforcement at which the costs of deterrence marginally exceed its benefits.”<sup>28</sup>

Whereas overenforcement relates to a characteristic of an enforcement mechanism or general penalty, overcriminalization focuses on overbroad statutes that criminalize allegedly non-culpable or harmless behavior. Overcriminalization applies to instances in which laws “impos[e] penal sanctions on conduct that should be solely a matter of individual morality” or “perhaps left to the good sense of the individual.”<sup>29</sup> Further, it may “punish conduct that traditionally would not be deemed morally blameworthy”<sup>30</sup> at all.

More broadly, overcriminalization can include “what should be denominated as a crime and when it should be enforced; who falls within the law’s strictures or, conversely, avoids liability altogether; and what should be the boundaries of punishment and the proper sentence in specific cases.”<sup>31</sup> The modern proliferation of federal criminal statutes<sup>32</sup> has fed arguments that Congress has excessively expanded the criminal sanction to regulate activities and govern situations where it does not belong.<sup>33</sup>

### 1. *The Drivers of Overenforcement*

Scholars note that the causes of overenforcement and overcriminalization are rooted in congressional halls and American newsrooms; the worst actors in a given industry drive the regulatory machinery by grabbing the attention of the lawmakers and news media.<sup>34</sup> One scholar states:

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26. See Richard A. Bierschbach & Alex Stein, *Overenforcement*, 93 GEO. L.J. 1743, 1744 (2005).

27. Tamar Frankel, *Implied Rights of Action*, 67 VA. L. REV. 553, 573 (1981).

28. *Id.*

29. See Sara Sun Beale, *The Many Faces of Overcriminalization: From Morals and Mattress Tags to Overfederalization*, 54 AM. U. L. REV. 747, 748 (2005).

30. See Larkin, *supra* note 14, at 719.

31. See Luna, *supra* note 18, at 713.

32. See Larkin, *supra* note 14, at 725–26 (noting numbers of statutes).

33. See, e.g., Green, *supra* note 18, at 1535.

34. See, e.g., Margaret H. Lemos & Max Minzner, *For-Profit Public Enforcement*, 127 HARV. L. REV. 853, 859 (2014) (noting that “public enforcement may sometimes be overzealous, particularly when politicians react to well-publicized scandals”).



Cognitive errors and biases tend to support a one way ratchet toward the enactment of additional crimes and harsher penalties. . . . These errors and biases lead people to recall media accounts of serious crimes, to overestimate their frequency, and to jump to the conclusion that additional harsher laws are needed. These flames are fanned by the news media, which has an economic incentive to portray violent crime in news programming as well as entertainment programming.<sup>35</sup>

Where media outlets “fan the flames” that stoke harsher laws, Congress converts the public outcry into codified law.<sup>36</sup> This is a rather uncontroversial move for politicians to make, especially in the face of charges that they fail to compromise on just about anything.<sup>37</sup> Toughening penalties against wrongdoers becomes an opportunity for increasingly rare unifying legislative activities and “ready-made publicity stunts.”<sup>38</sup> Indeed, “[c]onventional wisdom suggests that appearing tough on crime wins elections regardless of the underlying justification.”<sup>39</sup>

The political calculus leads Congress to a rather easy solution that is aided by two powerful factors. First, “prosecutors are especially effective lobbyists for criminal law expansion,”<sup>40</sup> often driving the bills across the finish line, and second, no opposing public interest groups push against stiffening penalties.<sup>41</sup> As has been noted, those concerned about overcriminalization argue that legislators enact additional “statutes that criminalize conduct that most people believe to be innocent, innocuous, or trivial,”<sup>42</sup> and an ever-expanding statutory framework results. Consequently, “[t]he politics of crime are peren-

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35. See Beale, *supra* note 29, at 773 (footnote omitted).

36. See Darryl K. Brown, *Democracy and Decriminalization*, 86 TEX. L. REV. 223, 232 (2007) (noting that “majority preferences lean strongly and consistently in favor of expanded offenses and more severe punishment”).

37. The Fraud Enforcement and Recovery Act, which recently extended liability under the FCA, passed the Senate by a vote of 92–4, and the House by a vote of 367–59. MICHAEL TABB, GREENE LLP, THE IMPACT OF 2010 HEALTH CARE LEGISLATION ON FALSE CLAIMS ACT LITIGATION 1 & n.2 (2013), available at <http://www.greenellp.com/wp-content/uploads/2011/04/Michael-Tabb-PPACA-Amendments.pdf>.

38. See Luna, *supra* note 18, at 719.

39. *Id.*

40. Brown, *supra* note 36, at 232.

41. *Id.* at 223.

42. *Id.* at 229.

nially perverse”<sup>43</sup>—there is simply no political incentive to think twice about expanding anti-crime statutes.

That is not to say all laws have boundless reaches. Within regulatory regimes, Congress has attempted to steer enforcers toward the worst actors by limiting application of powerful statutes to the most culpable actors. For example, within the white collar crime context, two showings—that of fraudulent scienter and a specific finding of harm—have been said to be generally “necessary to curb the injustice of overcriminalization.”<sup>44</sup> However, like the health care fraud context, in white collar criminal prosecutions scienter is generally difficult to prove,<sup>45</sup> and prosecutors often lack demonstrative evidence of fraudulent intent.<sup>46</sup> The same problem exists in identifying tangible harm, which leads to the development of a spiraled broadening of the law’s applicability.<sup>47</sup>

These difficulties in ascertaining and proving harm result in Congress drafting statutes with uncertain scienter requirements, criminalizing vague and ambiguous harms so as to potentially encompass a broad array of conduct. Congress thereby lets prosecutors determine what conduct to criminalize. Such statutes shift Congress’s legislative crime-making power to prosecutors and courts. They also facilitate criminalizing conduct in hindsight . . . . When Congress does not set minimum guidelines to govern law enforcement, there is no limit to the conduct that can be criminalized.<sup>48</sup>

As such, an inability to satisfy the required points of proof leads to a softening of those requirements, and, as a result, Congress cedes more and more power over the enforcement framework to federal prosecutors by writing vaguer laws.<sup>49</sup> This allows politicians “to appear tough on crime” while making sure they “avoid blame when laws do

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43. *Id.* at 223.

44. See Wesley Burrell, *The Right-to-Honest-Services Doctrine—Enron’s Final Victim: Pure Void-for-Vagueness in Skilling v. United States*, 44 LOY. L.A. L. REV. 1289, 1301 (2011).

45. *Id.* at 1302.

46. *Id.*

47. *Id.*

48. *Id.* at 1302–03 (footnotes omitted).

49. See Lucian E. Dervan, *White Collar Overcriminalization: Deterrence, Plea Bargaining, and the Loss of Innocence*, 101 KY. L.J. 723, 723–24 (2013) (noting “Congress’s tendency to create vague and overlapping criminal provisions in areas already criminalized in an effort to expand the tools available to prosecutors”).

not produce desirable results.”<sup>50</sup> As the penalties for—and applicability of—the statute grows, the pressure on the actors charged with enforcing broader statutes—and charged with distinguishing between cases in which the statute’s application is appropriate and situations in which its usage might be draconian—grows as well. The public wants accountability and looks toward federal prosecutors to provide it.

In an effort to satisfy this pressure and the “reputational incentives” present within the enforcement regime, federal prosecutors have to “prioritize financial recoveries” and rely on settlement in an effort to further impress the public and Congress.<sup>51</sup> Large monetary recoveries are easy to measure and make a strong case that the regulators and federal prosecutors are doing their jobs. Increasing recovery amounts further convey the message that fraud is ever-present, pushing Congress to ratchet up resources to fight it while simultaneously making the statute easier to violate.

Achieving settlement and recovering large settlements become easier when the legal framework is itself broad. Where “punishments become grossly disproportionate to the harm they seek to avoid” the regime “empower[s] prosecutors to stack charges against a defendant” to force a plea to avoid a trial.<sup>52</sup> This has a doubly positive effect for the DOJ: it avoids the costs and risks of litigation and allows for federal prosecutors to increase recovery amounts, which garners more attention for being tougher on fraud or crime. The pattern repeats itself.

As a result, the overbroad statute and a settlement-driven regime become highly intertwined and reinforcing; a “symbiotic relationship exists between [the two] because these legal phenomena . . . rely on each other for their very existence.”<sup>53</sup> Without the availability of settlement, “[n]ovel legal theories and overly-broad statutes would no longer be tools merely for posturing during charge and sentence bargaining, but would have to be defended and affirmed both morally and legally at trial.”<sup>54</sup> Instead, however, prosecutors’ theories of liability can get increasingly creative and aggressive with little limitation.

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50. Burrell, *supra* note 44, at 1303.

51. See Lemos & Minzner, *supra* note 34, at 880.

52. Larkin, *supra* note 14, at 720.

53. See Lucian E. Dervan, *Overcriminalization 2.0: The Symbiotic Relationship Between Plea Bargaining and Overcriminalization*, 7 J.L. ECON. & POL'Y 645, 645 (2011).

54. See *id.* (“Further, the significant costs of prosecuting individuals with creative, tenuous, and technical charges would not be an abstract possibility used in determining how great of an incentive to offer a defendant in return for pleading guilty. Instead, these costs

## 2. *The Effects of Overenforcement*

If overenforcement is initially caused by a perception that there is too little regulatory control over an industry's professionals, its consequences replant that control and discretion within the offices of federal prosecutors and regulators. The regime rewards them with a large dose of decisionmaking power, which threatens to lead to regulatory disorder. These concerns include the resulting (1) "excessive unchecked discretion in enforcement authorities" and the (2) "inevitable disparity among similarly situated persons."<sup>55</sup>

First, overbroad laws "give enforcement authorities far too much unchecked discretion to select those few cases that will actually be prosecuted."<sup>56</sup> A legal regime that is susceptible to overenforcement hands a substantial amount of discretion—a potentially "dangerous disparity of power"<sup>57</sup>—to federal prosecutors. This discretion includes both (1) choosing who may be the target of a legal regime and (2) determining the individualized penalties within that framework.

Selective enforcement defines a situation in which prosecutors (nearly single-handedly and with few limits) can determine who should be targeted by a regulatory framework.<sup>58</sup> In the case of overenforcement, "[i]f almost the entire community is guilty of some crime, . . . [t]he question of why a particular individual was selected becomes . . . debatable, particularly given that arrest and charging decisions are generally invisible . . ."<sup>59</sup> This opens the door to prosecutors initially pursuing providers who may not be the most culpable. Indeed, "[i]t is likely that the vast majority of some health care crimes will not interest a federal prosecutor unless it has a certain publicity value,"<sup>60</sup> and creates the potential that "prosecutors will make charging decisions based on irrational factors, such as the value that a par-

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would be a real consideration in determining whether justice is being served by bringing a prosecution at all.").

55. See Beale, *supra* note 29, at 749.

56. *Id.* at 766.

57. See Luna, *supra* note 18, at 725.

58. See Larkin, *supra* note 14, at 754 ("And there is no effective control over a prosecutor's decision.").

59. *Id.* at 752.

60. See Matthew P. Harrington, *Health Care Crimes: Avoiding Overenforcement*, 26 RUTGERS L.J. 111, 148 (1994) (noting that prosecutors' perceived application of the proposed amendments to the fraud and abuse laws in the early 1990s or laws that build on the amendments will seem arbitrary).

particular case holds for an ambitious lawyer or the number of points it will add to his batting average.”<sup>61</sup>

Besides selective enforcement, overenforcement can implicate concerns “about the degree of law enforcement’s response, such as complaints that police used excessive force . . . when lesser interventions would have sufficed.”<sup>62</sup> For regulatory frameworks in which numerous duplicative statutes are at the disposal of federal prosecutors, those enforcers still lean on the most powerful statute applicable to achieve maximum deterrent value. Ultimately, those targeted may not have engaged in misconduct deserving of the most powerful regulatory tool but are nonetheless charged with a violation of that statute; in an effort to achieve the largest recovery, prosecutors seek to fit the targeted actor’s conduct into it. In effect, a potential “race-to-the-top” ensues where prosecutors habitually overcharge defendants.

Second, the enforcement framework may be arbitrarily employed. Some actors may be likely to be “singled out for much harsher treatment than others who have engaged in precisely the same conduct” as “[o]nly a few cases of the many can be chosen.”<sup>63</sup> As a result, the regulated actors are targeted in what can be called “a penal lottery”—an enforcement framework dogged by inevitable disparities in meted penalties.<sup>64</sup> When the regulatory structure is in competition for resources and time with other initiatives, arbitrariness can multiply; some federal prosecutors will focus their energy and resources on regulating a particular industry, but others will not.<sup>65</sup> Within this regulatory structure, similarly situated actors may experience differential treatment, and those with varying degrees of culpability may have similar penalties assessed.

### *B. Random Enforcement and Definitional Spillover*

Disorder resulting from overcriminalization and overenforcement is compounded by the challenges of so-called “random” enforcement.<sup>66</sup> The random enforcement model, which holds down the

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61. Larkin, *supra* note 14, at 751–52 (footnotes omitted).

62. Burke, *supra* note 22, at 1004.

63. Beale, *supra* note 29, at 766.

64. *Id.*

65. See Harrington, *supra* note 60, at 148.

66. See Margaret H. Lemos & Alex Stein, *Strategic Enforcement*, 95 MINN. L. REV. 9 (2010); see also Ehud Guttel & Alon Harel, *Uncertainty Revisited: Legal Prediction and Legal Postdiction*, 107 MICH. L. REV. 467, 489 n.119 (2008) (“Due to budgetary constraints, the strategy of random enforcement is widely applied to areas such as health care and safety in

costs of the regulatory regime by pursuing a fraction of those who commit misconduct, depends on enforcement in a “relatively small number of occasions, but impose[s] heightened penalties.”<sup>67</sup> These tougher penalty amounts “are supposed to offset the diluted deterrence brought about by the reduced rate and correspondingly reduced probability of enforcement.”<sup>68</sup> And if the penalties are high enough, those considering committing the same misconduct will be deterred away from doing so.<sup>69</sup>

A regulatory framework dependent upon “random” enforcement must build into its penalty structure the possibility that a number of deserving actors will escape detection.<sup>70</sup> However, even with an efficiently-constructed regulatory framework, DOJ attorneys may actually be driven by concerns other than capturing those most deserving of fraud prosecution. A particular characteristic associated with random enforcement is that it “is cheap, but so is the justice that it delivers.”<sup>71</sup> Specifically, under the random model, a regulatory framework can be inefficient.<sup>72</sup> Additionally, a randomized model is limited in nature, and it “systematically imposes harsh penalties on a relatively small number of violators and lets all others go scot free,”<sup>73</sup> further contributing to the concern over arbitrary penalty amounts.<sup>74</sup>

Within a random enforcement framework, “because law enforcers and adjudicators choose this small number of violators from a large pool of suspects, they have an incentive to enforce the law only in easy cases in which violations can easily be proven.”<sup>75</sup> As a result, the enforcement framework may gravitate toward those overtreatment

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the workplace.”); Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 278–79 (1999).

67. Lemos & Stein, *supra* note 66, at 11.

68. *Id.* at 11–14 (noting that the “penalty is increased to offset the benefit that violators expect to derive from their *ex ante* prospect of not being caught” (emphasis added)).

69. *Id.* at 12.

70. *Id.* at 14–15 (“These constraints explain the presence of the randomized enforcement model, under which law enforcers apprehend and punish violators randomly and only once in a while, but the penalty is increased to offset the benefit that violators expect to derive from their *ex ante* prospect of not being caught. For example, when the regular fine for a violation is \$10,000, but law enforcers apprehend only one violator out of three, the fine for every convicted violator should be set at \$30,000.”).

71. *Id.* at 12.

72. *Id.*

73. *Id.* at 17.

74. *Id.* at 12.

75. *Id.* at 17.

cases for which settlement is easy to achieve<sup>76</sup>—nationwide, easy-to-replicate investigations and initiatives immediately come to mind.<sup>77</sup> This will “drive [enforcers] away from sophisticated violators who are both able and willing to conceal their misdeeds.”<sup>78</sup>

Finally, the random enforcement model may be further threatened by the problem of so-called “definitional spillover.”<sup>79</sup> Definitional spillover occurs when

adjudicators find the defendant liable under an overbroad liability rule that they correctly apply. By overbroad, we mean a liability rule that captures some cases that are not justified by its underlying social purpose . . . . The defendant’s particular case falls within the rule’s formal prohibition but outside the scope of the rule’s purpose.<sup>80</sup>

Over-deterrence clearly results when “definitional spillover” occurs, as “the total harm the defendant suffers from the imposition of liability is excessive relative to the social cost of his conduct.”<sup>81</sup> Additionally, “[t]he overbroad liability rule treats these defendants exactly wrong.”<sup>82</sup> Similar to the consequences of overcriminalization, capturing all individuals who violate an overbroad rule treats them “indiscriminately by holding each one liable” and “generates social costs by excessively deterring” socially-beneficial behavior.<sup>83</sup> From the perspective of the targets, an enforcement framework afflicted with definitional spillover is affected by problems with consistency, predictability, and fairness.

A regulatory framework susceptible to overenforcement due to an overbroad legal regulation, a random enforcement model, and definitional spillover is at risk for disorder. An introduction to the regulation of overtreatment—a regulatory regime that can be said to be at risk of this threat—follows.

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76. See Lemos & Minzner, *supra* note 34, at 890 (“A large recovery may be fairly easy for a government attorney to win if the government’s legal theory is strong and the sanction represents a drop in the bucket of the defendant’s total resources.”).

77. See, e.g., Joe Carlson, *55 More Hospitals Settle in Kyphoplasty Overpayment Cases*, MODERN HEALTHCARE (July 2, 2013), <http://www.modernhealthcare.com/article/20130702/NEWS/307029967>.

78. Lemos & Stein, *supra* note 66, at 12.

79. Bierschbach & Stein, *supra* note 26, at 1748.

80. *Id.*

81. *Id.*

82. *Id.* at 1755.

83. *Id.*

## II. OVERTREATMENT REGULATION

Over the last decade, a noticeable new theory of health care fraud liability has emerged. By linking the main cause of the health care cost crisis—overtreatment—with the severe penalties of the FCA, attorneys at the DOJ have prosecuted providers for administering too much health care by arguing the care administered was not medically necessary, and therefore, fraudulent.

In order to review the DOJ's overtreatment enforcement strategy in depth, it is worthwhile to first provide a brief definition of overtreatment and an explanation of its causes; this follows immediately below. To provide context, the recently proposed resolution of a major overtreatment investigation involving cardiac services—the nationwide implantable cardioverter defibrillator (“ICD”) investigation—will be presented as well. This initiative provides an illustration of the potential dangers of overcriminalization and overenforcement within the DOJ's chosen regulatory strategy of overtreatment.

### A. America's Overtreatment Problem

America has an overtreatment problem. Providers who “do too much” have become the norm in emergency rooms and family clinics across the United States due to a confluence of complex causes. All actors are at least partially blameworthy, from the American patient—who provides little resistance to cost increases due to insulating insurance and moral hazard—to health care providers—who are both encouraged to intervene to increase profits and to protect themselves from malpractice liability and taught to operate in autonomous silos in which they do not communicate with other specialists—to hospitals—who strive to fill all their beds and acquire more expensive and prestigious machinery in order to gain more market share. The result: hospitals admit too many patients and American providers administer too many procedures that are too costly. This is too often to the delight of the American “consumer-patient,”<sup>84</sup> who does not mind

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84. See Kristin L. Carman et al., *Evidence That Consumers Are Skeptical About Evidence-Based Health Care*, HEALTH AFFAIRS, July 2010, at 1, 4, available at <http://content.healthaffairs.org/content/early/2010/06/03/hlthaff.2009.0296.full.pdf+html> (sharing study results that found that thirty-three percent of survey respondents [American health care consumers] “agreed or strongly agreed with the statement that ‘medical treatments that work the best usually cost more than treatments that don’t work as well,’” and that, to the participants, “[t]he idea that getting high-quality care or the ‘right’ care could mean getting less care was counterintuitive,” with one respondent noting, “I don’t see how extra care can be harmful to your health. Care would only benefit you.”); see also David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms*,



an extra test or procedure in an effort to get a simple answer to a complex health concern.<sup>85</sup>

The result can be called overtreatment. Defined as care that is either too expensive, inefficient, unnecessary, or old fashioned, overtreatment has become a major driver of skyrocketing health care spending. According to health economists, up to *one in every three* dollars spent annually on U.S. health care is wasted, and a substantial percentage of the waste is due to inefficient and unnecessary medical care.<sup>86</sup> In a study released by the Institute of Medicine in 2011, which concluded that \$765 billion is squandered annually, three categories combined to make up \$530 billion, or 69%, of the total amount of annual wasted expenditures: (1) “[u]nnecessary [s]ervices” (including the overuse of, often overpriced, services and the effect of “[d]efensive medicine”); (2) “[e]xcessive [a]dministrative [c]osts” (“[d]uplicative costs [for] . . . insurance” and “[u]nproductive documentation”); and (3) “[i]nefficiently [d]elivered [s]ervices” (including “[m]edical errors[,] [u]ncoordinated care,” and “[i]nefficient operations”).<sup>87</sup> Applying a more limited definition (“care that, according to sound science and the patients’ own preferences, cannot possibly help them”), Donald Berwick and Andrew Hackbarth pegged the total amount that overtreatment costs American health care at

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*and the Trust “Reposed in the Workmen,”* 30 J. LEGAL STUD. 531, 547 (2001) (“Patients generally believe that ‘more is better’ when it comes to health care and perceive themselves to be the direct beneficiaries of their provider’s actions.”).

In fact, insured Americans are normed to demand any test or treatment through direct-to-consumer advertising and internet research. See Barry R. Furrow, *Doctors’ Dirty Little Secrets: The Dark Side of Medical Privacy*, 37 WASHBURN L.J. 283 (1998); Martin L. Hirsch, *Side Effects of Corporate Greed: Pharmaceutical Companies Need a Dose of Corporate Social Responsibility*, 9 MINN. J.L. SCI. & TECH. 607, 633 n.180 (2008) (“Direct-to-consumer advertising may encourage patients to pressure their physicians to prescribe specific medications.”); Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 AM. J.L. & MED. 7, 11–13 (2009) (noting the trend toward consumerism in health care).

85. See Lindsey Tanner, *HCA Probe Shines Light on Chest Pain Overtreatment*, ASSOCIATED PRESS (Aug. 8, 2012), <http://bigstory.ap.org/article/hca-probe-shines-light-chest-pain-overtreatment> (“Patients often want the quicker fix, and Yale University cardiologist Harlan Krumholz says many patients mistakenly think elective angioplasties will do a better job of keeping them alive.”); see also BROWNLEE, *supra* note 9, at 157–58 (raising the problem of demanding patients and physician acquiescence).

86. See Debra Sherman, *Stemming the Tide of Overtreatment in U.S. Healthcare*, REUTERS (Feb. 16, 2012), <http://www.reuters.com/article/2012/02/16/us-overtreatment-idUSTRE81F0UF20120216> (including MIT economist Jonathan Gruber’s estimated that the waste in health care approaches \$800 billion); see also INST. OF MED., *THE COST OF HEALTH CARE: HOW MUCH IS WASTE?* 1, [http://iom.edu/Reports/2011/~media/Files/widget/VSRT/healthcare-waste.swf](http://iom.edu/Reports/2011/~/media/Files/widget/VSRT/healthcare-waste.swf) (last accessed Aug. 16, 2013) [hereinafter *THE COST OF HEALTH CARE*].

87. See *THE COST OF HEALTH CARE*, *supra* note 86, at 3.

\$158 to \$226 billion annually.<sup>88</sup> Whatever the total amount, the waste in the system undoubtedly threatens the long-term solvency of the federal health care programs, and in particular, Medicare.

Reversal of this trend requires a reconstruction of the structure responsible for administering and delivering American health care and a reordering of incentives, something the ACA is purporting to spur.<sup>89</sup> As scholars and providers have suggested, potential solutions could include: (1) replacing fee-for-service and even prospective-payment systems with incentive-based, salaried compensation for providers,<sup>90</sup> (2) a reduction of patients' insensitivity to price through a system of direct cash payments to eliminate moral hazard,<sup>91</sup> and (3) increased collaborative relationships between different providers—in accountable care organizations (“ACOs”), for example—in order to better coordinate care and eliminate duplication.<sup>92</sup> Many ideas for reconstructing a new system have come from within the medical community itself.<sup>93</sup>

Nevertheless, as health care costs have continued to grow, federal prosecutors have increased their focus on providers who, for various reasons, have allegedly administered overtreatment, and thus, according to the DOJ, have committed health care fraud. There is no doubt

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88. Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in U.S. Health Care*, 307 JAMA 1513, 1514 (2012).

89. See Daschle & Frist, *supra* note 8.

90. See Editorial Board, *Fee-For-Service Rewards Volume: Our View*, USA TODAY (July 7, 2013), <http://www.usatoday.com/story/opinion/2013/07/07/fee-for-service-unnecessary-surgeries-editorials-debates/2497213/>.

91. See Christopher Robertson, *The Split Benefit: The Painless Way to Put Skin Back in the Health Care Game*, 98 CORNELL L. REV. 921, 939–40 (2013) (presenting a proposal that forces patients to be sensitive to the price of health care they incur).

92. *Accountable Care Organizations (ACO)*, CTRS. FOR MEDICARE & MEDICAID SERVS., (Mar. 22, 2013), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/aco/>.

93. See, e.g., CHOOSING WISELY: AN INITIATIVE OF THE ABIM FOUNDATION (2014), <http://www.choosingwisely.org/about-us/> (“*Choosing Wisely* aims to promote conversations between providers and patients by helping patients choose care that is: [s]upported by evidence; [n]ot duplicative of other tests or procedures already received; [f]ree from harm; [and] [t]ruly necessary.”); Bruce Japsen, *Doctors Call out 90 More Unnecessary Medical Tests, Procedures*, FORBES (Feb. 21, 2013), <http://www.forbes.com/sites/brucejapsen/2013/02/21/doctors-call-out-90-more-unnecessary-medical-tests-procedures/> (last accessed Aug. 15, 2013); cf. Rita Redberg, *Commentary, Less Is More*, INST. MED. (Sept. 2012), <http://www.iom.edu/~media/Files/Perspectives-Files/2012/Commentaries/VSR%20-%20Less%20Is%20More.pdf> (“There is increasing recognition among physicians that many of [their] patients are receiving too much health care. In a recent survey of primary care physicians identified by the American Medical Association (AMA) masterfile, 42 percent said that patients in their own practices were getting too much care.”).

that *some* overtreatment is fraudulently administered, but some overtreatment results from the divergence between clinical decision-making and government or insurance-created standards. Realizing the cost to the system of administering “too much care” and the absence of other pressures on providers to limit cost,<sup>94</sup> the DOJ has sought to regulate providers engaged in overtreatment by using the federal government’s most powerful anti-fraud tools. Consequently, in overtreatment cases, whether or not the provider violated the FCA is often determined by whether or not the care administered was medically necessary. Under this approach, solely by virtue of its excess, overtreatment is fraud.

*B. The Nationwide Overtreatment Investigation: ICD Update*

In early 2011, the DOJ began a nationwide review of the surgeries placing ICDs due to a suspicion that many of the expensive devices’ implantations were not medically necessary.<sup>95</sup> Medicare pays for the procedure, which is designed to prevent sudden cardiac death by regulating and correcting heartbeats of high-risk patients that are susceptible to irregularities and arrhythmias.<sup>96</sup> Even though Medicare covers the procedure, it places limits on the type of ICD placement it covers through a national coverage determination (“NCD”). One of the relevant NCD limitations for ICD placement regards timing: pursuant to this limitation, Medicare will cover only ICDs that are implanted more than forty days after an acute myocardial infarction, and outside of ninety days after a percutaneous coronary intervention (coronary angioplasty) or coronary artery bypass graph (“CABG”).<sup>97</sup>

After becoming aware that some ICDs were being placed outside the bounds of these Medicare NCD timing requirements, the DOJ

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94. See Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn’t Worked*, 101 GEO. L.J. 519 (2013) (noting how Medicare’s history and structure prevent it from improving quality and limiting cost).

95. See Joe Carlson, *Cardiac Arrests: Hospitals Anxious They Could Face Hefty False Claims Penalties in Implanted Cardiac Defibrillator Cases*, MODERN HEALTHCARE (July 21, 2012), <http://www.modernhealthcare.com/article/20120721/MAGAZINE/307219994>.

96. See *id.*; *What Is an Implantable Cardioverter Defibrillator?*, NAT’L INST. OF HEALTH: NAT’L HEART, LUNG, & BLOOD INST. (Nov. 9, 2011), <http://www.nhlbi.nih.gov/health/health-topics/topics/icd/> (“[An ICD] is a small device that’s placed in the chest or abdomen . . . to help treat irregular heartbeats called arrhythmias.”).

97. See David Mann, *Medicare ICD Guidelines Exegesis*, EP STUDIOS (Nov. 21, 2011), <http://www.epstudiossoftware.com/?p=812>. For a complete discussion of the ICD coverage determination by Medicare, see Jacqueline Fox, *The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust*, 79 U. CIN. L. REV. 1, 25–30 (2010).

began to look at when, specifically, providers placed ICDs in the chests of high-risk patients. The review focused particularly on the exact number of days between an adverse cardiac event and the ICD placements.<sup>98</sup> Based on the DOJ's chosen strategy in other overtreatment investigations, it appeared that the DOJ would submit that ICD placements outside Medicare's approved timeframe would be presumptively fraudulent and violative of the FCA. Providers and advocacy groups were worried about this newest DOJ initiative, and the concern centered on the fact that "the DOJ's focus [was] not on medical necessity," but rather "on *compliance with the national coverage policy*."<sup>99</sup>

As the investigation continued, a number of institutions landed under the DOJ's microscope, including the world-renowned Cleveland Clinic, for placing ICDs in the chests or abdomens of individuals too close to adverse cardiac events, and out of compliance with the Medicare NCD. Nevertheless, implicated clinicians defended their actions, arguing that the ICD placements at issue—specifically those placed outside NCD timing requirements—were medically appropriate and clinically necessary. The investigation has become a proxy for the larger modern medical-legal conflict, with federal prosecutors seeking to enforce a practice standard and draw a bright-line by invoking broad anti-fraud statutes, and providers arguing the individuality of each patient, the murkiness of medical necessity, and the importance of clinical autonomy.

Providers and practitioners argued that the DOJ's ICD initiative—and its chosen strategy—was illegitimate. Some noted that regulating ICD placement in this way was "based on a flawed legal premise."<sup>100</sup> Indeed, they argued, "the [Medicare] NCD describe[d] circumstances in which an ICD implantation [was] covered, but [did] not exclude coverage in other circumstances."<sup>101</sup> As such, placing an ICD outside the Medicare NCD was not presumptively unnecessary, and definitely not presumptively fraudulent, according to the lan-

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98. See Buck, *supra* note 9, at 491–94.

99. See *Lessons from the Department of Justice's Investigation of ICD Implants*, THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS (Sept. 7, 2012), <http://www.scai.org/Advocacy/Detail.aspx?cid=5273511b-afc7-49be-922b-48620940eb57>.

100. Jesse A. Witten & David M. Glaser, *The Government's Investigation of Medicare Billing for ICDs Is Based on a Flawed Legal Premise*, BNA'S HEALTH CARE FRAUD REPORT, June 1, 2011, at 1, available at <http://www.drinkerbiddle.com/resources/publications/2011/the-governments-investigation-of-medicare-billing-for-icds-is-based-on-a-flawed-legal-premise>.

101. *Id.*

guage of the relevant NCD itself.<sup>102</sup> Others argued that “the government’s expansive investigation into ICD procedures [was] notable because it turn[ed] in large part on whether the application of the NCD . . . [was] the sole proper basis for determining whether a medical procedure [was] necessary.”<sup>103</sup> This was particularly concerning, given the ambiguous, incomplete, and outdated NCD, according to providers.<sup>104</sup> This ambiguity was compounded by the fact that the American College of Cardiology Foundation, in conjunction with professional non-profit group Heart Rhythm Society (“HRS”), had developed appropriate use criteria (“AUC”) to guide providers on appropriate ICD placement that, unfortunately, clearly conflicted with the Medicare NCD.<sup>105</sup> According to practitioners, this “place[d physicians] in the difficult dilemma of trying to do the ‘right thing’ for their patients, while recognizing that the ‘right thing’ may not be covered by the payer or insurer.”<sup>106</sup> Even more, this “right thing” may subject the provider to a fraud investigation—and, in fact, it did.

After beginning the investigation, the DOJ reached out to HRS in January 2011 “to assist in an advisory role to lend expertise concerning proper guidelines for clinical decision making.”<sup>107</sup> According to commentators, the DOJ’s contact with HRS showed something noteworthy from the DOJ—specifically that it would be “extremely unlikely that the DOJ, with the assistance of HRS [would be] investigating or . . . likely to prosecute the occasional or even moderately frequent use of ‘reasonable’ off-guidelines cases.”<sup>108</sup> Still, members of HRS noted the “palpable fear in [their] community” and “expressed con-

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102. *Id.* (noting that “determining Medicare coverage for patients who are outside the NCD criteria requires a case-by-case evaluation” and these patients are not explicitly excluded from coverage).

103. David A. Feldman et al., *Shock to the Heart: Who’s to Blame? That ICD Could Mean a False Claim*, BECKER’S HOSPITAL REVIEW (July 11, 2013), <http://www.beckershospitalreview.com/legal-regulatory-issues/shock-to-the-heart-who-s-to-blame-that-icd-could-mean-a-false-claim.html>.

104. *Id.*

105. See Richard I. Fogel et al., *The Disconnect Between the Guidelines, the Appropriate Use Criteria, and Reimbursement Coverage Decisions*, 63 J. AM. COLL. CARDIOLOGY 12 (2014).

106. *Id.*

107. See Press Release, Heart Rhythm Soc., Heart Rhythm Society Statement Regarding Department of Justice Investigation (Jan. 21, 2011), <https://www.hrsonline.org/News/Press-Releases/2011/01/Department-of-Justice-Investigation>.

108. Larry Husten, *Heart Rhythm Society Advising DOJ in Investigation of ICD Implants*, CARDIOBRIEF (Jan. 21, 2011), <http://cardiobrief.org/2011/01/21/heart-rhythm-society-advising-doj-in-investigation-of-icd-implants>.

cern that the investigation would have an overall negative impact on public health.”<sup>109</sup>

More than eighteen months later, in August of 2012, the DOJ began “e-mailing hospitals across the country . . . with instructions to examine questionable implantable defibrillator surgeries on Medicare patients and estimate potential penalties under the False Claims Act.”<sup>110</sup> The DOJ also published a “Resolution Model” document that has since served as the basis for settlement with investigated providers. The Resolution Model document uses clinical and reimbursement standards to distinguish between FCA violations and non-fraudulent “technical” violations,<sup>111</sup> with which the DOJ does not seem concerned.

This Resolution Model provides six different classes of cases with six respective dispositions. Most dispositions either push for (1) excluding the class from enforcement, (2) assessing damages to varying degrees, and/or (3) seeking settlement.<sup>112</sup> For four of the six classes of cases, the DOJ has proposed assessing damages, and one of the classes has been excluded from the enforcement initiative altogether. For the remaining class of cases (called the “No Enforcement Categories”), the DOJ has proposed that no damages be sought.<sup>113</sup> For these providers, the DOJ has noted that ICD implants were “potentially violative of NCD time frames (or waiting periods),” but has said it will not enforce a penalty against these cases “pursuant to DOJ discretion in False Claims Act enforcement.”<sup>114</sup> This final class, the class of No Enforcement Categories, includes so-called “technical” violations, which are defined as cases that feature facts that demonstrate that

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109. *Id.*

110. Joe Carlson, *Feds Notify Hospitals of Liability for Wrongly Implanted Heart Devices*, MODERN HEALTHCARE (Aug. 30, 2012), <http://www.modernhealthcare.com/article/20120830/NEWS/308309943>.

111. *Id.*

112. See U.S. DEP'T OF JUSTICE, ICD INVESTIGATION MEDICAL REVIEW GUIDELINES/RESOLUTION MODEL 1–3 (Aug. 2012), available at <http://www.cardiosource.org/News-Media/Publications/Cardiology-Magazine/~media/Files/Advocacy/DOJ%20ICD%20selfresolution%20model.ashx> [hereinafter RESOLUTION MODEL] (listing the six categories: (1) “Covered by the NCD and/or Excluded from this Investigation,” (2) “DOJ No Enforcement Categories,” (3) “DOJ Category—With Enforcement,” (4) “Coding Error (Without Repeating Patterns),” (5) “Not Covered by NCD or DOJ Categories,” (6) “Not Medically Indicated”); see also Larry Husten, *ICD Investigation: DOJ Sends Resolution Model to Hospitals*, CARDIOBRIEF (Aug. 30, 2012), <http://cardiobrief.org/2012/08/30/icd-investigation-doj-sends-resolution-model-to-hospitals/>.

113. RESOLUTION MODEL, *supra* note 112, at 2.

114. *Id.* at 7.

“although the ICD was otherwise indicated, it technically violated the NCD because it was implanted near the end of—but still during—the . . . prohibited time frames.”<sup>115</sup>

By the DOJ’s stance, it is indicating that it will not pursue the cases in which the provider did violate the Medicare NCD, but the ICD was otherwise medically necessary. This means that no health fraud prosecution will be maintained against many providers who placed the ICD outside of the Medicare NCD. Interestingly, the DOJ has referenced its discretion in deciding not to pursue these providers, seemingly implying that a technical violation (a violation of Medicare’s timing guidelines) is legally different from an *unreasonable* or *harmful* deviation (for which settlement will be sought). The DOJ’s decision not to pursue these providers may indicate that the NCD may be inaccurate or at least that the payment standard policy differed from the quickly developing clinical standard of care. What is surprising to many providers is that the DOJ is not seeking settlement with these providers who committed a “technical” violation.

Oddly, going forward, providers are explicitly told to heed the Medicare NCD in providing treatment to beneficiaries. The DOJ was clear to note that the “Resolution Model is *not* CMS policy” and “does not replace, update or interpret NCD 20.4 [the NCD at issue] and should not be relied upon or utilized in any manner to determine whether an ICD is payable by Medicare.”<sup>116</sup> As of early 2014, the DOJ has not publicly stated why the ICD investigation was initially launched,<sup>117</sup> nor has the DOJ answered some of the more prickly questions addressing the Resolution Model, in particular whether the DOJ will require Corporate Integrity Agreements with the resulting settlements.

Within the Resolution Model, the DOJ also notes that “multipliers”—the ability of the DOJ to assess up to treble damages for violations of the FCA—“will be determined during discussions with each facility and will be based upon many factors, including, but not limited to . . . patient harm, patterns, compliance efforts and effective-

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115. *Id.* at 9.

116. *Id.* at 1; *see also* Feldman, *supra* note 103 (explaining that the Resolution Model “does not . . . clarify how hospitals should handle Medicare coverage claims for ICD implantation procedures going forward”).

117. Jesse A. Witten, *What’s New in Hospital Fraud and Abuse?*, AM. HEALTH LAWYERS ASS’N (Sept. 29, 2013), [http://www.healthlawyers.org/Events/Programs/Materials/Documents/FC13/VI\\_witten.pdf](http://www.healthlawyers.org/Events/Programs/Materials/Documents/FC13/VI_witten.pdf).

ness . . . and knowledge evidence.”<sup>118</sup> In effect, the DOJ is seeking to apply a higher statutory penalty to cases in which “knowledge evidence”—evidence that the provider was knowingly committing health care fraud—exists, as well as to cases in which patient harm occurred. Quite clearly, the DOJ is fashioning its own individualized remedy for a number of providers, given its wide discretion to do so under the FCA.

The HRS has since responded with a statement that expressed hope but also disappointment. Noting that HRS made the “difficult decision to work with the DOJ to protect patient access to life saving therapies, and to ensure that the federal government was aware of and considered evidence-based medicine and the realities of clinical practice during their investigation,” the HRS noted that, in creating the enforcement categories, “in some circumstances our counsel was not accepted, and we are troubled by some aspects of the final decision.”<sup>119</sup> It further noted that a future priority will be to address the “misalignment between the Medicare NCD and the ACC/AHA/HRS guidelines” in an effort to “align payment policy with evidence-based medicine.”<sup>120</sup>

Sympathetic bloggers have noted that, by virtue of this enforcement model, doctors are “rendered powerless” through the DOJ’s “new secretive rule-making approach.”<sup>121</sup> Others have asked how the DOJ can “justify the use of multipliers in the resolution model” if “a hospital lacks the scienter for violation of the FCA.”<sup>122</sup> Finally, others have noted that “using the NCD criteria as the sole determinant of medical necessity without accounting for on-site clinical decision making leads to inaccurate conclusions, and that the NCD, which was issued in 2005, does not reflect current clinical guidance or recent advances in medical knowledge.”<sup>123</sup> Nevertheless, the first settlement was announced in September 2013 when MedCath Corporation

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118. RESOLUTION MODEL, *supra* note 112, at 2 n.2.

119. Westby G. Fisher, *DOJ Hands Heart Rhythm Society and Hospitals Its Decision on Defibrillators*, DR. WES BLOG (Sept. 4, 2012), <http://drwes.blogspot.com/2012/09/doj-hands-heart-rhythm-society-and.html>.

120. *Id.*

121. *Id.*

122. Bradley M. Smyer, *New Developments in the Department of Justice’s National ICD Investigation*, COMPLIANCE TODAY, Feb. 2013, at 43, 45, available at [http://www.hcca-info.org/Portals/0/PDFs/Resources/Compliance\\_Today/0213/CT\\_0213\\_Smyer.pdf](http://www.hcca-info.org/Portals/0/PDFs/Resources/Compliance_Today/0213/CT_0213_Smyer.pdf).

123. Feldman, *supra* note 103.



agreed to pay \$6.1 million to settle claims resulting from ICD placements at six of its former hospitals.<sup>124</sup>

The DOJ's decision to exempt technical violations from damage assessments is quite notable, however, even if the proposed penalty structure vis-a-vis each provider is quite vague. Perhaps this is a result of consultation with a clinically expert party (HRS), or a realization that striving for settlement with those providers would be a clear example of using the FCA to enforce a reimbursement standard—a usage even broader than the questionable practice of using the FCA to resolve “allegations of regulatory noncompliance.”<sup>125</sup> This decision not to pursue the providers who placed ICDs outside the Medicare NCD was not a trivial one, nor was it expected, given the breadth of the statute and the wide application seen in previous DOJ initiatives that stretched nationwide.<sup>126</sup> As commentators have noted, this seems to indicate that “the DOJ appears to have shown some appreciation for the notion that determining medical necessity is not always as simple as mechanically applying the NCD criteria.”<sup>127</sup>

Whether this is a sign of a new restrained enforcement strategy remains to be seen. The DOJ's decision to consult the HRS has major effects on clinical practice; procedurally, there is no requirement for regulators to consult with disinterested clinical experts. Still, the number of “innocent” providers who were ensnared in the initial investigation and the fact that the DOJ has been able to push for individualized penalties demonstrates that the initiative still suffers from many of the defects of overenforcement. This will be investigated more fully below.

### III. THE “POTENTIALLY CRIPPLING”<sup>128</sup> STATUTE

The vastness of liability that characterizes the FCA has been well documented,<sup>129</sup> and this article will not delve deeply into the history

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124. See *Department of Justice ICD Investigation Update: First Settlement Announced*, DRINKER BIDDLE (Oct. 3, 2013), <http://www.drinkerbiddle.com/resources/publications/2013/Department-of-Justice-ICD-Investigation-Update-First-Settlement-Announced->.

125. See Joan H. Krause, *Ethical Lawyering in the Gray Areas: Health Care Fraud and Abuse*, 34 J.L. MED. & ETHICS 121, 122 (2006) (emphasis omitted).

126. See *supra* note 77 and accompanying text.

127. See Feldman, *supra* note 103.

128. See generally John T. Boese, *When Angry Patients Become Angry Prosecutors: Medical Necessity Determinations, Quality of Care and the Qui Tam Law*, 43 ST. LOUIS U. L.J. 53 (1999).

129. See, e.g., Timothy P. Blanchard, *Medicare Medical Necessity Determinations Revisited: Abuse of Discretion and Abuse of Process in the War Against Medicare Fraud and Abuse*, 43 ST.

of the Act. Clearly, since the modern FCA came into being—typically pegged as when the 1986 amendments to the Act took effect—it has left an indelible mark on the medical profession, and, unforgettably, on a number of medical professionals. That it justifiably applies to prevent the scourge of fraud and abuse within the health care system has been a truism nearly unanimously held by those in the halls of Congress.<sup>130</sup>

Its specific provisions are well known. The statute is a civil law, with a standard requiring only a “preponderance of the evidence” for liability and sheltering it from a number of criminal law’s defendant-focused protections. Its intent standard, “knowingly,” is explicitly defined as “deliberate ignorance” or “reckless disregard,”<sup>131</sup> and some courts have defined it as requiring only a “negligence-plus” mens rea.<sup>132</sup> Its qui tam provisions deputize private citizens,<sup>133</sup> giving the DOJ access to typically confidential key facts.

Recent changes have made it more potent. Since the passage of the ACA, a violation of the anti-kickback statute (“AKS”)<sup>134</sup> is explicitly a false claim for purposes of FCA liability, no matter the challenges associated with proof.<sup>135</sup> The so-called public disclosure bar, which prevented opportunistic relators from bringing lawsuits based upon information that had already been previously publicly disclosed, has

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LOUIS U. L.J. 91, 92 (1999) (referring to the FCA as “draconian”); Sarah Helene Duggin, *The Impact of the War over the Corporate Attorney-Client Privilege on the Business of American Health Care*, 22 J. CONTEMP. HEALTH L. & POL’Y 301, 335–36 n.172 (2006) (“The False Claims Act, a statute dating back to the post-Civil War era, is among the most draconian of these measures. . . . Federal authorities frequently use the statute as a sword.”); Christopher L. Martin, Jr., *Reining in Lincoln’s Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CALIF. L. REV. 227, 235 (2013) (“In practice, damages under the False Claims Act vastly exceed those available under other civil actions.”).

130. See *supra* note 37.

131. 31 U.S.C. § 3729(b) (2012).

132. See *United States v. Krizek*, 111 F.3d 934, 942–43 (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 F.3d 410, 433 n.26 (Fed. Cl. 1999) (“[U]nder the False Claims Act, reckless disregard may be considered the equivalent of ‘aggravated form of gross negligence, or gross negligence-plus.’”).

133. See 31 U.S.C. § 3730(b) (2012).

134. 42 U.S.C. § 1320a-7b(b) (2012).

135. See John T. Boese & Beth C. McClain, *Why Thompson Is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 ALA. L. REV. 1 (1999). On a related note, it remains unclear whether the AKS requires any type of criminal intent following the ACA amendments. See Elizabeth R. Sheyn, *Toward a Specific Intent Requirement in White Collar Crime Statutes: How the Patient Protection and Affordable Care Act of 2010 Sheds Light on the “General Intent Revolution,”* 64 FLA. L. REV. 449 (2012).

been narrowed.<sup>136</sup> In fact, the submission of a claim—once a necessary showing for FCA liability—is no longer required; retention of an overpayment by a provider or health care entity can now provide a basis for an FCA violation.<sup>137</sup>

When wielded against individuals who intentionally defraud the government, the FCA is a productive and powerful tool, but when the federal government stretches the statute to apply to health care providers who have allegedly engaged in overtreatment, the regulatory regime risks becoming imprecise due to its broad reach and blunt application. Two particular FCA provisions contribute to the broad nature of the statute: (1) the relatively low intent requirement and (2) the substantial statutorily-mandated penalties. The two provisions work to cast a wide net for potential violators and to impose heavy penalties against providers who are ensnared in that net.

#### A. *The Intent Requirement*

Unlike other health care fraud statutes,<sup>138</sup> the FCA specifically defines its intent requirement within its provisions.<sup>139</sup> In order to establish liability, the FCA requires the provider to act “knowingly,” which is defined as having “actual knowledge,”<sup>140</sup> as “act[ing] in deliberate ignorance of the truth or falsity of the information,”<sup>141</sup> or as “act[ing] in reckless disregard of the truth or falsity of the information.”<sup>142</sup> Beyond the “recklessness” mens rea required by the statute, Congress and some courts made the FCA’s intent standard elastic by referring to the required intent standard as “gross negligence ‘plus.’”<sup>143</sup>

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136. See Tabb, *supra* note 37.

137. Compare 31 U.S.C. 3729(a)(1)(F) (2012), with *id.* § 3729(b)(3).

138. See, e.g., 18 U.S.C. § 287 (2012) (requiring that the individual “know[]” a claim to be “false, fictitious, or fraudulent,” but providing no guidance); 18 U.S.C. § 1347 (2012) (uses “knowingly” and “willfully” but does not define the terms).

139. 31 U.S.C. § 3729(a)–(b).

140. *Id.* § 3729(b)(1)(A)(i).

141. *Id.* § 3729(b)(1)(A)(ii).

142. *Id.* § 3729(b)(1)(A)(iii).

143. Some courts have noted that something approaching gross negligence “plus” must be demonstrated to show the requisite intent. See *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (citing the congressional report describing the intent standard as requiring the individual “to make such inquiry as would be reasonable and prudent to conduct under the circumstances. . . . Only those who act in ‘gross negligence’ of this duty will be found liable under the False Claims Act.” (internal quotation marks omitted)); *Miller v. United States*, 550 F.2d 17, 23 (Ct. Cl. 1977) (holding “extreme negligence” as sufficing for FCA liability); *United States v. Massenburg*, No. Civ. A. 2:03-0437, 2004 WL 2370694, at \*4 (S.D. W. Va. Oct. 21, 2004) (“The government may well prove at trial that this negligence was actually the ‘gross negligence-plus’ standard that the

As the DOJ has used the FCA against health care providers, this intent standard has offered little protection for providers who, while not “knowing” that they were filing a false claim with the government, made a negligent decision that related to the filing of a claim with the federal government. For example, in a recent investigation, the DOJ has alleged FCA liability for providers who wrongly (according to the federal government) admitted patients for a relatively new surgery and accurately billed Medicare for that inpatient surgery.<sup>144</sup> This expanding intent standard has mirrored generally widening liability for health care entities, including a recent high-profile FCA case against a medical device company in which the false claims were filed by hospitals that were unaware of the fact that the bills were for care administered in violation of the AKS (the administering physicians were the only actors aware).<sup>145</sup> There, the First Circuit made clear that the submitting party need not have any fraudulent intent in order to maintain an FCA claim against an actor who caused the false claim to be presented.<sup>146</sup>

Given the reduced proof of intent required for FCA liability, individuals who make negligent mistakes could be liable under the FCA. Further, the federal government has a powerful argument when it alleges that *any* billing error to the federal health care programs is *at least* grossly negligent because the billing regulations are undoubtedly

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False Claims Act is designed to deter.”). *But see* United States *ex rel.* Baltazar v. Warden, 635 F.3d 866, 869 (7th Cir. 2011) (“[F]raud is actionable under the False Claims Act, while negligent errors are not.”); Minn. Ass’n of Nurse Anesthetists v. Allina Health System Corp., 276 F.3d 1032, 1053 (8th Cir. 2002) (“[I]t is important to remember that the standard for liability is knowing, not negligent, presentation of a false claim.”); United States *ex rel.* Augustine v. Century Health Servs., Inc., 136 F. Supp. 2d 876, 888 (M.D. Tenn. 2000) (“simple negligence and innocent mistakes, however, do not rise to [the] level of scienter” required by the FCA.”).

144. *See supra* note 77 and accompanying text.

145. *See* United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011).

146. The hospital that was unaware of the physicians’ illegal actions could only arguably be negligent, in that it was not, but should have been, aware that the physicians were violating the AKS. *See id.*

complex.<sup>147</sup> When the federal government is swinging this hammer, “everything looks like a nail.”<sup>148</sup>

*B. The Penalty Provisions*

No provision in health care fraud regulation is more potent than the FCA’s penalty structure. The Act explicitly *requires* application of a minimal fine of \$5,000 and a maximum penalty of \$10,000 per *claim* (adjusted to \$5,500 and \$11,000 according to the FCA primer), in addition to an award of three times the amount of financial harm suffered by the federal government.<sup>149</sup> Because it is set by statute, a handful of district courts have found that instituting at least the minimum penalty amount is non-discretionary.<sup>150</sup> Further, as is clear from the statutory language, this damage amount applies to each *claim*—meaning a provider is penalized for *each* billed service administered.<sup>151</sup>

The Act is unique in that the penalty provision explicitly provides a minimum amount a court must award—instead of, for example,

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147. See *Rehabilitation Ass’n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (“There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.”).

148. See Larkin, *supra* note 14, at 740 (noting that narrowly chartered agencies enforcing rules may attempt to overstate the importance of their investigations, stating “[i]f the only tool that one has to use is a hammer, everything looks like a nail”).

149. See 31 U.S.C. § 3729 (2012); U.S. DEP’T OF JUSTICE, THE FALSE CLAIMS ACT: A PRIMER, [http://www.justice.gov/civil/docs\\_forms/C-FRAUDS\\_FCA\\_Primer.pdf](http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Primer.pdf).

150. See *United States ex rel. Lamberts v. Stokes*, 640 F. Supp. 2d 927, 933 (W.D. Mich. 2009) (noting that “[a] district court has ‘considerable discretion’ in determining the amount of a penalty,” but mentioning that “the Court must impose a penalty ranging from a minimum of \$5,500 to a maximum of \$11,000 per violation”); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 242 (D.P.R. 2000) (“The legislative history of the 1986 amendments makes clear that civil penalties are ‘automatic and mandatory for each claim which is false.’ Thus, up to a certain point, the number of civil penalties, or whether to even assess civil penalties, is not discretionary. ‘This forfeiture provision is mandatory; it leaves the trial court without discretion to alter the statutory amount.’” (citation omitted) (quoting *United States v. Hughes*, 585 F.2d 284, 286 (7th Cir. 1978))); *United States v. Bottini*, 19 F. Supp. 2d 632, 641 (W.D. La. 1997) (noting that “[t]he court has the discretion to assess a civil penalty as to each of the two claims found to be false and fraudulent at an amount between \$5,000.00 and \$10,000.00” [the old statutory amount]); *United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1018 (W.D. Mo. 1995) (“[T]he Court rules that it lacks the discretion or inherent power under the FCA to award damages below the range set forth therein.”).

151. See Krause, *supra* note 16, at 125.

providing that courts fashion any penalty amount *up to* a maximum of \$11,000.<sup>152</sup> Not only do those found in violation of the FCA have to pay a large fine, but they are also subject to the administrative penalty of exclusion through the Department of Health and Human Services (“HHS”), in which the HHS Secretary can ban them from contracting with the federal government for a set period of time—and sometimes permanently.<sup>153</sup>

Although the statute does provide for the recovery of treble damages of financial harm suffered by the federal government, the majority of statutorily imposed FCA penalties will often arise out of the mandated per-claim penalty.<sup>154</sup> Measuring the majority of the penalties based upon how many claims providers file—as opposed to primarily linking the penalty to the magnitude or substance of the overall harm suffered by the federal government (that is, taxpayers), or even suffered by patients themselves—provides the potential for seemingly disordered results.<sup>155</sup> As the FCA does not require that the government prove tangible harm in order to demonstrate the existence of actual damages, the statute’s elasticity opens it up for use in different types of scenarios.

This penalty structure—initially erected in order to deter defendants from selling defective military goods in which the sale occurred either in bulk or for a few deliveries of a large amount of goods<sup>156</sup>—may be susceptible to distortion when applied to the health care industry because the average American provider treats thousands of patients and, as a result, files thousands and thousands of claims with the federal government annually.<sup>157</sup> The theoretical potential for

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152. *See supra* note 150.

153. *See* 42 U.S.C. § 1320a-7 (2012) (including mandatory and permissible exclusion).

154. *See* Krause, *supra* note 16, at 143–44 (noting that, in the famous case of George Krizek, the U.S. sought \$81 million in total damages (largely due to the statutory penalty) after Medicare overpaid Mr. Krizek a comparatively meager \$245,000).

155. *See id.*, at 144 (“Thus, in the health care context, FCA liability is greater for providers who submit the largest *number* of claims, even if those claims result in relatively little financial harm to the government.”); *see also* United States *ex rel.* Smith v. Gilbert Realty Co., Inc., 840 F. Supp. 71, 74–75 (E.D. Mich. 1993) (finding the penalty “extremely harsh and unjust” and awarding \$35,000 where actual government damages totaled \$1,630 and FCA civil penalties totaled \$290,000—a ratio of 1:178).

156. *See* Pamela Bucy et. al., *State, Statutes, and Fraud: A Study of Emerging State Efforts to Combat White Collar Crime*, 31 CARDOZO L. REV. 1523, 1526 (2010) (noting that “the FCA provided the federal government with a way to deal with deliveries of defective or non-existent military supplies to the Union Army”).

157. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., INNOVATORS’ GUIDE TO NAVIGATING MEDICARE, VERSION 2.0, at 3 (2010), <http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsG>

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astronomical statutorily mandated penalties becomes a real possibility. Clearly, as the provider sees more patients, the potential FCA fine grows.

In order to illustrate the potential disorder of this regulatory framework, four examples of the anomalous results and a summary table follow below.

Example 1: First, ten doctors in a clinic administer a procedure to 10,000 patients in a given year. The physicians defer to a company that sold them EMR software as to what the billing code should be for this procedure; as a result, all ten wrongly bill Medicare after using an incorrect code for the procedure. Coding the procedure in the incorrect way causes Medicare to overpay \$10 per procedure. These mistakes would subject the clinic to an FCA fine of \$55.3 million to \$110.3 million.<sup>158</sup>

Example 2: Second, in a classic example of the federal government's strategy of policing overtreatment, these same ten doctors administer a new and clinically advanced procedure for 10,000 patients in a given year. Even though Medicare has not explicitly endorsed this type of procedure in its NCD, some practitioners nationwide provide the procedure, because it is likely in the best medical interest of the patients according to the practitioners' clinical expertise, and Medicare will immediately pay for the procedure. Further, according to the settling hospitals, Medicare has implicitly endorsed performing the procedure on an inpatient basis, and patients with private insurance receive the procedure with little pushback from insurance companies.<sup>159</sup> Still, by providing the procedure against the explicit guidance of Medicare's NCD—and then billing Medicare for the procedure—the physicians open themselves up to serious FCA liability.

A \$55 million to \$110 million penalty amount could be sought against the providers, added to any financial damage the federal government suffered due to the procedure (this would be the cost of the procedure, multiplied by 10,000 patients, multiplied by three). With a hypothetical reimbursement amount of \$15,000 per procedure, the

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uide5\_10\_10.pdf (noting that Medicare's budget is \$460 billion annually); Peter Roskam, *Medicare Needs a Digital Elliot Ness*, HUFF POST: THE BLOG (June 22, 2010), [http://www.huffingtonpost.com/peter-roskam/medicare-needs-a-digital\\_b\\_620759.html](http://www.huffingtonpost.com/peter-roskam/medicare-needs-a-digital_b_620759.html) (noting that Medicare processes \$460 billion in claims each year).

158. This total penalty amount is the product of 10,000 and \$5,500 to \$11,000 added to the product of 10,000 (claims), three (trebled damages), and \$10 (damage sustained per procedure).

159. *See, e.g.*, Buck, *supra* note 9, at 504.

total FCA liability would approach \$505 to \$560 million. Notably, this liability total holds even where the procedure was medically necessary according to the treating physician, administered in a clinically sound manner, and resulted in successful clinical outcomes for all patients. Even more interestingly, if the procedure was *not* medically necessary, *not* administered in a clinically sound manner, and did *not* result in a successful clinical outcome, the total FCA liability would be the *exact same* amount.

Example 3: Third, a similar ten-doctor clinic treats the same 10,000 patients in a given year. However, this clinic engages in a fraudulent scheme called “upcoding” in which physicians intentionally bill Medicare for a more expensive procedure than the one they administer. Specifically, the clinic’s physicians complete the procedure on an outpatient basis, but bill Medicare as if it were performed as an inpatient procedure. Because of the miscoding, Medicare pays for an inpatient clinic stay, overpaying by a hypothetical \$1,000 per procedure. Under the FCA, the federal government would be eligible to seek between \$85 million and \$140 million in this scenario.<sup>160</sup>

Example 4: Finally, a ten-doctor clinic notices that the meager 10,000 patients to whom they administer a certain procedure in a given year are not enough to support their lavish lifestyles. They agree to fabricate the names of 1,000 more patients and bill Medicare under false social security numbers for a procedure costing \$15,000. These physicians would be subject to a \$50.5 million to \$56 million penalty under the FCA.<sup>161</sup>

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160. This total is reached by multiplying the damage sustained by the federal government by three, and then by 10,000 (for each claim), totaling \$30 million. The FCA’s mandatory penalty is \$5,500 to \$11,000. Multiplying this range by the amount of claims (10,000) totals \$55 million to \$110 million. When added to the first total, the penalty falls between \$85 million and \$140 million.

161. This total is first reached by calculating treble damages (1,000 patients multiplied by \$15,000 and three), which totals \$45 million. This is added to the statutory penalty of 1,000 multiplied by \$5,500 to \$11,000, which totals \$5.5 million to \$11 million. The sum of these products is \$50.5 million to \$56 million.



GRAPH 1

Scenario	Financial Harm Based Upon Medically-Illegitimate Care <sup>162</sup>	Intentional Fraudulent Scheme	Patients Affected	Median Total FCA Liability (in millions)
Example 1	\$100,000	No	10,000	\$82.8
Example 2	\$0	No	10,000	\$532.5
Example 3	\$10 million	Yes	10,000	\$112.5
Example 4	\$15 million	Yes	1,000	\$53.3

### C. Damages Calculations

The four examples demonstrate the potentially idiosyncratic nature of the FCA penalty calculation. The two arguably “worst” cases—scenarios in which physicians engage in an intentional fraudulent scheme and allow profits to color their clinical decision-making—would result in the second- and fourth-highest FCA liability, respectively. The scenario that features the most financial harm to Medicare results in the lowest FCA liability amount. The one scenario in which the physicians seemingly do not bill Medicare for *any* unnecessary medical services is the scenario with a liability amount exceeding half of one billion dollars—outpacing all other scenarios’ totals by more than \$400 million.

Generally, these examples demonstrate how dependent the damages calculation is on the *number* of total claims (the fewest number of patients affected garnered the lowest FCA liability amount), and not on the magnitude or totality of the harm inflicted, nor the brazenness of a particular provider’s acts. The FCA statute does not mandate multiplying damages for egregious breaches of the physicians’ duty to their patients or even patient harm, nor is it affected by large amounts of financial harm suffered by the federal health care programs. At bottom, how *false* the “technical falsity” is does not matter, nor does it matter how socially harmful a provider’s behavior is. A comparatively “innocent” and “cheaper” (per claim) mistake may carry enormous legal liability, whereas a relatively expensive and blatantly fraudulent scheme may carry less.

These observations demonstrate the potential for distortion of the current penalty structure—the statute itself lacks aggravating fac-

162. For purposes of this analysis, “harm based upon medically illegitimate care” is defined as dollars that Medicare paid that it should not have.

tors for egregious behavior and/or substantial patient harm and lacks mitigating factors when those factors are absent.<sup>163</sup> And where the FCA provides for a broad range of potential penalties, federal prosecutors are emboldened to choose both the targets of health care fraud investigations and the proposed penalty amount with little structural limitation. This opportunity for federal prosecutors opens the door to application of the statute to all kinds of clinical scenarios, including the costly problem of overtreatment.

#### IV. THE DISORDERING THREATS

Fourteen years ago, Professor Pamela Bucy noted that an “aggressive law enforcement machine” was “poised to pursue health care fraud,” armed with “weapons” that could “demolish a health care provider.”<sup>164</sup> And since that prophetic statement, health care fraud enforcement has ballooned, with the DOJ setting new annual records for fraud recoveries, individuals prosecuted, and cases closed on nearly an annual basis.<sup>165</sup> The application of the fraud statutes—and in particular, the FCA—has continued to grow into the 21st century, and will continue to do so under the ACA.<sup>166</sup>

Two particular characteristics of the regime—addressing both the procedure and the substance of the regulation of overtreatment—complicate the enforcement framework. First, procedurally, the effect of settlement-made law injects inconsistency into the regulation of overtreatment regulation, resulting in limited (if any) precedent. Second, the showings of harm and intent, factors traditionally separating the culpable from the innocent in other legal regimes, have limited effect in the regulation of overtreatment. Both types of characteristics—those related to settlement-made law and those related to the substantive underlying misconduct within overtreatment—are explained below.

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163. See 31 U.S.C. § 3729 (2012).

164. Pamela Bucy, *The Path from Regulator to Hunter*, 44 ST. LOUIS U. L.J. 3, 40 (2000).

165. See TRAC REPORTS, *supra* note 11; Press Release, U.S. Dep’t of Health & Human Servs., Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly \$4.1 Billion (Feb. 14, 2012), <http://www.hhs.gov/news/press/2012pres/02/20120214a.html>.

166. Press Release, U.S. Dep’t of Justice, Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud (Feb. 26, 2014), <http://www.justice.gov/opa/pr/2014/February/14-ag-206.html>.

A. *The Effect of Relying on Settlement*

A notable characteristic of the overtreatment enforcement regime is that few overtreatment *allegations* and *investigations* become overtreatment *cases*.<sup>167</sup> This is clear due to the fact that “virtually all false claims cases” are settled.<sup>168</sup> Given the potential costs of litigation and statutory penalties of an FCA violation, most providers targeted by an overtreatment investigation quickly settle any allegations and move on, knowing that any attempt at fighting them at trial risks their livelihoods and professional identities.<sup>169</sup>

Unsurprisingly perhaps, federal prosecutors often seem content with settling FCA allegations. Settlement saves litigation costs, avoids the risk of bad precedent, and may achieve the same level of deterrence as would a trial.<sup>170</sup> Similar to the DOJ’s demonstrated strategy of using targeted Corporate Integrity Agreements (“CIAs”) and individual settlements when regulating pharmaceutical companies under the fraud statutes, which allows the DOJ to “appear to be tough on health care fraud” while “avoid[ing] the risk that some of their fraud theories may not stand up in court,”<sup>171</sup> settling with providers who have allegedly engaged in overtreatment has the same effect.

The fact that its regulation largely depends upon settlement makes overtreatment susceptible to overenforcement, and may—from the providers’ perspectives—ultimately risk becoming illegitimate. Those providers who settle

may . . . feel deeply wronged if the provider truly believes that the interpretation of program requirements urged by the government or relator is wrong (or that, in any event, the billing was not culpable) and that the settlement was ex-

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167. See Buck, *supra* note 9, at 505 n.287; Jost & Davies, *supra* note 66, at 307 (“To a provider who faces the risk of penalties often running into the millions of dollars, the finality of swift settlement will often look quite attractive compared to the risk of a much larger judgment and possibly criminal penalties or exclusion if the case goes to trial. By settling early, the provider avoids future litigation costs, which might well be substantial.”).

168. Jost & Davies, *supra* note 66, at 307.

169. See Boese & McClain, *supra* note 135, at 18; Blanchard, *supra* note 129, at 114; see also Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors’ “Bad Law” Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 1029 (2009) (noting that investigations cost the provider financially, as well as “disruption of the practice, damage to reputation,” and “resultant ostracism or termination of necessary business relationships”).

170. Jost & Davies, *supra* note 66, at 308.

171. See Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1053–55 (2012) (noting the mutual desire in pharmaceutical fraud cases, from both the government and the targeted company, to settle).

torted from it because of the threat of massive penalties under the civil FCA and criminal penalties or exclusion.<sup>172</sup>

Startlingly, it could be the case that those engaged in legitimate treatment may actually be *more* likely to settle given the likelihood that they “fear the untoward effects of a fraud suit.”<sup>173</sup> This assertion has major implications for an enforcement mechanism that relies nearly exclusively on settlement. Notwithstanding these concerns, a settlement-driven regulatory scheme has resulted.<sup>174</sup>

With the cascading settlements for allegedly unnecessary medical services come particular challenges that threaten to clutter and weaken the enforcement framework. Specifically, the reliance on settlement (1) provides no clear precedent or strong condemnation of what the law *prevents*, (2) fails to avail itself of the important component of community involvement and judicial input, (3) relies too heavily on federal prosecutorial discretion, and (4) exacts reputational costs on investigated providers even absent settlement.<sup>175</sup> Brief summaries of these challenges follow below.

### 1. *No Clear Statement*

With few cases to test theories and make factual findings, the enforcement regime lacks an authoritative and cohesive statement of what, exactly, the law *prevents*—and where, in particular, the *limits* to that law are located. In general, where overcriminalization has taken hold, “[i]t becomes a formidable task for the average person to know what the law forbids, because the moral code offers no lodestar.”<sup>176</sup> More fundamentally, where a legal rule is overenforced, it “tends to weaken the moral force of criminal law.”<sup>177</sup>

The enforcement of a legal regime presents society’s opportunity to clearly and demonstrably declare certain behavior unacceptable. But in a regime susceptible to overcriminalization, the overuse of a legal rule “erodes the law’s ability to signal that certain conduct and certain people are out of bounds.”<sup>178</sup> Society’s message is murky, and this message is further clouded in a regime with few demonstrable le-

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172. Jost & Davies, *supra* note 66, at 310–11.

173. See Krause, *supra* note 16, at 208.

174. *Id.* at 205–06.

175. See Johnson, *supra* note 169.

176. Larkin, *supra* note 14, at 720.

177. Luna, *supra* note 18, at 729.

178. Larkin, *supra* note 14, at 750.

gal standards to begin with, in an industry that—particularly for cutting-edge procedures—often dwells in uncertainty.

In the overtreatment context, this confusion is evident among settling providers. Exemplified by settling hospitals during the so-called kyphoplasty initiative, providers expressed confusion over what misconduct they had committed, and noted that they had not acted fraudulently, and probably clinically correctly.<sup>179</sup> This confusion seemed understandable; the DOJ had entered into settlements with hospitals nationwide for performing a relatively new procedure on an inpatient basis instead of on an outpatient basis,<sup>180</sup> even while clinical guidance seemed to require inpatient treatment.<sup>181</sup>

Beyond the settling providers, when the DOJ achieves a settlement, the public is often left unclear as to whether the provider committed intentional fraud, or simply whether the federal prosecutors' conception of medical necessity differed from the providers' initial determination. In overtreatment regulation, both types of providers are likely to become ensnared in an investigation, and both providers' pictures are similarly likely to be splashed across newspaper headlines, along with their statements that they did nothing wrong.

## 2. *Stunted and Skewed Development*

In addition to failing to strongly condemn certain behavior, the overtreatment enforcement framework fails to provide a structurally guaranteed opportunity for other parties who may have a vested interest in the outcome of an investigation to have input in its enforcement. In a regime dependent on settlement, no opportunity exists for third parties—including patients, medical boards, trade organizations, and even judges—to influence the framework. Instead, the federal prosecutor operates in something of an echo chamber, often with little meaningful challenge to her legal theory or investigatory strategy.

Undoubtedly, the starkest absence from the overtreatment enforcement framework is that of the judiciary, and the development of the FCA itself has been stunted.<sup>182</sup> No “FCA common law” has developed; instead, one must cobble resulting settlements together to dis-

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179. See Buck, *supra* note 9, at 497–99.

180. *Id.* at 504.

181. *Id.* at 497–99. This initiative was started after a *qui tam* complaint was filed against a medical device company for deceptive sales and marketing of kyphoplasty kits. See *id.* at 496–97.

182. See Krause, *supra* note 16, at 205–06 (noting the development of the law is stifled).

cern a pattern of enforcement. This is particularly the case in the overtreatment context, where, often, patient harm is not obvious (or non-existent) and the provider's intent may not be ascertainable.<sup>183</sup>

This may be unsurprising, considering that the federal government is driving the enforcement framework and its prosecutors are authoring its newest theories of liability. However, by avoiding trials, the regime silences other voices that may have an interest in influencing it—and limits the citizenry from being able to infuse the law with the “conscience of the community.”<sup>184</sup> In their role as jurors, citizens can prevent overreaching and overenforcement and assign culpability.<sup>185</sup> This interaction gives the citizenry an important opportunity to influence the application and meaning of the law.<sup>186</sup>

In addition to largely shutting out the medical community, the enforcement regime forecloses the opportunity to secure a consultation point with a disinterested clinical expert. In a move that surprised commentators, the DOJ reached out to the HRS in order to review the medical necessity of ICD placement, and this likely led to the more granular and reasoned Resolution Model.<sup>187</sup> This demonstrates the importance of such a consultation as well as the absence of such a consultation in other overtreatment investigations.

As a result, in many investigations, there is no party to ensure that legal enforcement does not impose on clinical practice to the detriment of patients. Because the DOJ may lack firsthand expertise on clinical impact, the regulators must take it upon themselves to reach out to external clinical experts to determine whether or not the medical care at issue was inefficient and medically unnecessary, or, alternatively, whether it was a socially and medically beneficial cutting-edge procedure. Within many overtreatment investigations, discerning this type of distinction is hard enough for clinical experts; it is virtually impossible for federal prosecutors. But even this clinical consultation is not guaranteed in a settlement-based regime.

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183. See *infra* Part IV.B.2.

184. Jessica L. West, *Is Injustice Relevant? Narrative and Blameworthiness in Protester Trials*, 86 TEMP. L. REV. 107, 138 (2013) (internal quotation marks omitted).

185. *Id.* at 138–39 (“Because criminal trials function as evaluations of culpability, juries have an important role in deciding whether an individual’s action is blameworthy. By undertaking this evaluation, juries provide a backstop against government overreaching, overcriminalization, and the application of statutes that have ossified outdated values or social mores.”).

186. See Jenny E. Carroll, *Nullification as Law*, 102 GEO. L.J. 579 (2014).

187. See RESOLUTION MODEL, *supra* note 112.

### 3. *The Creation of “Superlegislators”*

Federal prosecutors own the decision as to whether or not to initially open an overtreatment investigation. With little resistance from within the provisions of the FCA, an impressive financial return on investment, and the ease with which settlement can often be achieved, the discretion of the prosecutor becomes paramount. Given these factors, it seems difficult to argue for investigatory restraint within this enforcement regime, especially when prosecutors are “under constant public pressure to do more, catch more, and be tougher.”<sup>188</sup> As a result, the federal prosecutor’s goal of preventing behavior that harms taxpayers—a constant concern in the prosecution of health care fraud<sup>189</sup>—may be deified to the exclusion of other policy concerns.<sup>190</sup> The prosecutor has uncommon power in deciding when and where to regulate overtreatment as health care fraud:

Perhaps even more disturbing is the fact that federalization will lead to a situation wherein the U.S. Attorney becomes, in effect, a “superlegislator,” deciding the extent to which the law will be applied over large classes of crime. Because resources are limited, the prosecutor alone decides which cases will go to court and which will not.<sup>191</sup>

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188. Johnson, *supra* note 169, at 1017.

189. See Press Release, U.S. Dep’t of Health and Human Servs., Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud (Feb. 11, 2013), <http://www.hhs.gov/news/press/2013pres/02/20130211a.html> (“This was a record-breaking year for the Departments of Justice and Health and Human Services in our collaborative effort to crack down on health care fraud and protect valuable taxpayer dollars,” said Attorney General Holder. . . . “This report demonstrates our serious commitment to prosecuting health care fraud and safeguarding our world-class health care programs from abuse.”); Press Release, U.S. Dep’t of Just., Obama Administration Announces Ground-Breaking Public-Private Partnership to Prevent Health Care Fraud (July 26, 2012), <http://www.justice.gov/opa/pr/2012/July/12-ag-926.html> [hereinafter, Partnership Press Release] (quoting Attorney General Eric Holder as saying “[t]his administration has established a record of success in combating devastating fraud crimes, but there is more we can and must do to protect patients, consumers, essential health care programs, and precious taxpayer dollars”); see also David A. Hyman & Joel V. Williamson, *Fraud and Abuse: Regulatory Alternatives in a “Competitive” Health Care Era*, 19 LOY. U. L.J. 1133, 1165–66 (1988) (noting that the Anti-Kickback Statute “was designed to safeguard the integrity of the Medicare program and to protect patients and taxpayers from profiteering and abusive practices”).

190. See Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 276 (2004) (“Given the balance of power, it should come as no surprise that prosecutors have the power to ‘encourage’ settlements, even where abstract legal analysis might favor the defendant. . . . Such concerns may be an inevitable consequence of the prosecutorial discretion granted by the fraud laws.”).

191. See Harrington, *supra* note 60, at 148.

Beyond deciding the targets and penalties within the enforcement framework, prosecutors operating in a regime subject to over-criminalization are able to “trip up morally blameless parties” and “to coerce guilty pleas from defendants seeking only to avoid unduly harsh punishments.”<sup>192</sup>

Recognizing the potential for FCA overuse against health care providers and responding to pressure to limit application of the FCA,<sup>193</sup> then-Deputy Attorney General Eric Holder issued a guidance memorandum in 1998, cautioning federal prosecutors and health care fraud coordinators to be judicious about its use.<sup>194</sup> In the document “Guidance on the Use of the False Claims Act in Civil Health Care Matters,” Holder warned:

While the broad reach and substantial damages and civil penalties under the Act make it one of the Department’s most powerful tools, Departmental attorneys are obligated to use their authority under the Act in a fair and responsible manner. This is particularly important in the context of national initiatives, which can have a broad impact on health care providers across the country.<sup>195</sup>

Further, Holder encouraged federal prosecutors to carefully examine whether or not the provider acted with requisite fraudulent intent, directing the DOJ to examine the “pervasiveness or magnitude of the false claims” in order to determine whether or not the claims “support[ed] an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes.”<sup>196</sup> Holder gave additional general guidance for prosecuting corporations in a subsequent 1999 memorandum.<sup>197</sup>

Federal prosecutors often constitute the primary fact-finder within other legal regimes, but in the overtreatment enforcement context,

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192. Larkin, *supra* note 14, at 735.

193. See Hyman, *supra* note 84, at 556–57 (noting that guidelines were a result of an “impressive lobbying campaign seeking a moratorium on enforcement actions” following questionable FCA investigations by the DOJ and OIG).

194. Memorandum from Eric H. Holder, Jr., Deputy Att’y Gen. of Dep’t of Justice, on Guidance on the Use of the False Claims Act in Civil Health Care Matters (June 3, 1998), <http://www.justice.gov/dag/readingroom/chcm.htm> [hereinafter Holder Memorandum].

195. *Id.*

196. *Id.*

197. See Memorandum from Eric H. Holder, Jr., Deputy Att’y Gen. of Dep’t of Justice, to All Component Heads and United States Attorneys, Bringing Criminal Charges Against Corporations (June 16, 1999), *available at* <http://www.justice.gov/criminal/fraud/documents/reports/1999/charging-corps.PDF>.



governed nearly exclusively by settlement, the prosecutor resembles something approaching the *sole* arbiter of justice. For a system in which nearly every provider settles, and the investigation itself brings with it some reputational penalty for the targeted provider, the initial decision of whether or not to investigate a particular provider—that is, *whom* the government decides to target—easily becomes the most important determination in the enforcement framework.<sup>198</sup>

#### 4. *The Punitive Power of the Fraud Investigation*

In addition to relying on settlement, the DOJ is able to count on the power of the investigation *itself* to force a change in provider behavior. This is because even when the DOJ decides not to seek damages or otherwise impose liability, the personal and individual cost of the investigation on one's medical reputation is substantial.<sup>199</sup> The cloud of impropriety—formed the moment an investigation of a particular provider is commenced—also impacts other physicians' practice patterns and professional view of the targeted provider.<sup>200</sup>

The punitive nature of a health care fraud investigation is personally consequential for providers; a fraud investigation and prosecution can impose significant costs due to “the importance of reputation” in the industry.<sup>201</sup> Indeed, “[t]he risk to reputation from a fraud charge is especially severe among professionals . . . whose good name is crucial in their business,” and “the interest in avoiding the stigma of dishonesty is very substantial.”<sup>202</sup> The DOJ's failure to appropriately narrow its investigation can inflict substantial reputational harm.<sup>203</sup>

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198. See Brown, *supra* note 36, at 223–24 (introducing the majoritarian view of overcriminalization as “expand[ing] the discretion of prosecutors to the point of lawlessness because, with broad codes, they can effectively pick and choose offenders as well as offenses”).

199. See Johnson, *supra* note 169, at 1000–02 (noting that the fraud investigation can serve as its own penalty). Indeed, “[t]he costs of the inquiry or investigation include financial costs, disruption of the practice, damage to reputation, resultant ostracism or termination of necessary business relationships, stress, shame, and other losses that are quite significant.” *Id.* at 1029. See also Frank LaSalle, *The Civil False Claims Act: The Need for a Heightened Burden of Proof as a Prerequisite for Forfeiture*, 28 AKRON L. REV. 497, 525 (1995) (“In the case of a contractor or health care provider, the allegation of fraud could seriously damage its business opportunities.”).

200. See Johnson, *supra* note 169, at 1029.

201. See Edward P. Richards & Thomas R. McLean, *Physicians in Managed Care: A Multi-dimensional Analysis of New Trends in Liability and Business Risk*, 18 J. LEGAL MED. 443, 465 n.115 (1997).

202. LaSalle, *supra* note 199, at 525.

203. Johnson, *supra* note 169, at 1029–30 (“At the same time, regulators enforcing standards want to assure that they uncover the few bad apples and so may cast a broad in-

And, as Professor Joan Krause has noted, over-regulation of health care fraud may increase provider distrust and, ultimately, destroy provider buy-in to the overall regulatory framework.<sup>204</sup> Contributing to providers' distrust of the regulatory scheme is the sense that the rules are "unfair and irrational"<sup>205</sup>—an allegation undoubtedly strengthened when innocent providers are subject to fraud investigations that place their reputations in peril.

Further, to some providers administering overtreatment subjected to a DOJ investigation, FCA application may constitute definitional spillover, as defined above. The FCA, created initially to prevent and punish individuals who were selling defective armaments to Union soldiers during the Civil War<sup>206</sup> and modernized during various amendments to apply to cases in which an individual or entity attempts to defraud the federal government more generally, was not intended for use as a standard of care regulation nor a rationing tool.

Definitional spillover occurs when some providers are captured within the regulatory regime and their cases are "not justified by its underlying social purpose."<sup>207</sup> Providers investigated by the federal government but who administered an ICD placement pursuant to their own clinical judgment—albeit outside the Medicare NCD—would be caught in an enforcement regime that is not intended to apply to them. The social purpose of preventing and punishing health care fraud—intentional deceit and unlawful conversion of taxpayer dollars—is not served by capturing actors when the NCD diverges from defensible clinical expertise.

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investigative net. This broad net would be expected to catch the small number of violators, but it would also be expected to catch a number of doctors who will not be charged with violations. The regulator who justifies casting the investigative net broadly as triggering 'only' an inquiry or further investigation but not necessarily sanctions fails to appreciate the substantial penalties that are inherent in the investigation itself. The intent of the law—protection of patients—is subverted by a 'catch-and-release' surveillance system. . . . At a minimum, regulators should set the parameters for investigation and inquiry as narrowly as possible to achieve the goals that they desire, and in a fashion that does not contradict the formal legal standard. They should recognize that they have to balance the risk that some violators will not be caught if the investigative parameters are too narrow with the risk that the majority of doctors will gear their practice to avoid being investigated.").

204. See Krause, *supra* note 16, at 127.

205. See Diane E. Hoffman, *Physicians Who Break the Law*, 53 ST. LOUIS U. L.J. 1049, 1054 (2009).

206. See THE FALSE CLAIMS ACT: A PRIMER, *supra* note 149.

207. Bierschbach & Stein, *supra* note 26, at 1748.

*B. The Limits of Harm and Intent*

In overtreatment regulation, settling providers and entities commonly trumpet their innocence. Often accompanying the DOJ's press release announcing the newest settlement with those trying to defraud the health care system, settling providers and entities note (1) that they "did not know" they were doing anything wrong, and (2) that they did not actually inflict any harm (either on their patients or on taxpayers). These statements invoke the two showings that typically measure the extent of an actor's misconduct under the law—intent and harm.<sup>208</sup> By stating that they did not know they were doing anything wrong, the provider or entity is noting that they did not act with the requisite intent under the FCA, and by noting that no harm occurred, they are invoking the age-old doctrine of "no harm, no foul."<sup>209</sup> Through these statements, the settling actor is indicating that they did not deserve to be targeted and that the sanction or penalty they face is undeserved.<sup>210</sup>

But these attempts are fleeting. In overtreatment regulation, largely due to the reliance on settlement, the lack of proof of intent and no showing of clear, discernible harm opens the regime to further inconsistency—and puts it at further risk of overenforcement.

*1. The Harm Challenge*

First, regarding the harm principle, Professor Krause, in a prophetic work more than a decade ago, aptly and adroitly analyzed the "harm problem" in FCA application to health care fraud.<sup>211</sup> Krause concluded that the courts' (and the federal government's) inconsistent treatment of the fiscal harm requirement in FCA enforcement raised questions about the legitimacy of the regime.<sup>212</sup> Particularly, Krause noted that:

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208. See Burrell, *supra* note 44, at 1301 (noting the importance of the two standards in the white collar crime context).

209. Courts invoke this limitation on liability in a number of contexts. See, e.g., *In re DiMartino v. Aquidneck Court Assocs.*, 108 B.R. 394, 403 (D.R.I. 1989) ("The no-harm-no-foul rule of the basketball court should be applied in this law court.").

210. See Luna, *supra* note 18, at 714 (noting that, in the criminal context, "the criminal sanction should be reserved for specific behaviors and mental states that are so wrongful and harmful to their direct victims or the general public as to justify the official condemnation and denial of freedom that flow from a guilty verdict").

211. See generally Krause, *supra* note 16 (documenting multiple courts' treatments of the harm requirement under the FCA).

212. See *id.* at 217 (noting that "[w]ithout a limiting principle to distinguish conduct that is truly deserving of censure under the FCA from minor noncompliance that does not

Traditionally, health care FCA cases have involved claims for services that were not provided at all or were not provided as indicated on the bill. The theory of government harm in these cases is straightforward: the government paid for items or services that it did not receive, and has been damaged by the amount of the (over)payment. The further the cases stray from this paradigm, however, the less clear it is that the government has suffered actionable harm.<sup>213</sup>

This concern is shared—and accentuated—in the regulation of overtreatment. In the overtreatment context, the care billed for *was* administered, and, like in the ICD initiative above, did not harm a patient (and likely was clinically beneficial), but the DOJ uses the FCA to penalize the provider for some aspect of that care.

Generally, federal prosecutors and health care regulators seek to prevent and remedy two chief harms through health care fraud initiatives and prosecutions.<sup>214</sup> First and foremost, they seek to prevent harm to taxpayers, and second, they seek to prevent harm to patients. According to the DOJ itself, health care prosecutions pursue “perpetrators intent on lining their own pockets at the expense of the American taxpayer, patients, and private insurers,” with a particular concern on the “long term solvency of Medicare and Medicaid.”<sup>215</sup> Even though Attorney General Holder has noted that the federal government’s anti-fraud efforts are focused on protecting patients, consumers, programs, and taxpayers,<sup>216</sup> it is clear that the primary focus seeks to limit and prevent harm to the American taxpayer.<sup>217</sup> According to

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affect government payment decisions, the health care industry may come to believe that the law is being enforced unfairly”).

213. *Id.* at 142 (footnote omitted).

214. *See, e.g.*, Partnership Press Release, *supra* note 189 (quoting Attorney General Eric Holder as saying, “[t]his administration has established a record of success in combating devastating fraud crimes, but there is more we can and must do to protect patients, consumers, essential health care programs, and precious taxpayer dollars”); *see also* Hyman, *supra* note 189, at 1165–66. (noting that the Anti-Kickback Statute “was designed to safeguard the integrity of the Medicare program and to protect patients and taxpayers from profiteering and abusive practices”).

215. *HEAT: A Year of Tackling Health Care Fraud*, U.S. DEP’T OF JUSTICE (Aug. 27, 2010), <http://blogs.justice.gov/main/archives/934>; *see, e.g.*, Holder Memorandum, *supra* note 194; *see also* Josh Savitz & Erica Trachtman, *False Statements and False Claims*, 49 AM. CRIM. L. REV. 703, 737 (2012) (“The Patient Protection and Affordable Care Act (‘PPACA’), enacted in March 2010, expanded the scope of the False Claims Act in an effort to combat health care fraud and recover taxpayer dollars.”).

216. *See* Partnership Press Release, *supra* note 189.

217. American taxpayers pay \$554 billion dollars each year for Medicare and pay roughly \$403 billion per year for Medicaid. *See* BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 762 (7th ed. 2013); *see also* Colleen Shalby & Jason Kane,

Acting Associate Attorney General Tony West, “protecting taxpayers from fraud, waste, and abuse [is] . . . one of the Attorney General’s top priorities.”<sup>218</sup>

In addition to protecting American taxpayers, the DOJ seeks to prevent harm to patients.<sup>219</sup> Throughout the 1990s, the DOJ opened investigations and prosecuted cases targeting providers who failed to meet a quality of care standard.<sup>220</sup> In these cases, the federal government sought to use typical anti-fraud tools to both punish those responsible for truly abhorrent health care and elevate the quality of care administered, and the goals of preventing patient harm and preventing taxpayer harm were connected. Those who provided bad care and billed the federal government for that care were, quite clearly, defrauding the government by billing for worthless services.<sup>221</sup>

In overtreatment initiatives, however, the harm is difficult to discern because it is often unknown. Even though the administration of unnecessary care is indisputably harmful,<sup>222</sup> the question of whether or not the patient received unnecessary care *is* the debated determinative question in the overtreatment context. If the treatment was

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*Medicaid: Your Questions Answered*, PBS NEWSHOUR (Oct. 3, 2012), <http://www.pbs.org/newshour/rundown/2012/10/medicaid-your-questions-answered.html> (including Christina Bellantoni and Phil Galewitz’s discussion of medicare costs). Within the DOJ’s FY 2013 Budget Request, the DOJ notes that it “focuses its investigative and litigation resources to eliminating fraud, returning ill-gotten gains to the Treasury and others, and strengthening our public health care programs.” U.S. DEP’T OF JUSTICE, FY 2013 BUDGET REQUEST: HEALTH CARE FRAUD 1, *available at* <http://www.justice.gov/sites/default/files/jmd/legacy/2014/06/30/health-care-fraud.pdf>. To this end, the DOJ requested nearly \$72 million in budget increases to “expand DOJ’s investigative and litigation capacity to address health care fraud.” *Id.*

218. See Press Release, U.S. Dep’t of Justice, Acting Associate Attorney General Tony West Speaks at Pen and Pad Briefing Announcing Record Civil FY 2012 Recoveries (Dec. 4, 2012), <http://www.justice.gov/iso/opa/asg/speeches/2012/asg-speech-1212041.html>).

219. See Press Release, U.S. Dep’t of Justice, Assistant Attorney General Tony West Speaks at American Bar Association Day at the University of Chicago Law School (Apr. 27, 2011), <http://www.justice.gov/iso/opa/civil/speeches/2011/civ-speech-110427.html> (“We’ve been particularly effective in fighting health care fraud, over the last two years opening more health care fraud matters, securing larger judgments and fines, negotiating higher settlements and recovering more money—over \$8B—than ever before. . . . And there are cases that clearly illustrate how health care fraud can undermine quality care and patient safety.”).

220. Devin S. Schindler, *Pay for Performance, Quality of Care and the Revitalization of the False Claims Act*, 19 HEALTH MATRIX 387, 396–400 (2009).

221. *Id.*

222. See Barry R. Furrow, *The Patient Injury Epidemic: Medical Malpractice Litigation as a Curative Tool*, 4 DREXEL L. REV. 41, 90 (2011) (“Unnecessary care that lacks therapeutic benefit is presumptively poor quality care, and it arguably represents malpractice if harm occurs to the patient.”).

unnecessary, the patient was harmed; if the treatment was clinically defensible, the patient likely was not. The determination is not a legal one; it is medical. And the conclusion as to whether the procedure was medically necessary or not for the patient directly informs the question as to whether or not the taxpayer was harmed. For example, within the ICD initiative, if providers who placed the ICD at Day 38<sup>223</sup> committed only a “technical violation” but benefitted their patients, an allegation of harm becomes difficult to prove. Instead, the government tasked with paying for “reasonable and necessary”<sup>224</sup> medical care could not have suffered any loss.

## 2. *The Problem of Intent*

Obviously, for health fraud allegations resolved by settlement, federal prosecutors do not have to carry the burden of proving fraudulent intent—whatever, exactly, that now means.<sup>225</sup> The initial determinations of which providers administer treatment that is “false,” and which providers are “deceptive” enough to draw an investigation become paramount. Conversely, in other scenarios and industries where the FCA and other fraud statutes are employed, the requirement that the defendant act with fraudulent intent separates the schemer from the non-fraudulent negligent actor; it is the difference between the intentional deceptive act and an unreasonable but unintentional mistake.

But in the regulation of overtreatment, enforced largely by settlement, the intent of the provider is comparatively unimportant.<sup>226</sup> Instead, a provider’s intent is often left unclear; it is simply inferred by the DOJ and the public from the alleged *egregiousness* or *unreasonableness* of the care administered because there is often no other metric with which to measure. Whether the DOJ has evidence that a provider engaged in fraudulent behavior or was simply negligent—typically a major distinction in the law—may not be a dispositive distinction for

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223. ICDs placed within forty days of a myocardial infarction were deemed to be “technical” violations. See RESOLUTION MODEL, *supra* note 112, at 9.

224. See 42 U.S.C. § 1395y (2012).

225. See generally Sheyn, *supra* note 135.

226. This tracks the minimization of fraudulent intent in health care fraud cases more generally. See Hoffman, *supra* note 205, at 1060 (“[I]t appears that some physicians are prosecuted for unintentional violations of the law. . . . The absence of intent is not determinative.”).

the imposition of liability or the opening of an investigation. The fact that one was merely negligent may not offer any protection.<sup>227</sup>

Early on in the investigation, no distinction among providers is made.<sup>228</sup> For example, in the ICD investigation, it is unclear whether fraudulent intent mattered in the initial stages of the investigation, especially because the DOJ swept up all providers who performed ICDs outside of Medicare's timing requirements. The question of *why* the providers performed ICD placements outside of the NCD timing requirement was simply one to be answered later in the investigation. The DOJ uses clinical reasonableness as a standard to separate those who committed health care fraud from those who may have committed "technical" violations.

The challenges associated with proving intent in these cases are further complicated by five practical problems associated with initially establishing fraudulent intent in all overtreatment cases. Even where a provider acts with fraudulent intent, it is often difficult to discern. And given how damaging fraud investigations can be to providers, where provider intent is not clear from the early facts of the case, a drawn-out overtreatment investigation can quickly become a costly exercise in debating granular medical regulations and practice standards (to which the law and the blunt FCA would seem to be ill-equipped to speak).

*No fact-finding.* First, as aforementioned, few trials in this context ever occur, and the regime lacks judicial involvement or review. As a result, the fact-finding function of the legal process is shortchanged. Because the government rarely has to prove a provider's intent, both the public, and more importantly, other providers, do not know whether the settling provider acted culpably—and had participated in a fraudulent scheme—or whether they were a victim of a seemingly-roving enforcement mechanism. Settling providers are happy to argue their innocence,<sup>229</sup> noting that their reasons for being outside the

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227. Ryan Winkler, *The Civil False Claims Act and Its Unreasonably Broad Scope of Liability: The Need for Real "Clarifications" Following the Fraud Enforcement and Recovery Act of 2009*, 60 CLEV. ST. L. REV. 533, 547 (2012).

228. *See id.* ("Moreover, it appears that merely negligent defendants are now subject to liability under the amended FCA.")

229. *See North Ohio Heart Reaches Settlement; Continues to Provide High-Quality Cardiac Care*, NORTH OHIO HEART: OHIO MEDICAL GROUP (Jan. 4, 2013), <http://blog.partnersforyourhealth.com/Blog/bid/93734/North-Ohio-Heart-Reaches-Settlement-Continues-to-Provide-High-Quality-Cardiac-Care> [hereinafter NOHC Blog Post] (quoting a statement issued by John Schaeffer, M.D., Chairman and President, North Ohio Heart Center: "[t]he settlement is not an admission of wrongdoing; rather, we settled this matter so we can put it behind us and move forward"); Saabira Chaudhuri,

norm were legitimate<sup>230</sup> or that they were following government-endorsed guidance,<sup>231</sup> while the DOJ calls the settling doctors greedy and irresponsible.<sup>232</sup>

*The limitation of hindsight.* Second, because medical expertise advances so quickly, particularly in specialties in which cutting-edge treatments are often employed, it is difficult to retroactively review a clinical decision made five or ten years earlier. Many overtreatment investigations are focused on cutting-edge medical procedures,<sup>233</sup> for which the clinical standard of care has not cemented. Because of this, it is comparatively easy for the DOJ to retroactively point toward a procedure that, with the assistance of hindsight, looks unnecessary or wasteful.<sup>234</sup> But just because the cutting-edge procedure was not done in accordance with today's medical standards does not make its administration ten years ago wasteful, nor does it demonstrate the existence of fraudulent intent on behalf of the provider.

*Lack of consensus.* Third, within the complex world of medical practice, clinical disagreement is often the norm. By using a fact-specific clinical guideline as the demarcation line between appropriate care and fraudulent care, the DOJ may over-capture physicians who provide satisfactory and non-fraudulent care within the regulato-

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*DaVita Agrees to \$55M Settlement*, DENVER POST (July 3, 2012), [http://www.denverpost.com/ci\\_20996923/davita-agrees-55m-settlement](http://www.denverpost.com/ci_20996923/davita-agrees-55m-settlement) (“DaVita and its affiliated physicians did nothing wrong and stand by their anemia management practices,” the company said.); John Commins, *Rex Healthcare to Pay \$1.9M to Settle Fraud Claims*, HEALTHLEADERS MEDIA (Apr. 5, 2011), <http://www.healthleadersmedia.com/page-2/HEP-264523/Rex-Healthcare-to-Pay-19M-to-Settle-Fraud-Claims> (“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.”).

230. See NOHC Blog Post, *supra* note 229 (“As leaders in cardiac care, we have always been early adopters of new technology when we believe using it will help improve our patients’ lives.”).

231. See Commins, *supra* note 229 (“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.”).

232. For his part, Steven M. Dettelbach, the U.S. Attorney for the Northern District of Ohio, admonished that “[p]atient health and taxpayer dollars have to come before greed.” Press Release, U.S. Dep’t of Justice, EMH Regional Medical Center and North Ohio Heart Center to Pay \$4.4 Million to Resolve False Claims Act Allegations (Jan. 4, 2013), <http://www.justice.gov/usao/ohn/news/2013/04janemh.html> [hereinafter EMH Regional Medical Center].

233. See *supra* notes 95–127 and accompanying text; see also Buck, *supra* note 9, at 497–99.

234. *Id.*; see also NOHC Blog Post, *supra* note 229 (noting that the procedures covered by settlement were “cutting edge at the time” and that “[c]ardiac care has progressed significantly in just the past few years”).



ry net. For example, multiple physicians could debate and disagree on a given course of treatment, but whether or not the physicians who subscribe to the minority position actually engaged in fraud is a wholly separate question, dependent—unsurprisingly—on the provider’s intent. Even when procedures are no longer viewed as cutting-edge procedures, clinical agreement can be difficult to achieve.<sup>235</sup> These debates further cloud the culpability analysis.<sup>236</sup>

Because there can be wide disagreement within the medical community itself, it is both (1) difficult to demonstrate that a provider “outside the norm” was aware that she was so, and (2) easy to find providers who are “outside the norm”—potential targets of an investigation—because the standard has not fully gelled.<sup>237</sup> In many clinical areas, no norm exists: medicine is as much an “art” as it is a science—practice patterns are often viewed as individualized and personal,<sup>238</sup> and standardization is often seen as hostile to the unique practice of medicine.<sup>239</sup> Characterizing each medical decision as exclusively “appropriate” or “fraudulent” overgeneralizes and disregards the complexity involved in providing care.<sup>240</sup>

*Mere awareness is not enough.* Fourth, providers may be aware of different procedures’ reimbursement rates—and may know which are the most lucrative. Within Medicare’s reimbursement system, providers know that if they provide extra, unnecessary treatments, they will

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235. See Maxwell J. Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 ARIZ. ST. L.J. 1165, 1218–19 (2012).

236. See, e.g., Hoffman, *supra* note 205, at 1075 (discussing the application of laws to physicians when the standard of care is not unified and noting the “laws are medically questionable” and “make arguments to harshly treat these physicians more difficult”).

237. Once identified (which takes time), medical guidelines can easily become stale and are subject to loopholes that “enable clinicians to practice individualized medicine.” See Mehlman, *supra* note 235, at 1218–19.

238. See S.C. Panda, *Medicine: Science or Art?*, 4 MENS SANA MONOGRAPHS 127 (2006), available at <http://www.msmonographs.org/printarticle.asp?issn=0973-1229;year=2006;volume=4;issue=1;spage=127;epage=138;aulast=Panda>. Many physicians are hostile to the move toward standardizing medical practice, calling it “cookbook medicine,” but many policy-makers believe in standardization. See Andis Robeznieks, *Not ‘Cookbook Medicine,’* MODERN HEALTHCARE (June 1, 2013), <http://www.modernhealthcare.com/article/20130601/MAGAZINE/306019990/1138>.

239. See Robeznieks, *supra* note 238.

240. In 2006, when the North Ohio Heart Center in Northeastern Ohio was placing drug-eluting stents at four times the national average, experts called their behavior “reasonable” and noted that “doctors in a particular geographic area tend to be unaware if the way they are treating their patients is markedly different from the practices of their peers in other areas.” Reed Abelson, *Heart Procedure Is off the Charts in an Ohio City*, N.Y. TIMES (Aug. 18, 2006), [http://www.nytimes.com/2006/08/18/business/18stent.html?pagewanted=all&\\_r=1&](http://www.nytimes.com/2006/08/18/business/18stent.html?pagewanted=all&_r=1&).

most likely experience higher revenue, due to Medicare's inability heretofore to limit volume in any meaningful way.<sup>241</sup> These incentives to aggressively treat may impact a provider's administration of health care, but whether or not the provider is acting greedily, irresponsibly, or fraudulently is another question entirely.<sup>242</sup> Nor does being aware of reimbursement rates mean that the provider is acting out of his "desire . . . to maximize profits" instead of "the medical needs of patients."<sup>243</sup>

Expecting providers to stand against their own economic interests when the health care administration and delivery system has been structured to incentivize them to be aware of, and exploit, profit concerns, seems at least confusing, and perhaps unjust. Indeed, "[p]rovider responses to the incentives offered by public health care financing program payment structures cannot always easily be categorized as legitimate or illegitimate. Rather, they lie along a continuum ranging from beneficial to inexcusable."<sup>244</sup> The distinctions, if they exist, are fine; they depend on a finely-tuned regulatory scheme, not the largest club in the government's arsenal.

*Resulting potential under-capture.* Finally, and perhaps most surprisingly, the problems inherent in the overtreatment enforcement regime work not only to over-capture individuals who may not have acted with the requisite fraudulent intent, but may under-capture a number of providers who act *with* requisite fraudulent intent but who elude detection. As Professors Lemos and Stein note, "By allowing law enforcers to seek penalties in just a few cases out of many, the model will incentivize them to concentrate their efforts on easy cases . . ." Those sophisticated violators who conceal their misdeeds "consequently will acquire a practical immunity against prosecutions, while the law enforcers go after and impose harsh penalties upon small-time offenders."<sup>245</sup>

In overtreatment regulation, these "sophisticated violators" are the providers who administer the extra procedure not to benefit the

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241. See FURROW ET AL., *supra* note 222, at 789–91 (noting that physicians increase volume of services administered to achieve higher Medicare reimbursement without limitation).

242. See EMH Regional Medical Center, *supra* note 232 (capturing descriptive words used by the U.S. attorney in a recently settled case).

243. See Press Release, U.S. Dep't of Justice, Fifty-Five Hospitals to Pay U.S. More Than \$34 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (July 2, 2013), <http://www.justice.gov/opa/pr/2013/July/13-civ-745.htm>.

244. Jost & Davies, *supra* note 66, at 254.

245. Lemos & Stein, *supra* note 66, at 12.

patient, but rather, to increase their reimbursement amount, but do so in a way that does not raise the attention of the DOJ. If the provider's overtreatment—administration of an unnecessary open heart surgery for an elderly patient, for example—does not clearly fall outside of the norm of other providers or an easy-to-apply medical standard, the DOJ likely never initiates an investigation, no matter the wrongfulness of the clinical care offered to a particular individual patient. As a consequence, providers may be incentivized to protect one another by standardizing wasteful procedures—and herd immunity results.

Outside of the *qui tam* mechanism, investigators have limited tools to distinguish the cases in which the provider is acting in the interests of the patient (those cases in which it truly is the case that the individual could be benefited by the procedure, for example) from the cases in which the provider is instead acting in his own self-interest, knowing that his administered care will not raise a red flag. If it truly is the case that individuals will only get flagged if they are outside the clinical norm, then crooked providers can simply offer care that is within—or close to—that norm, all the while seeking primarily to line their own pockets. This strongly highlights the importance of maintaining a cooperative regulatory scheme between the legal regulators and the medical professionals; conversely, increasing tension between the two further leads to major investigatory challenges. A disordered framework has a tendency to instill and foster an “us against them” mentality in the medical profession.

## V. RECALIBRATING THE REGULATORY STRUCTURE

Perhaps the most likely fix of overtreatment overenforcement will come from the institution that may shoulder the most blame for building the overbroad enforcement framework in the first place. In August of 2013, Representative Howard Coble (R-NC) introduced a bill entitled the “Fairness in Health Care Claims, Guidance, and Investigations Act,”<sup>246</sup> noting that “[t]he tension between the medical profession and federal investigators has never been higher.”<sup>247</sup> Representative Coble’s bill radically constricts usage of the FCA, and would impact—and perhaps end—its application to cases of clinically defen-

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246. H.R. 2931, 113th Cong. (2013), [www.govtrack.us/congress/bills/113/hr2931/text](http://www.govtrack.us/congress/bills/113/hr2931/text).

247. Ed McDonald, *Coble Introduces Hospital Fairness Bill*, CONGRESSMAN HOWARD COBLE NEWS (Aug. 1, 2013), <http://coble.house.gov/news/documentsingle.aspx?DocumentID=345007>.

sible overtreatment by installing four dramatic requirements in advance of an FCA investigation. Specifically, the proposed law would (1) require the Attorney General to certify that the allegations are “viable” and “appropriately pursued,” (2) limit application to underlying claims reflecting “a material amount,” (3) grant immunity to providers who submit bills “in good faith reliance on erroneous information,” and (4) raise the standard of proof for all FCA cases—from the current civil standard of preponderance of the evidence to a higher standard of clear and convincing evidence.<sup>248</sup>

Coble appears to be concerned about over-application of the FCA to non-culpable conduct within the health care industry. He is quoted on his website as noting:

The U.S. Justice Department is claiming that hospitals that admit patients for an overnight stay, instead of simply observing, treating and discharging their patients, are committing fraud. My hope is that this legislation will help ease this tension.

....

Whether patients realize this or not, . . . the actions of the Justice Department are diminishing the quality of care that hospitals can provide to many patients. Sending patients home against doctors’ orders is unwise. This bill will allow hospitals to concentrate on patients and not confusing and duplicative regulations.<sup>249</sup>

Unsurprisingly, the American Hospital Association (“AHA”) has heralded Coble’s proposal.<sup>250</sup> By requiring Attorney General review, immunizing providers who are misled by voluminous regulations, and ratcheting up the intent standard for all FCA cases, the bill would undoubtedly have an impact on the regulation of overtreatment.

Apart from the political feasibility of Representative Coble’s proposal, his suggestions begin to address some of the concerns raised by overenforcement theory, the breadth of the FCA, and both the procedural and substantive challenges that complicate the regulation of overtreatment. His suggestions counsel toward narrowing health fraud investigations so they only target those most deserving of a

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248. See H.R. 2931.

249. See McDonald, *supra* note 247.

250. See Aaron M. Danzig, *Sometimes a Mistake Is Just a Mistake: Bill Introduced in the House of Representatives to Push Back Against Aggressive Department of Justice Health Care False Claims Investigations*, LEXOLOGY (Aug. 13, 2013), <http://www.lexology.com/library/detail.aspx?g=f2a1edb9-d398-4d18-a071-00196a7c7f82>.

health fraud investigation. At the least, they attempt to introduce clear rules governing the application of the FCA in the health fraud context.

Notwithstanding Coble's proposal, generally, by both (1) being cognizant of the scope of the investigation and (2) adopting a practice of consulting with the medical community, federal prosecutors would be able to change the regulation of overtreatment without completely rebuilding the enforcement regime. A mandatory consultation with a disinterested clinical expert would not only steer fraud investigations toward those who committed intentional and harmful health care fraud, but would also address some of the intransigent sources of medical-legal dissonance—particularly the failure of communication between law and medicine<sup>251</sup>—within the complex industry of American health care. If providers feel that health fraud regulation is fair and ordered, they will be more likely to cooperate within that framework. Sensing a reasonable enforcement framework, providers may become more likely to assist in regulating their own profession instead of turning inward against the lawyers, as they currently do.<sup>252</sup>

Above all, the determination of whether fraud occurred should no longer be solely legal, aggressive, and adversarial determinations, but instead, should be medical, flexible, and cooperative determinations. Namely, a new regime would incorporate more medical expertise, foster more cooperation between the government prosecutors and potential targets of investigation, and feature a range of acceptable clinical practice. This would further legitimize the regime, and, ultimately, encourage provider buy-in because if providers respect the enforcement regime, they will heed its prohibitions<sup>253</sup> and can actually assist in the execution of the law.<sup>254</sup>

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251. See Johnson, *supra* note 169, at 1014 (noting that “doctors hear about legal risk from colleagues,” and that “the more that lawyers tell doctors that what they have heard is untrue, the more the untrue stories may be viewed as accurate”).

252. See *id.* at 1010 (noting “physicians’ fears of the risk of legal entanglement”).

253. See Stephen Townley, *The Hydraulics of Fighting Terrorism*, 29 *HAMLIN L. REV.* 65, 108 (2006) (noting that “cooperative regulation permits and fosters the development of trust between regulators and those subject to regulation” which further legitimates the regime, and “laws that are seen as legitimate are often obeyed”); see also Josh Bowers & Paul H. Robinson, *Perceptions of Fairness and Justice: The Shared Aims and Occasional Conflicts of Legitimacy and Moral Credibility*, 47 *WAKE FOREST L. REV.* 211, 265 n.261 (2012) (noting that individuals who perceived a legal regime as fair are more likely to cooperate in the enforcement of the regime).

254. See Michael L. Rich, *Lessons of Disloyalty in the World of Criminal Informants*, 49 *AM. CRIM. L. REV.* 1493, 1522 (2012) (“When people believe that the law and law enforcement

In addition to ratcheting down the tension that currently exists between providers and the law,<sup>255</sup> a system that ceded more power to a disinterested clinical expert would allow medicine, and modern clinical standards that change quickly, to drive the regulation of fraud, likely scrubbing it of some of the causes of overenforcement. By incorporating the expertise of the medical profession—whether housing particular medical experts within certain DOJ offices or mandating the consultation of a group of trusted medical advisers *before* beginning an investigation—“technical” or regulatory violations would likely never yield a time-consuming and reputation-risking health care fraud investigation. Instead, the clinical expert would presumably be able to assist in discerning the difference between a harmful fraudulent act and a clinically beneficial one before any reputational penalties result. She would be able to note that ICDs placed within thirty-eight days of a myocardial infarction, based upon the underlying clinical realities of the patients at issue, should not be characterized as fraudulent.

In addition to steering the investigation, adding an independent medical liaison within the DOJ investigation could allow for investigated providers to petition the office, arguing at the outset that the clinical care administered was legitimate and appropriate.<sup>256</sup> After careful review, the petition could be granted, in which case the investigation would close, or the petition could be dismissed, after which the investigation would continue. This would work to protect the discretion of the federal prosecutors, but would also allow an individual from the medical community to determine which cases were worth pursuing, based upon her clinical expertise. Within a cooperative regulatory framework, targeted providers may be less combative with the prosecutors, less hostile to the legal regime, and more willing to admit to mistakes—especially if they know an independent clinical expert is a member of the investigatory team.

In addition to building structures that would enhance collaboration and cooperation between the regulators and the regulated, and

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are legitimate, they are more willing to actively cooperate with police by, for instance, reporting crimes in their neighborhoods.”).

255. See McDonald, *supra* note 247.

256. This system could resemble the Stark Law’s self-disclosure protocol. See *Self-Referral Disclosure Protocol*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 21, 2013), [http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self\\_Referral\\_Disclosure\\_Protocol.html](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html). Perhaps the DOJ could field calls from providers notifying it of administration of care that would otherwise raise red flags.

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in order to protect against the damaging effects of prosecuting those engaged in overtreatment that is innovative and legitimate, there should be a wider range of acceptable behavior available to providers. As long as patients are not being harmed, the treatment is not clearly unnecessary, the quality of care is excellent, and there is no discernible pattern of any scheme, providers at or close to the norm—particularly in cutting-edge procedures and subspecialties—should be given deserved autonomy in making clinical decisions without having to worry about a blindsiding call from the DOJ. For example, those who place ICDs in “technical violation” of the Medicare NCD guidelines should be given a pass, not a notice of investigation.

## VI. CONCLUSION

Focused narrowly on limiting rising costs, federal prosecutors have sought to apply the anti-fraud tools to cases of overtreatment without attention to the impact of the strategy or the requisite flexibility that is needed to regulate both a multifaceted industry and a unique practice such as medicine. Recent overtreatment investigations and settlements provide cloudy guidance, stoke provider distrust of the regulatory regime, and characterize a framework that seems unconcerned with only pursuing culpable actors who intentionally inflict harm on the federal health care programs and/or its beneficiaries.

By employing a random and seemingly disordered enforcement framework, federal prosecutors have risked further stoking tension between the medical and legal industries, and instead, may actually be deterring beneficial conduct. With a regulatory framework so susceptible to overuse and overenforcement, it seems time for a recalibration of health care fraud enforcement—one focused on a cooperative enterprise that prevents and punishes those who inflict clear, discernible harm. Anything less risks continuing an unsustainable overdose of enforcement.

