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USING THE FALSE CLAIMS ACT TO SECOND-GUESS WHAT PATIENTS NEED:  
HUNGRY RELATORS, OUTSIZED DOJ RECOVERIES, AND THE ADVERSE  
CONSEQUENCES FOR AMERICAN HEALTH CARE

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## Working Paper

### Using The False Claims Act To Second-Guess What Patients Need: Hungry Relators, Outsized DOJ Recoveries, And The Adverse Consequences For American Health Care

By Mark W. Pearlstein and Laura McLane

#### Introduction

Politicians are often heard decrying fraud and abuse in the health care system, particularly where government payers like Medicare and Medicaid are involved. There is no question that such fraud occurs: indeed, cases involving physicians billing payers for patients they did not see, or for treatments they did not provide, most certainly exist. Among other remedies, fraud of this kind is often redressed through a Civil War era statute known as the False Claims Act (FCA),<sup>1</sup> which holds government contractors, including health care providers, civilly liable to the United States for treble damages and penalties if they knowingly or recklessly submit false or fraudulent claims to a government payer, such as Medicare or Medicaid. When a provider bills for something that was not done, the FCA provides an appropriate remedy, consistent with the purpose of the statute: to punish and deter receipt of government funds through fraud.

But the FCA has expanded far beyond this worthy objective, and a discussion about reform is in order. When the Department of Justice (DOJ) announced record FCA recoveries totaling \$5.69 billion at the end of fiscal 2014, \$2.3 billion of those recoveries concerned settlements and judgments in the health care industry, many by providers accused of billing for allegedly unnecessary patient care—i.e., care or treatment that the government claims patients did not need.<sup>2</sup> Similarly, in 2015, the majority of DOJ's \$1.9 billion in health care FCA recoveries involved settlements of allegations alleging medically unnecessary care.<sup>3</sup> And over half of DOJ's \$4.7 billion in FCA recoveries in 2016 concerned health care, including recoveries involving medically unnecessary care or services; DOJ also announced that it has “recovered \$19.3 billion in health care fraud claims from January 2009 to the end of fiscal year 2016 – 57 percent of the health care fraud dollars recovered in the 30 years since the 1986 amendments to the False Claims Act.”<sup>4</sup>

A reader might say, so what? If a provider gives care that a patient does not need and bills for it, shouldn't the provider suffer the consequences? In clear cases, yes; a physician who performs an amputation for a hangnail and bills for it likely committed fraud within the intended meaning of the FCA. But the problem is this: in most cases, medical necessity is a matter of substantial disagreement as to which reasonable, qualified physicians can—and do—differ. Subjective physician judgment inherently leads to differences of opinion among physicians, bringing to mind

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<sup>1</sup> 31 U.S.C. § 3729 *et seq.*

<sup>2</sup> <https://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014>

<sup>3</sup> <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>

<sup>4</sup> <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016>

the aphorism that if four physicians are asked for their views on a particular procedure, the result will be at least five different opinions (because even a single physician's subjective views of a patient's needs may change). In most instances, each of these opinions would be reasonable and consistent with applicable standards of care. As such, FCA cases alleging lack of medical necessity often devolve into battles between or among expert witnesses who disagree on the central issue of patient need.

Using the FCA—a fraud statute—to police questions of medical necessity except in very clear cases strays far from the statute's intended purposes. But this has not stopped the government from pursuing these types of claims which, combined with other theories of liability often pursued in FCA cases in health care (such as allegations that claims were false because care was substandard—subject matter traditionally reserved for the medical malpractice/negligence realm), render the FCA an ever-expanding booby trap of potentially catastrophic liability for providers of health care in the United States.

These problems are compounded by the fact that FCA cases are increasingly brought by private “whistleblowers” (called “relators”) in the government's name, who stand to reap substantial financial benefit based on a percentage of any recovery from the defendant. According to DOJ, between 2009 and June 2016, more than 4,700 *qui tam* actions were filed by relators. In that timeframe, relators were rewarded over \$3 billion.<sup>5</sup> It should come as no surprise that *qui tam* relators, supported and indeed sought out by a well-funded relators' bar, have every incentive to not only bring suit, but to go big: large providers are a target, and relators will invariably allege that, for example, the purported medically unnecessary care extended to all corners of a hospital system, or to all of a provider's outpatient clinics nationwide. And given that large providers often serve some of the neediest patient populations who depend on public insurance programs to cover their health care costs, the ultimate impact of the threat of such broad and potentially catastrophic liability is to limit access to care for the most economically disadvantaged.

The procedural trajectory of a typical FCA case alone imposes significant burden and cost on a provider, whether or not the provider has done anything wrong (which, again, is often a highly subjective question). The government is required by the statute to investigate the claims in a relator's FCA complaint, which is filed under seal such that the defendant does not have access to it. The investigation often takes several years as a result of government-requested judicial extensions of the 60-day seal (i.e., investigation) period set forth in the FCA. The provider typically catches wind that an investigation is ongoing only when it is served with a subpoena for documents from the government. The provider incurs substantial costs and endures significant disruption to its operations and personnel in responding to the government's investigation; among other things, the provider often must collect and produce hundreds of thousands if not millions of documents and make employees available for testimony or interviews. Judicial intervention to minimize the burden imposed by the government's investigation is rarely granted (and therefore is rarely sought).

At the end of its investigation, the government decides whether to proceed with (i.e., intervene in) the lawsuit and take over its prosecution. Even if the government declines to intervene, the relator

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<sup>5</sup> <https://www.justice.gov/opa/speech/acting-assoc-attorney-general-bill-baer-delivers-remarks-individual-accountability>

still can—and, these days, often does—go forward on the government’s behalf. In either event, it is only at this point that the complaint is finally unsealed and served on the defendant. In other words, the government’s expensive, often multi-year investigation all takes place before litigation even begins; regardless of the investigation’s outcome, a provider’s reward for enduring it is usually a ticket to defending itself in litigation in federal district court.

Inevitably, many providers choose to settle at some point during this process, not because they did anything wrong, but because the ongoing costs of the investigation and litigation, enterprise risks of not settling and being found liable—massive damages and penalties, and possible suspension or exclusion from participating in government health care programs—are simply too great.

We use the term “choose” here loosely because the decision whether to settle or fight is, in most situations, a Hobson’s choice, a reality demonstrated by the case of *United States ex rel. Drakeford v. Tuomey Health System*. While not a medical necessity case, *Tuomey* is a cautionary procedural tale for all FCA defendants, particularly in health care. In October 2005, Dr. Michael Drakeford filed his *qui tam* complaint against Tuomey Healthcare System, alleging False Claims Act claims based on Stark law violations. After ten years of government investigation and litigation, including two jury trials, two trips to the United States Court of Appeals for the Fourth Circuit, and a staggering trial judgment of \$237 million Tuomey ultimately settled with the Department of Justice on October 16, 2015 for \$72.4 million. Tuomey was on the doorstep of bankruptcy by the time it settled (the settlement also involved Tuomey’s sale to another health system). The relator, Dr. Drakeford, received hefty compensation for initiating the lawsuit: \$18.1 million plus an additional \$2.5 million payment for attorneys’ costs and fees.

Aggressive use of the FCA against health care providers shows no signs of relenting, and any provider that contracts with the government is at risk that care deemed by a physician to be medically necessary and appropriate at the time it was given may later be challenged by a relator and/or DOJ. The adverse consequences of using the FCA as a tool to police issues of medical judgment by labeling them “fraud” are likely vastly underreported. However, at a minimum, they include increasing the cost of health care, decreasing patient access to health care (particularly in needier patient populations), impairing a provider’s ability to attract and retain physicians and staff due to adverse reputational impact, and deterring physicians from performing otherwise necessary treatments out of fear of being labeled a fraudster. These effects are explored in further detail, below.

FCA reform is necessary, particularly in health care. But there is little appetite for reform in Congress, whose track record with respect to the FCA in recent history is to make such cases easier, rather than harder, to pursue. Nonetheless, the conversation needs to start. To that end, several reform ideas are discussed in the final section of this article.

### **The False Claims Act: How It Works**

The FCA is sometimes referred to as the “Lincoln Law.” It was passed in 1863 to address, on a civil basis, fraud committed by government contractors on the Union army during the Civil War. The FCA in its original form was designed to combat “fraud” in the sense that most people

understand that word; it was aimed at objectively deceptive conduct such as billing the government multiple times for the same mules, repainting rotted ships and selling them as new, and selling gunpowder barrels containing sawdust.

The statute enumerates a number of different ways one can violate it, but the FCA’s most classic prohibition concerns “presenting or causing another to present a false or fraudulent claim for payment or approval” to a federal government payer, and doing so “knowingly.” 31 U.S.C. § 3729(a)(1)(A). “Knowingly” as used in the statute is a bit misleading though, because under the FCA, knowledge can be established through proof of recklessness; a defendant’s actual knowledge that a claim was false or fraudulent need not be proven. The false or fraudulent nature of the claim must also be material to the government’s payment decision (the meaning of materiality under the FCA was discussed at length last year by the United States Supreme Court in *Universal Health Servs., Inc. v. United States ex rel. Escobar*.<sup>6</sup>)

There is a 6-year statute of limitations under the FCA with a discovery rule that can extend that period for up to 10 years (at least in the case of government-initiated actions), meaning that an FCA complaint can theoretically encompass allegedly false claims going back for a decade, thus increasing the risk of staggering liability.

Many states have parallel statutes prohibiting false claims. Federal FCA claims are often brought in conjunction with relevant state provisions in situations where state as well as federal funds are involved. The state provisions are usually treated by courts and litigants as imposing virtually identical prohibitions as their federal counterpart.

The consequences of a defendant being found to have violated the FCA are severe—so severe, in fact, that the Supreme Court in *Escobar* was clear that the statute is “essentially punitive.”<sup>7</sup> Under the FCA, damages are automatically trebled, and penalties are assessed on a per claim basis—notably, the range of available penalties doubled last year from \$5,500-\$11,000 per claim to \$10,781-\$21,563 per claim, and more recently was further bumped up to \$10,957-\$21,916 per claim. In a case involving a nationwide health care provider that provides services to thousands of patients and submits hundreds of thousands of claims for reimbursement, it is easy to see how FCA penalties can quickly skyrocket into the hundreds of millions if not billions, rendering their threat a game changer.

As discussed above, FCA suits can be brought directly by the government, or by a private party known as a *qui tam* relator. (A diagram laying out how the legal process typically unfolds can be found at Appendix A.) A series of amendments to the FCA beginning in 1986 have made the FCA more appealing to relators. Among other things, the 1986 amendments enhanced the so-called “relator’s share” provisions such that now, if the government intervenes and recovers money from the defendant, the relator is guaranteed to receive between 15-25% of the proceeds, plus attorney’s fees and costs. If the government declines to intervene and the relator goes forward and recovers money on the government’s behalf, the relator’s guaranteed share of that recovery escalates to 25-30% plus attorney’s fees and costs. Subsequent amendments in 2009 (pursuant to the Fraud Enforcement and Recovery Act) and 2010 (pursuant to the Affordable Care Act) made FCA claims

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<sup>6</sup> *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002-04 (2016).

<sup>7</sup> *Universal Health Servs.*, 136 S. Ct. at 1996.

easier for relators and the government to pursue by relaxing various requirements and expanding the grounds for liability. The particulars of those amendments are beyond the scope of this article, but the point is that the legislative trend with respect to the FCA has been to expand the pool of (1) those who can bring claims as relators, (2) those against whom claims can be brought, and (3) the types of conduct that can constitute “fraud” within the meaning of the statute.

The deck has become increasingly stacked in favor of *qui tam* relators and against defendants. In the past, the government’s decision not to intervene was often the death of the case, as relators frequently would not proceed. This is no longer true: the FCA’s *qui tam* provisions, as amended, have spawned a well-funded and increasingly sophisticated relators’ bar, with the means to finance FCA litigation for years in the hopes of a pot of gold at the end, regardless of what the government does. Representing relators has become a big business, and there is no shortage of disgruntled employees, former employees and others who are more than happy to oblige by serving as relators in the hope of receiving a big pay-day.

### **Prime FCA Targets: Large Health Care Providers**

Given the financial incentives available to relators, it is not surprising that large health care providers with a nationwide or broader presence are among the prime targets of FCA cases; the bigger the provider, the more claims it submits to government payers, and the more damages and penalties that may be recoverable. While FCA claims are most certainly brought against small physician practices, such small-provider cases are not the ones sought out by leading relators’ lawyers and their clients. A big provider has a target on its back, for the simple reason that any recovery from that provider is likely to be large, and so too will be the relator’s share of that recovery.

FCA claims asserted against large providers often do not allege paradigmatic fraud like billing for patients who do not exist or treatments that did not occur. They tend to converge on the fringes, straining reasonable interpretations of the statute’s boundaries. Often, these claims will allege company-wide “schemes” that purportedly resulted in the submission of masses of allegedly false claims by physicians employed by or affiliated with a provider. Importantly, the large providers targeted by these claims are also the ones that have the infrastructure to provide care to lower-income patient populations covered by programs such as Medicaid, for whom access to health care is otherwise limited or nonexistent. Such larger providers, of course, are attractive targets for *qui tam* complaints and government investigations, presenting a bit of a paradox in that the providers most targeted in FCA actions are also the ones serving the underserved patient populations in the most need of care.

To be clear, nobody contends that any provider should get a free pass on fraud simply because of the patients it serves. The point, however, is that the increasingly aggressive and creative use of the FCA to police issues never intended be anywhere near the statute’s scope carries with it a host of unintended consequences for patients and the health care system in general, as discussed in more detail later in this article.

### **Nationwide Medical Necessity Claims: A Hunting Ground for Deep-Pocketed Defendants**

Lack of medical necessity is one of the most common theories of FCA liability pursued by relators and the government against large health care providers. The usual theory is that physicians provided care that was not medically necessary or where a less costly form of care would have sufficed, and the provider then billed for it. To name just a few examples, these cases may allege that unnecessary medications were prescribed, unnecessary medical or dental procedures were performed, or unnecessary hospital admissions were ordered.

In order to bring the broadest possible claims, complaints in medical necessity FCA cases usually allege a corporate scheme designed to induce physicians to provide unnecessary care—often, the allegation will be that the organization pressured or incentivized physicians and others, through compensation structures or other means, to over-treat. An organization that tracks physician productivity will be viewed with automatic suspicion—common business practices such as productivity metrics and goals will be characterized by relators and the government as mechanisms to encourage overtreatment by tracking and rewarding productive physicians and penalizing physicians who are not productive. Thus, the theory goes, physicians are pressured to provide more care than they otherwise would. Productivity metrics are viewed as evidence of wrongdoing notwithstanding the fairly straightforward fact that it is impossible to run a health care organization (whether for-profit or not) without keeping track of the amount of services being provided to patients.

Even if a corporate provider in fact “schemed” to encourage overutilization by tracking productivity and rewarding highly productive physicians, this does not actually prove that overutilization occurred. It is well-settled that a corporate scheme that did not result in the submission of false claims does not violate the FCA.<sup>8</sup> Physicians are bound by ethical rules that preclude them from providing unnecessary patient care to patients,<sup>9</sup> and the notion, which lies at the foundation of many FCA cases, that an organization routinely prevailed on scores of physicians on a nationwide basis to risk their licenses by providing unnecessary care is untenable. Could an occasional physician be influenced to over treat? Maybe. Of course, in our experience, those physicians are the exception. The vast majority of physicians genuinely seek to do what is in their patients’ best interests.

The fact of the matter is that, as a rule, physicians resist perceived interference with their clinical judgment. And because one physician’s subjective clinical judgment can vary significantly from another’s, necessity cases are a bad fit for the FCA, except in the most egregious situations. Indeed, FCA cases alleging lack of medical necessity typically devolve into a battle of experts on each side. Experts are often used by both the government and provider as early as the investigation stage, as the provider attempts to convince the government not to intervene, and the government seeks to convince the provider to enter into a settlement. Competing expert results based on the experts’ review of patients’ medical records, without the benefit of a face to face patient interaction, are often at the heart of these discussions, with the government’s expert inevitably coming to a higher “error rate” (i.e., percentage of procedures deemed unnecessary or where an

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<sup>8</sup> See, e.g., *United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (“The False Claims Act, then, focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme.”); *United States ex rel. Hagerty v. Cybertronics, Inc.*, 95 F. Supp.3d 240 (D. Mass. 2015) (holding that a relator’s allegations of a scheme to provide unnecessary surgeries were insufficient without details of allegedly false claims submitted to the government).

<sup>9</sup> See, e.g., American Medical Association Code of Medical Ethics (imposing duty of honesty on physicians).

alternative procedure is deemed preferable) than the provider's expert. And, of course, if the case proceeds to litigation, dueling medical experts will be a central feature of the case during discovery, dispositive motion practice and (if it gets that far) at trial. Amid the fog of war occasioned by multiple experts debating whether one medical treatment versus another was necessary for a patient or group of patients, it is easy to forget that the issue in any FCA case is not what expert has the better opinion, but whether the defendant committed knowing or reckless *fraud* on the United States government.

Medical experts in necessity cases play another important role for the government or a relator, who will try to establish broad geographical "fraud" without having to actually prove that each individual treatment at issue was unnecessary. Instead, the government and/or a relator will attempt to use a short cut pursuant to which their expert's error rate, based on the percentage of medically unnecessary treatments within a statistically valid sample, is extrapolated beyond the sample to establish a far broader fraud. Take, for example, a sample of patients who received a particular surgical procedure. If the government's expert claims that 30% of the procedures performed in the sample were medically unnecessary, the government will then attempt to extrapolate beyond the sample and claim that 30% of *all* of the procedures performed on the provider's patients were unnecessary.

Courts have met efforts to sample and extrapolate to prove broad FCA liability with mixed reactions, given that extrapolation is not authorized by the statute, and because it effectively relieves the government of its burden of proof as to a substantial portion of its case.<sup>10</sup> In fact, extrapolation in medical necessity cases rests on an inherently false premise: the judgment of a Massachusetts physician about how to treat a particular patient says nothing about the appropriateness of judgments made by different physicians treating different patients in different states. Nonetheless, in evaluating litigation risk, providers have no choice but to assume that extrapolation may be permitted and used.

Whether or not extrapolation is permitted, the big problem with most medical necessity cases brought under the FCA is that they boil down to the government's attempt to substitute its judgment, through its expert, for that of the treating physician. This permits the government to do indirectly what Congress has prohibited it from doing directly: insert itself into the patient-physician relationship. Federal law forbids the federal government from exercising "any supervision or control over the practice of medicine or the manner in which medical services are provided . . . ." 42 U.S.C. § 1395. But medical necessity claims under the FCA run directly into the prohibitions of this statute, retroactively second-guessing physician decision-making (without the benefit of seeing the patient), while wielding a virtual Sword of Damocles—the threat of treble damages and massive penalties—if the provider chooses to fight. And, in addition to the direct

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<sup>10</sup> See, e.g., *United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 07-cv-00604, 2016 U.S. Dist. LEXIS 80160, at \*35 (N.D. Tex. June 20, 2016) ("In this context, statistical sampling of the type done by [the expert] . . . cannot establish liability for fraud in submitting claims for ineligible patients, as the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians."); *United States ex rel. Michaels v. Agape Senior Community*, No. 12-cv-3466, 2015 U.S. Dist. LEXIS 82379, at \*24 (D.S.C. June 25, 2015) (rejecting sampling to prove liability and damages and certifying question for interlocutory appeal to Fourth Circuit), *aff'd in part, dismissed in part, United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017) (dismissing as improvidently granted the relators' appeal of the court's statistical sampling ruling); *United States ex rel. Martin v. LifeCare Centers of America, Inc.*, No. 08-cv-251, 2014 WL 4816006, at \*17-18 (E.D. Tenn. Sept. 29, 2014) (allowing sampling and extrapolation to prove liability).



monetary threat, the government (HHS-OIG) holds an additional lever that perpetually looms in the background: the threat of suspension or exclusion from the public health care programs like Medicare and Medicaid, otherwise known as the health care “death penalty.”

At the end of the day, medical necessity is an inherently subjective concept. As many defendants have therefore argued, if reasonable medical professionals disagree about whether a treatment or procedure is necessary, there simply cannot be fraud within the meaning of the FCA. Imposing punitive FCA liability in such cases is simply unfair, and bears no relationship to what the FCA was designed to accomplish. A number of federal court decisions have agreed with defendants on this point.<sup>11</sup> The problem is, by the time a defendant gets a chance to address this issue on a motion to dismiss or at summary judgment, it usually has endured a lengthy, expensive and largely one-sided government investigation. Many provider defendants choose not to incur the costs of taking it this far, not because they believe their physicians over-treated patients, but because waiting for an opportunity to address the issues in litigation simply costs too much, and outcomes in litigation are never guaranteed. Even if a provider elects to litigate a case through summary judgment, it is a rare provider that takes a case all the way to trial given the uncertainties and extreme risks associated with a loss.<sup>12</sup>

Finally, even when a provider elects to settle, it is only partly the end of the story. More often than not, the provider will need to enter into a Corporate Integrity Agreement (CIA) with HHS-OIG, as the price for HHS-OIG refraining from exercising its right to exclude the provider from participation in federal health care programs. CIAs impose a number of compliance, monitoring and reporting requirements on the provider, often for a five year period. OIG has a substantial amount of discretion with respect to the terms of CIAs, which can come in various forms and degrees of invasiveness with respect to an organization’s business and clinical operations. For example, HHS-OIG has in some cases has insisted on “quality of care” CIAs in addition to “Necessity” CIAs. In a quality of care CIA, physicians’ decisions and care are subject to constant monitoring on the issue of whether the care provided was of sufficient quality. . In any event, compliance with a CIA is typically very expensive and burdensome, and a provider that fails to

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<sup>11</sup> See, e.g., *United States ex rel. Polukoff v. St. Mark’s et al.*, No. 16-cv-00304, 2017 U.S. Dist. LEXIS 8167, at \*2 (Jan. 17, 2017 D. Utah) (“Opinions, medical judgments, and ‘conclusions about which reasonable minds may differ cannot be false’ for the purposes of an FCA claim.”); *United States ex rel. Paradies v. Aseracare, Inc.*, 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016) (“A mere difference of opinion between physicians, *without more*, is not enough to show falsity.”); *United States ex rel. Hockett v. Columbia/HCA*, 498 F. Supp. 2d 25, 65 n.29 (D.D.C. 2007) (“[W]here reasonable medical minds might differ over the preferred course of treatment, FCA liability will be inappropriate.”); *United States ex rel. Lockyer v. Haw. Pac. Health*, 490 F. Supp. 2d 1062, 1075 (D. Haw. 2007) (“[A] practice which may constitute a technical violation of one expert’s assessment but is in compliance with another expert’s opinion does not give rise to fraud.”); but see *United States ex rel. Hayward v. SaveSeniorCare LLC*, No. 11-cv-00821, 2016 U.S. Dist. LEXIS 132336, at \*43-44 (M.D. Tenn. Sept. 27, 2016) (rejecting defense based on difference of medical opinion where complaint alleged clinicians were driven by corporate policies to provide unnecessary therapy).

<sup>12</sup> The case against Tuomey Health Care System, while not a medical necessity case, stands as a cautionary tale for health care providers faced with the trial versus settlement dilemma. Tuomey opted to go to trial on FCA allegations premised on underlying violations of the Stark law. A jury in the District of South Carolina returned a verdict against Tuomey, finding that it submitted 21,730 false claims to Medicare. The judge assessed \$237,454,195 in damages and penalties against Tuomey, a crushing sum which exceeded the hospital system’s annual revenue. The Fourth Circuit affirmed. (Tuomey and DOJ subsequently settled for \$72.4M, which was viewed as the hospital system’s only option to stay operational, given the size of the judgment).

comply may face FCA liability anew, as failure to comply with a CIA's provisions has itself been used as a basis for an FCA claim.<sup>13</sup>

A final word about FCA claims in health care: they take many forms. While this article has focused on FCA cases alleging lack of medical necessity, there are a variety of other broad theories frequently employed against health care providers, sometimes in conjunction with necessity claims, and sometimes on their own. These include claims alleging poor quality of care (known as "worthless services" claims), claims for retaining overpayments received from government payers (the "reverse false claims" theory), and claims based purely on ancillary regulatory violations (so-called certification claims). Each of these could be the subject of its own article, but the point is that there is no shortage of legal theories that are levied against health care providers under the auspices of the FCA. Chances are, creative relators' counsel will continue to come up with novel theories of FCA liability. While these may give rise to big year-end numbers for DOJ, at a certain point, hard questions about the costs of such creativity for patients and the health care system will need to be addressed.

### **The Adverse Consequences For Health Care**

Cases involving disputes between the government or a relator on the one hand, and a provider on the other hand, about medical necessity are far outside the heartland of what the FCA was designed to address. Nonetheless, such cases are a reality, and with them comes a host of adverse consequences as the price of ferreting out this purported "fraud." There are the obvious drains on provider resources, discussed above. The costs associated with defending an investigation and eventual litigation can be massive, as can the costs of settlement or verdict.

But the costs go far beyond those directly endured by providers. DOJ advertises that it has recovered nearly \$20 billion in health care FCA matters since 2009. While the recovered funds certainly include cases involving "traditional fraud" (e.g., the fake patients or fake treatments scenario), they also include necessity cases of the type discussed in this article. The often substantial recoveries, along with defense and other costs (like the costs associated with a CIA) necessarily drive up the overall cost of health care. Indeed, even for providers that have yet to be targeted, the costs of operating in an environment where a potential bounty-hunting relator lurks around every corner are high, even if a provider has a flawless compliance program.

A word about deterrence is important. Among the purposes of the FCA is to deter would-be fraudsters, but there are other unintended deterrent effects of the statute, which disproportionately impact underserved patient populations. Providers may be deterred from accepting publicly insured patients or expanding into underserved markets, in part due to fears of becoming a target.

The reputational sting of being labeled a fraudster also impedes patient access to care. Every substantial FCA settlement is accompanied by a press release from DOJ and/or the relevant U.S. Attorney's Office containing strong language about the purportedly abusive and fraudulent behavior covered by the settlement. Quality physicians may be reluctant to join a provider that is embroiled in an FCA case, or that has settled one and is functioning under a resulting CIA. The same is true for non-physician employees. The consequences of such bad publicity reverberate

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<sup>13</sup> *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-cv-287, 2015 U.S. Dist. LEXIS 94448 (E.D. Pa. July 21, 2015).

beyond personnel, and have a deterrent effect on lenders and investors, such as private equity investors who otherwise might back a provider's expansion into previously underserved areas.

Finally, physicians, conscious that a relator or aggressive prosecutor may be perpetually sitting on their shoulder, may unintentionally undertreat, or to decline to pursue more innovative treatment options, out of fear of being accused of fraud. Such a chilling and insidious effect on physician decision-making is at odds with any legitimate animating purpose of FCA.

### **Time For A Conversation About Reform**

While there is no question that the FCA serves a purpose to punish and deter true fraud, the pendulum has swung too far, and reform is necessary. While there is little impetus for meaningful reform in Congress, the subject needs to be on the table. There are many ways to skin the proverbial cat, and almost anything would be a start. To get the conversation started with a focus on health care, below are four potential reforms that would weed out massive FCA claims based on tenuous theories such as lack of medical necessity.

No extrapolation: Any discussion of FCA reform should include imposing express prohibitions on the use of extrapolation to prove liability in cases based on the treatment or care of patients. In other words, in medical necessity cases, the government or a relator should be required to prove each of the allegedly false claims without the sampling short-cut that extrapolation provides. As one leading FCA commentator has observed, “[t]here is little doubt that if DOJ brought an FCA case based on five false claims, it could not prove one of them and then argue the other four are just like the first one. If that is true, why should DOJ be excused from proving each claim is false when it brings an FCA case based on 5,000 or 50,000 false claims?”<sup>14</sup>

While extrapolation is not authorized by the FCA, given that some courts have allowed it, an amendment to the statute to clarify its impermissibility should be added, which would most certainly reduce meritless claims against health care providers (and possibly others, as this reform need not be limited to health care), or reasonably limit their scope.

Reduce relators' share: As this article makes clear, relators have too much to gain, and providers have too much to lose, creating a perverse incentive structure that forces costly settlements in cases involving conduct that nobody in Lincoln's era would have recognized as fraud. Some incentive to encourage legitimate relators to “blow the whistle” on fraud is necessary. But the relator's share provisions of the FCA have become the tail that wags the dog. Consideration should be given to a significant reduction of the relator's share percentage to a level that would still cause relators to come forward, but not inspire relators and their counsel to gin up “creative” claims. An alternative concept might be a fixed award regardless of the size of the government's recovery. After all, reporting fraud is reporting fraud, and it is not obvious why a relator reporting fraud within a large organization that submits a high volume of claims should reap more benefit than a relator who reports fraud within a smaller organization. Modifications of this type would have the added benefit of ensuring that more of the money actually recovered pursuant to the FCA ends up in the hands of the government—the actual victim of the alleged fraud—rather than a private party.

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<sup>14</sup> John T. Boese, Civil False Claims and Qui Tam Actions, § 2.03(C)(4).

Relators' role ends at intervention decision: The government's election to decline to intervene should be the end of the story; allowing relators to go forward, where the government has chosen not to do so, exposes defendants to costly litigation in which they must defend claims that the government did not see fit to pursue. While opponents would argue that the government declines for many reasons having nothing to do with the merits and does not have the resources to pursue every meritorious qui tam claim, the counter is that defendants cannot pick and choose, and must defend *any* FCA claim that a relator decides to pursue, regardless of what the government—the real party in interest—does. Some leveling of the playing field is necessary. Moreover, once a relator has brought claims to the government's attention, the government has been put on notice of the fraud, and the purpose behind the FCA's whistleblowing function has been achieved.

Tighter seal period: At a minimum, the length of the investigation period needs to be reined in, given that we live in a world where FCA defendants likely face litigation regardless of the investigation's outcome. The government should not be able to obtain routine seal extensions that allow the 60-day seal period to drag out for years. While some courts have become more vigilant about holding DOJ's feet to the fire during investigations, as a general matter the "good cause" standard that DOJ must meet to justify an extension has been fairly forgiving. 60 days may be too short, but two or more years is far too long for a provider to be under the cloud of a one-sided investigation. A modification to the seal period to reflect these considerations, or a tightening of the good cause requirement to give it more teeth, should be considered so that providers do not have to expend millions of dollars and thousands of man hours over the course of years, only to face litigation at the end.

## **Conclusion**

The FCA's aggressive use in health care cases by both the government and private parties means that nowadays, allegations go well beyond "fraud" in any traditional sense of that word, allowing the government and relators' lawyers to retroactively second-guess physician decision-making, all the while wielding the formidable threat of treble damages and potentially crippling penalties. Proponents of the aggressive and expansive use of the FCA argue that the statute reduces health care costs by uncovering and stopping reimbursement fraud, but they typically fail to acknowledge the other side of the coin: relators are incentivized to bring creative and often meritless FCA cases, and business realities force providers to settle such cases regardless of their merit. This reality imposes a strain the American health care system, by both increasing health care costs and impairing access to care. Accordingly, now is the time for realistic discussions about reasonable reform.

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APPENDIX A

The Typical False Claims Act Process

