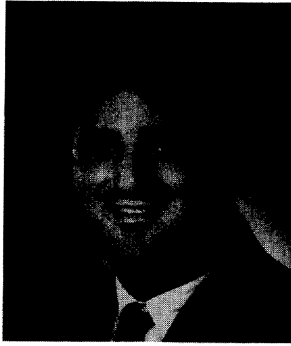




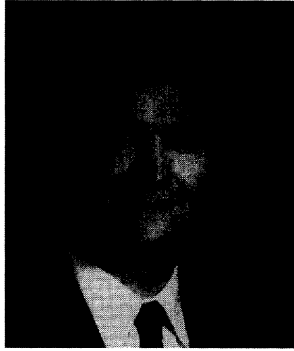
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PROLIFIC PLAINTIFFS OR RABID RELATORS? RECENT DEVELOPMENTS IN FALSE CLAIMS ACT LITIGATION

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INTRODUCTION

The False Claims Act¹ (“FCA”), which penalizes parties who knowingly submit false claims for payment to the government, is arguably the single most potent weapon in the federal health care law enforcement arsenal. Part of the potency of the FCA is that it provides for a private right of action, paying “whistleblowers” a bounty of any recovery that results.² Recent developments in the use of the FCA reveal that it may be fertile ground for abuse by private whistleblowers and the government. The FCA has played a significant role in federal health care law enforcement, resulting in hundreds of millions of dollars in settlements and judgments for fraudulent false claims.³ It is possible, however, that FCA victories come at a significant cost: compromising innocent defendants’ due process rights and imposing substantial duress on those accused.

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1. 31 U.S.C. §§ 3729-3733 (2002).

2. *Id.* § 3729(b).

3. The General Accounting Office (“GAO”) reported that since 1996, the Department of Health and Human Services’ (“HHS”) Office of the Inspector General (“OIG”) has estimated that Medicare improperly paid billions of dollars each year, including more than \$13 billion in fiscal year 2002 alone. U.S. GEN. ACCOUNTING OFFICE, GAO-03-1030T, FEDERAL BUDGET OPPORTUNITIES FOR OVERSIGHT AND IMPROVED USE OF TAXPAYER FUNDS, STATEMENT OF DAVID M. WALKER, COMPTROLLER GENERAL OF THE UNITED STATES 15 (July 17, 2003).

This Article discusses the history of the FCA (Part I) and recent trends toward potentially abusive prosecution under the FCA, including improper use of the complaint seal rules (Part II), predication of actions under the FCA based upon alleged Stark Law violations (Part III), and coercion through the use of oppressive discovery (Part IV). Additionally, the Article cites numerous examples of situations in which the government arguably has misused the FCA (Part V). After providing a thorough history and analysis of the FCA, this Article concludes by encouraging the judiciary to more closely scrutinize the use of the FCA and advocating for administrative enforcement reform in the agencies responsible for initiating investigation and prosecution of potential violations of the FCA.

I. FALSE CLAIMS ACT

The FCA, once known as “Lincoln’s Law,” was first passed during the Civil War in response to fraud in military procurement contracts.⁴ The statute incorporated the English law concept of the *qui tam* relator, a whistleblower who brings suit on behalf of the government and receives a percentage of any award.⁵ The statute was amended on several occasions, primarily to enhance the *qui tam* provisions to encourage relators with new information to bring suit while preventing parasitic suits based on public knowledge.⁶ The most recent amendment to the FCA was in 1986.⁷ That amendment raised the award from double to treble damages, increased the penalties from \$2,000 to a range from \$5,000 to \$10,000, and fine-tuned the *qui tam* provisions.⁸ The penalty for violating the FCA may also include exclusion from the Medicare program, a death knell for many Medicare providers.⁹

In addition to the potential for significant penalties under the FCA, the costs, both legal and administrative, to defend against such an investigation can be astronomical depending on the breadth and depth of the investigation. Consequently, many innocent health care providers targeted in FCA investigations elect to settle rather than defend against the case.

Since the 1986 amendment, the government and private *qui tam* relators have applied the statute against Medicare and Medicaid providers with increasing aggression. Since its inception, and prior to the 1986 Amendment,

4. Act of March 2, 1863, ch. 67, 12 Stat. 696.

5. *Qui tam* is short for “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,” meaning “who as well for the king as for himself sues in this matter.” BLACK’S LAW DICTIONARY 1262 (7th ed. 1999).

6. *Wercinski v. Int’l Bus. Machs. Corp.*, 982 F. Supp. 449, 455-56 (S.D. Tex. 1997).

7. False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. § 3729 (2004)).

8. *Id.*

9. See, e.g., Neal A. Cooper, Note, *Third Party Liability or the False Claims Act: It is Time for Consultants to Pay the Price for Their Bad Advice*, 29 J. MARSHALL L. REV. 923, 923-24 (1996).

the FCA has applied only to claims that are actually false, such as claims for services never provided, fraudulent invoices,¹⁰ mislabeled or shoddy goods,¹¹ and fraudulent statements.¹² However, after the 1986 amendment, relators attempted to use the fact that a health care provider personally signs Medicare claim forms to expand the FCA to include a “false certification” theory.¹³ Under the false certification theory, a claim that accurately reflects the services provided and the fees charged (i.e., true information) could nonetheless be “false” for purposes of the FCA if it included an inaccurate certification that the claimant complied with applicable statutes and regulations.¹⁴ Some courts have accepted a limited false certification theory, finding it applicable only “when certification is a prerequisite to obtaining a government benefit.”¹⁵

The next attempt by the government and relators to expand the FCA was with an “implied false certification” theory. Under the “implied false certification” or “implied certification” theory, a party submitting an otherwise true but unsigned claim form could violate the FCA because the submission of the claim itself implies compliance with all laws and regulations affecting the party’s right to receive payment under the claim.¹⁶ The implied false certification theory has not been as well received as the false certification theory, and several federal circuit courts have declined the opportunity to accept it.¹⁷

10. *See, e.g.*, *United States v. Ueber*, 299 F.2d 310 (6th Cir. 1962) (billing overhead, an indirect cost, as time and materials, a direct cost); *United States v. Aerodex, Inc.*, 469 F.2d 1003 (5th Cir. 1972) (providing used aircraft bearings and billing for new bearings).

11. *See, e.g.*, *United States v. Bornstein*, 423 U.S. 303 (1976) (providing falsely branded radio tubes); *Henry v. United States*, 424 F.2d 677 (5th Cir. 1970) (providing substandard pine oil disinfectant); *United States v. Milton Marks Corp.*, 240 F.2d 838 (3d Cir. 1957) (providing defective ammunition cartridge clips); *United States v. Nat’l Wholesalers*, 236 F.2d 944 (9th Cir. 1956) (providing surreptitiously mislabeled motor vehicle generators).

12. *See, e.g.*, *United States v. McNinch*, 356 U.S. 595 (1958) (providing fictitious credit reports to obtain FHA loans); *United States v. Lurie*, 222 F.2d 11 (7th Cir. 1955) (providing fraudulent certificates in order to procure veterans’ preferences in the purchase of war surplus property).

13. *See, e.g.*, *United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996); *United States ex rel. Hill v. California*, 129 F.3d 128 (9th Cir. 1997) (unpublished table decision).

14. *Hopper*, 91 F.3d at 1266.

15. *Id.*

16. *See, e.g.*, Form CMS 1500 (Medicare Part B claim form) and the certification language thereon; *see Hopper*, 91 F.3d at 1261; *see also Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429 (Fed. Cl. 1994), *aff’d*, 57 F.3d 1084 (Fed. Cir. 1995) (unpublished table decision).

17. *United States ex rel. Willard v. Humana Health Plan of Tex.*, 336 F.3d 375, 382 (5th Cir. 2003); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 n.8 (4th Cir. 1999); *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1164 n.8 (10th Cir. 1999).

II. FALSE CLAIMS ACT SEAL PROVISION—SIGNIFICANT AREA OF POTENTIAL ABUSE

A. *Due Process Considerations*

1. *Description of Seal Provision in False Claims Act*

By statute, qui tam complaints brought under the FCA must be filed in camera (for the judge's eyes only) under seal, with no notification to the defendant, and initially for no less than sixty days.¹⁸ Notice is only provided to the defendant upon further order of the court in which the case is filed.¹⁹ At the same time that the suit is filed, the relator must furnish the U.S. Attorney General with a copy of the complaint, along with "all material evidence and information the person possesses" concerning the action.²⁰ Within the original sixty-day period following the Attorney General's receipt of the relator's complaint and additional documentation, the Attorney General must decide whether the government will: (1) intervene in the action by filing a Notice of Intervention,²¹ after which the relator's direct involvement with the case virtually ceases; (2) decline to intervene in the action, in which case the relator may pursue the case without assistance from the government; or (3) move the court to extend the seal for an additional amount of time.²² It is the third option—extending the seal period—that is ripe for abuse by the government and relators resulting in deprivation of a defendant's constitutional due process rights of self-defense.

2. *History and Original Intent of the Seal Under False Claims Act*

The seal provision of the FCA is unique in federal civil law, as no other statute allows the filing of a complaint in a civil case under seal. The seal provision was added to the statute in 1986 at the request of the Department of Justice ("DOJ") to alleviate the concern that "the public filing of overlapping false claims allegations could potentially 'tip off' investigation targets when the criminal inquiry is at a sensitive stage."²³ Congress granted the DOJ's request to a limited extent by adding a provision that requires all relators'

18. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

31 U.S.C. § 3730(b)(2) (1986).

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.* §§ 3730(b)(2)-(3).

23. S. REP. NO. 99-345, at 24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5289.

complaints to be filed with the DOJ under seal for sixty days.²⁴ Senate Report 345 specifically stated:

By providing for sealed complaints, the Committee does not intend to affect defendants' rights in any way. . . . The initial 60-day sealing of the allegations has the same effect as if the qui tam relator had brought his information to the Government and notified the Government of his intent to sue. . . . The Committee feels that with the vast majority of cases, 60 days is an adequate amount of time to allow Government coordination, review and decision. Consequently, 'good cause' [as required for an extension] would not be established merely upon a showing that the Government was overburdened and had not had a chance to address the complaint.²⁵

Plainly, extension of the sixty-day period is not intended to be a tool of administrative fiat, but rather a matter of judicial grace, permissible only where circumstances necessitate.

3. *Potential for Relators and the Government to Abuse the Seal Provision*

The addition of the seal provision to the FCA gave both the Attorney General and relators the opportunity to abuse the seal provision. The government's and relators' temptation to abuse the seal is clear—filing suit without being required to notify the defendant for potentially a very long time allows the filing party to gain a significant advantage over the defendant by providing the plaintiff with a significant amount of time to fully prepare its case before the defendant even knows that a problem exists. During the time the case is under seal, the government can also conduct extensive pre-trial motions practice (e.g., motions to amend complaint or to transfer the case) ex parte while such motions would otherwise be subject to a defendant's responsive pleadings. Such an advantage is arguably given at the expense of the defendant's constitutional due process rights. Relators and the government may abuse the seal provisions under the FCA in a number of ways, including: (a) the government's solicitation of relators to gain the protection of the seal, which is otherwise only available to the relator, for the government's complaint against a defendant; (b) misrepresentation or falsehoods by the government or relators to inappropriately, and possibly fraudulently, obtain or extend a seal; (c) use of the seal by the government or relators to gain a

24. 31 U.S.C. § 3730(b)(2) (1986).

25. S. REP. NO. 99-345, at 24-25.

tactical advantage in settlement negotiations with the defendant; and (d) use of subpoena power during seal period to conduct (perhaps extensive) one-sided discovery against defendants.

a. Government solicitation of relators to obtain seal protection

Under the FCA today, the government is able to urge a relator to file a suit and then proceed to simultaneously use the seal as a sword and a shield: threatening to unsheathe it if the defendants refuse to settle while hiding its actions behind it.²⁶ However, the recent history of the FCA clearly establishes that the qui tam provisions are not intended to allow private citizens to bring suits when the government is able to proceed on its own.²⁷ The “[FCA] must be analyzed in the context of its twin goals of rejecting suits which the government is capable of pursuing itself, while promoting those which the government is not equipped to bring on its own.”²⁸

The Sixth Circuit in *United States ex rel. McKenzie v. BellSouth Telecommunications, Inc.*,²⁹ has considered the history of the FCA and the development of the qui tam provisions, noting that prior to 1943, the whistleblower rules “led to abuse,” permitting anyone to bring even a parasitic action and receive fifty percent of the amount recovered.³⁰ The attempt to correct this problem, the 1943 amended statute,³¹ swung the pendulum too far in the other direction, barring relators from bringing suit “even in cases where

26. See, e.g., *Improper Medicare Billing by Hospitals Nationwide for Investigational Devices and Procedures: Hearing Before the S. Permanent Subcomm. on Investigations of the Comm. on Gov't Affairs*, 104th Cong. 1 (1996) (statement of Kevin Cosens). In this hearing a relator, Kevin Cosens, testified before the Senate Permanent Subcommittee on Investigations, Committee on Governmental Affairs. Mr. Cosens testified that, in a case in which the government was already aware of and investigating the underlying acts alleged to constitute false claims, Mr. Cosens was approached as a witness, and without any additional incentive was cooperating. *Id.* at 8. He next testified: “Finally I was asked by the office of HHS-IG and the Department of Justice to come forward as a whistle-blower and encouraged to file a suit under the [FCA] based on the false use of Medicare billing codes to submit claims for payment for non-covered devices and procedures.” *Id.* (emphasis added). Mr. Cosens’ testimony about the government’s assistance continued:

If my name was to come out, my career would be over. I was asking the government lawyers what type of protection there would be for myself, and the government lawyers mentioned the witness protection program and the Federal [FCA]. And since my life was not in immediate danger they recommended and explained to me about the Federal [FCA]. They then gave me the names of three private attorneys and told me to go and seek counsel.

Id. at 14. The government not only encouraged the relator to file a qui tam lawsuit based on allegations they were already investigating, they acted as a referral service for an attorney.

27. *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 704 (8th Cir. 1995).

28. *Id.* at 702.

29. *United States ex rel. McKenzie v. BellSouth Telecomm., Inc.*, 123 F.3d 935 (6th Cir. 1997).

30. *Id.* at 938.

31. 31 U.S.C. § 231 (1943) (current version at 31 U.S.C. § 3729 (2003)).

the qui tam plaintiff supplied the information to the government before filing the claim.”³² The court found the 1986 statute to be balanced in an attempt to encourage those with information to bring the information forward while avoiding parasitic lawsuits.³³ The FCA as written today requires that the relator must be the “original source” of the information used to allege a FCA violation.³⁴

The *McKenzie* court concluded that its ruling, requiring the relator “to alert the government that a fraud is being perpetrated against it,” did more “to promote the FCA’s mission” than if the relator could proceed without prior notice to the government.³⁵ The court twice used the word “alert,” emphasizing that the requirement for the relator to provide the initial notification to the government best served the purpose of the FCA.³⁶ It is impossible, however, for a relator to provide the initial notification of fraud to the government when the government approached the relator to be a witness in the very investigation for which the complaint is filed. In such a scenario, recruiting a relator only to gain the benefit of the FCA seal does nothing to further the FCA’s mission because the government already has been alerted to the alleged fraud, but uses a straw man relator to gain the use of the seal in bad faith. Therefore, the government’s indirect use of the seal becomes abuse because it serves no legitimate government purpose.

In order to fully analyze this issue, an instructive discussion of the history of the FCA and the intent of Congress can be found in *Wercinski v. International Business Machines Corp.*,³⁷ a case involving a motion to dismiss a FCA case for lack of subject matter jurisdiction. First, the court noted that in 1943 the “FCA was amended to reduce the number of such ‘parasitical suits’ filed by opportunistic relators who used, as the basis of their FCA claim, information already known to the government.”³⁸ The court quoted the Ninth Circuit Court of Appeals in *Wang v. FMC Corp.*,³⁹ which stated that “[q]ui tam suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on crime. In such a scheme, there is little point in rewarding a second toot.”⁴⁰

The *Wercinski* court then addressed the purpose behind the original source bar, which prevented the government from being forced to share a recovery with a relator when the government was already in a position to conduct an investigation. As the court said:

32. *McKenzie*, 123 F.3d at 938.

33. *Id.* at 943.

34. 31 U.S.C. § 3730(e)(4) (2003).

35. *McKenzie*, 123 F.3d at 943.

36. *Id.*

37. *Wercinski v. Int’l Bus. Machs. Corp.*, 982 F. Supp. 449 (S.D. Tex. 1997).

38. *Id.* at 455.

39. *Wang v. FMC Corp.*, 975 F.2d 1412, 1419 (9th Cir. 1992).

40. *Wercinski*, 982 F. Supp. at 456 (quoting *Wang*, 975 F.2d at 1419).

When, as in this case, the government has been alerted to potential wrongdoing and [is] in possession of all the information it needs to begin an investigation, qui tam actions brought by relators whose only contribution is to reinforce what the government already knows are unnecessary, resulting only in a reduction [of] the Government's potential recovery.⁴¹

The court's analysis of the purpose behind the "original source bar" applies not only to subject matter jurisdiction, but also to the government's bad faith recruiting of a relator to gain the ability to use the FCA seal.⁴² When the government approaches a potential relator during an investigation, clearly the government is already "alerted to potential wrongdoing" and is "in possession of all the information it needed to begin an investigation." Therefore, the government's recruitment of a relator has but one use: to unlawfully purchase a seal at the price of the relator's statutory share of any recovery against the defendant.

b. Misrepresentations and falsehoods to improperly extend seal

Just as it is improper and abusive to wrongfully obtain a seal under the FCA, wrongfully extending a seal (regardless whether such extension was initially legitimate) is also abusive. The government may, by a showing of good cause, request a judicial extension of the seal.⁴³ Reasons given for extensions of the seal by the Attorney General (which reasons would also be useful for qui tam relators) have included: the voluminous nature of the investigation,⁴⁴ settlement negotiations,⁴⁵ and the resignation and replacement of DOJ attorneys assigned to the case.⁴⁶ In other contexts, these reasons to seek extensions of time may be reasonable; however, in the context of seeking an extension of a seal, which deprives the defendant of his or her due process rights, these rationales are not legitimate reasons for extensions. Instead, these rationales may have been engineered to disingenuously extend the seal to allow the opportunity for prolonged, one-sided discovery. Cases from the

41. *Id.* at 460.

42. *Id.*

43. 31 U.S.C. § 3730(b)(3) (2004).

44. Memorandum in Support of U.S. Application for Third Extension of Time, United States *ex rel.* Cosen v. Providence Med. Ctr., W.D. Wash., C.A. No. 2:94-974 (No. 16).

45. United States *ex rel.* Costa v. Baker & Taylor, Inc., 955 F. Supp. 1188, 1189-90 (N.D. Cal. 1997); United States *ex rel.* Lacorte v. Smithkline Beecham Clinical Labs., Inc., No. Civ.A.97-0942, 1998 WL 840012, at *1 (E.D. La. Nov. 12, 1998).

46. Memorandum in Support of U.S. Application for Fifth Extension of Time, United States *ex rel.* Cosen v. Providence Med. Ctr., W.D. Wash., C.A. No. 2:94-974 (No. 29).

sealed indictment analysis under the Federal Rules of Criminal Procedure, as discussed more fully in subpart 5, are instructive on this point.

In *United States v. Rogers*,⁴⁷ the court found that the government sealed the indictment to pursue an investigation into other charges, hoping to obtain a new indictment and join all the charges for trial. The court stated:

In short, this court cannot agree that a unilateral extension by the government of the limitations period under the guise of 'gathering evidence' would be a 'legitimate prosecutorial objective' in view of the length of the delay . . . involved and the court's conclusion that the evidence sought to be gathered by the government beyond the limitations period was not related to or necessary for the prosecution of the charges under indictment.⁴⁸

In *United States v. Maroun*,⁴⁹ the court found that the government persuaded the magistrate to seal the indictment by means of an implicit misrepresentation, and therefore dismissed the indictment.⁵⁰ In fact, the entire sealed qui tam action may be an implied misrepresentation by the government if the government already has knowledge of the allegations and has previously investigated such allegation before successfully inducing a relator to file a qui tam action.

c. Use of seal to gain tactical advantage in settlement negotiations

The government's use of the seal in order to gain a tactical advantage in settlement negotiations with the defendant does not further a legitimate government purpose. In *United States ex rel. Costa v. Baker & Taylor, Inc.*,⁵¹ the court considered the congressional record of the adoption of the 1986 amendment to the FCA. The court noted:

The memorandum further suggests that the government has engaged in settlement negotiations with B & T. The defendants are proceeding in these matters based on plaintiffs' representations. They are apparently discussing the settlement of a case without knowing with certainty the allegations leveled against them. Each of the plaintiff parties has

47. *United States v. Rogers*, 781 F. Supp. 1181, 1191 (S.D. Miss. 1991).

48. *Id.*

49. *United States v. Maroun*, 699 F. Supp. 5 (D. Mass. 1988).

50. *Id.* at 7.

51. *United States ex rel. Costa v. Baker & Taylor, Inc.*, 955 F. Supp. 1188 (N.D. Cal. 1997).

suggested that keeping the file under seal serves the defendants' interests by avoiding unflattering publicity; *the court is not, however, convinced that the defendants' current state of ignorance is a blissful one.*⁵²

In addition, the *Costa* court directly refuted any contention that settlement negotiations were a legitimate basis to extend the FCA seal by stating, "Congress enacted the seal provision to facilitate law enforcement, *not to provide an extra bargaining chip in settlement negotiations.*"⁵³ Therefore, under the court's reasoning, any attempt to force a defendant to settle FCA claims by filing a sealed complaint or extending a seal is an abuse of the seal provision under the FCA.

4. *Abuse of Seal Violates Defendant's Constitutional Due Process Rights*

While under seal, the statute of limitations is tolled.⁵⁴ Therefore, in cases involving the improper use of the FCA, it is likely that the applicable statutes of limitations also have been improperly tolled, trammeling the defendant's constitutional due process protections. A statute of limitations is nothing more than the codification of a defendant's due process right to defend himself or itself prior to the time "when the basic facts may have become obscured by the passage of time."⁵⁵ Even in the absence of the statute of limitations (or in FCA cases, the unusual inapplicability of the statute of limitations), a defendant retains the right to provide a competent defense.⁵⁶

The sealing provision of the FCA was extensively considered in *Costa*, in which the court noted that "[t]he sixty-day period during which the complaint would be sealed was intended as a compromise, allowing the government to complete its investigation and formulate and adopt a litigation strategy without seriously injuring the interests of the defendant."⁵⁷ Further, the *Costa* court stated:

Defendants have a legitimate interest in building their defense while the evidence is still fresh. The public has a right to monitor the activities of government agencies and the

52. *Id.* at 1190 (emphasis added).

53. *Id.* at 1191 (emphasis added).

54. *United States ex rel. Wilkins v. N. Am. Const. Corp.*, No. Civ.A.H-95-5614, 2001 WL 34109383, at *13 (S.D. Tex. Sept. 26, 2001); *United States ex rel. Downey v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1171 (D.N.M. 2001).

55. *Toussie v. United States*, 397 U.S. 112, 114 (1970).

56. U.S. CONST. amend. V.

57. *Costa*, 955 F. Supp. at 1189 (citations omitted) (citing S. REP. NO. 99-345, at 23-24 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5288-89).

courts. In this case, the government appears to be fully engaged in its discovery, without giving the defendants the opportunity even to answer the complaint.⁵⁸

The *Costa* court concluded that “[t]his practice of conducting one-sided discovery for months or years while the case is under seal was not contemplated by Congress and is not authorized by the statute.”⁵⁹ Plainly, the period during which the FCA seal is in place, and the concurrent tolling of the statute of limitations, furnishes the government and relators an opportunity to abuse the FCA by surreptitiously investigating a complaint of which a defendant is ignorant.

5. *Analysis of Seal Violations by Analogy to Federal Rules of Criminal Procedure*

When a party is sued in private and without notice, the party is deprived of the opportunity to defend itself, thus compromising its right to due process.⁶⁰ To date, no case law under the FCA has stated the proper remedy for the injury to a defendant’s due process rights caused by an unreasonably long seal period.⁶¹ Only in criminal law have courts followed a statutory procedural framework for claims filed under seal.⁶² Thus, the only seal provision comparable to that of the FCA, with instructive and comparable case law, is found in the analogous Rule 6(e)(4) of the Federal Rules of Criminal Procedure, which provides:

The magistrate judge to whom an indictment is returned may direct that the indictment be kept secret until the defendant is in custody or has been released pending trial. The clerk must then seal the indictment, and no person may disclose the indictment’s existence except as necessary to issue or execute a warrant or summons.⁶³

The case law interpreting Rule 6(e)(4) creates a three-part inquiry when the sealing of an indictment is challenged. The first test is to determine whether the indictment was sealed for a proper purpose. If not, the indictment

58. *Id.* at 1189-90.

59. *Id.* at 1191.

60. U.S. CONST. amend. V.

61. *But see* *Leland v. Target Corp.*, No. 02-C-0815, 2003 WL 22389119, at **6-7 (N.D. Ill. Oct. 20, 2003) (discussing the role of the Due Process Clause in assessing prejudice from prosecutorial delay and explaining that due process is violated where “a defendant . . . demonstrate[s] that the government intentionally delayed to gain a tactical advantage and that actual prejudice resulted”).

62. FED. R. CRIM. P. 6(e)(4).

63. *Id.*

would not be “found” (i.e., effectively filed for the purposes of the statute of limitations) until it is unsealed.⁶⁴ The second test is whether the time the indictment remained under seal (i.e., from the actual filing date until the found date) was reasonable.⁶⁵ In the event the period of time during which the complaint was under seal is deemed unreasonable, then the analysis of the third test becomes necessary—whether the defendant was actually prejudiced between the time the indictment was sealed and the time it was unsealed. If the defendant suffered actual prejudice, the statute of limitations would not be tolled, and the indictment would be found as of the date of the unsealing.⁶⁶

a. First test—legitimate government purpose

The first test in determining whether a sealed lawsuit should relate back to the original filing date is whether the indictment or complaint was sealed for a legitimate government purpose.⁶⁷ Neither the use of the seal for tactical advantages nor the provision of false or misleading information to obtain or extend the seal furthers a legitimate government purpose.⁶⁸ The first test examines both whether the action was properly sealed and whether the seal was properly extended. These queries have been previously explored in Part II.A.3, discussing abuses of the FCA seal provisions.

b. Second test—reasonableness of length of seal

The second of the three tests in determining whether a sealed lawsuit will relate back is a determination of the reasonableness of the seal’s duration. As noted in Part II.A.2, the Congressional Record reveals Congress’ belief that sixty days “is an adequate amount of time to allow [g]overnment coordination, review and decision.”⁶⁹ The Senate Report goes on to state: “The [g]overnment should not, in any way, be allowed to unnecessarily delay lifting of the seal from the civil complaint or processing of the *qui tam* litigation.”⁷⁰ Therefore, extending the seal significantly beyond the initial

64. *United States v. Shell*, 961 F.2d 138, 141 (9th Cir. 1992), *reh’g granted*, 974 F.2d 1035 (9th Cir. 1992) (opinion withdrawn on other grounds); *United States v. Srulowitz*, 819 F.2d 37, 40 (2d Cir. 1987); *United States v. Southland Corp.*, 760 F.2d 1366, 1379-80 (2d Cir. 1985); *United States v. Michael*, 180 F.2d 55, 56-57 (3d Cir. 1949).

65. *Shell*, 961 F.2d at 141; *Srulowitz*, 819 F.2d at 40; *Southland*, 760 F.2d at 1379-80; *Michael*, 180 F.2d at 56-57.

66. *Shell*, 961 F.2d at 142; *United States v. Thompson*, 287 F.3d 1244, 1248 (10th Cir. 2002); *United States v. Watson*, 690 F.2d 15, 16-17 (2d Cir. 1979).

67. *United States v. Maroun*, 699 F. Supp. 5, 6 (D. Mass. 1988); *United States v. Rogers*, 781 F. Supp. 1181, 1190 (S.D. Miss. 1991); *United States v. Sharpe*, 995 F.2d 49, 52 (5th Cir. 1993); *Thompson*, 287 F.3d at 1252.

68. See discussion *infra* Part II.A.6.

69. S. REP. NO. 99-345, at 24-25 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5289-90.

70. *Id.* at 25.

sixty-day period may be deemed unreasonable, paving the way for further analysis under the third test in determining relation back.

c. Third test—substantial prejudice to defendant

(1) In general—showing of prejudice necessary

The third test to determine whether a sealed action should relate back to the original filing date upon its unsealing is whether the defendant is able to show substantial prejudice from the delay.⁷¹ Some courts have determined that the length of delay itself is sufficient to create a presumption of prejudice, as enunciated by the U.S. Supreme Court in *Doggett v. United States*.⁷² In *Doggett*, the court stated:

[I]mpairment of one's defense is the most difficult form of speedy trial prejudice to prove because time's erosion of exculpatory evidence and testimony 'can rarely be shown' Thus, we generally have to recognize that excessive delay presumptively compromises the reliability of a trial in ways that neither party can prove or, for that matter, identify.⁷³

The applicability of Federal Rule of Criminal Procedure 6(e)(4) to FCA cases and to defendant's due process right to a timely defense was discussed at length in *United States v. Watson*.⁷⁴ The *Watson* court began by noting that the tolling of the statute of limitations by the filing of an indictment was normally reasonable, as a defendant was put on timely notice by the filing of charges.⁷⁵ The *Watson* court then compared such a public filing to the filing of a sealed indictment and concluded that in a non-public filing, such tolling was not facially reasonable, as the defendant was not put on notice by a secret document.⁷⁶ The court concluded that "there must be limits . . . on the [g]overnment's privilege to toll the statute of limitations by a sealed indictment."⁷⁷ The decision in *Watson* was later revised to add that "when the defendant can show substantial prejudice, the indictment must be dismissed,

71. *Thompson*, 287 F.3d at 1254; *Sharpe*, 995 F.2d at 51; *United States v. Srulowitz*, 819 F.2d 37, 40 (2d Cir. 1987).

72. *Doggett v. United States*, 505 U.S. 647 (1992). *Doggett* was a speedy trial case, but the analysis of time depriving the defendant of the ability to demonstrate prejudice is equally applicable to a due process argument.

73. *Id.* at 655 (citation omitted).

74. *United States v. Watson*, 599 F.2d 1149 (2d Cir. 1979), *modified*, *United States v. Muse*, 633 F.2d 1041 (2d Cir. 1980).

75. *Id.* at 1154.

76. *Id.*

77. *Id.*

for even a legitimate prosecutorial interest is then insufficient to effectuate statute of limitations policies."⁷⁸

One of the most significant prejudices suffered by a defendant as a result of an extraordinary delay in prosecution is its inability to identify with particularity the content and relevance of documents it would have had in its possession had the government proceeded within a reasonable period of time. If a defendant were required to demonstrate prejudice for even the most "patently unjustified delay of virtually limitless duration," a due process violation could not be found, even when the inability to demonstrate prejudice was caused by the delay.⁷⁹ Such a rule would "give the government carte blanche, creating potential for abuse,"⁸⁰ and would reward the government for intentional or negligent delay.

A defendant may also demonstrate substantial prejudice from the government's intentional destruction of potentially exculpatory records. For example, the government periodically orders Medicare fiscal intermediaries to "[d]iscard any [pacemaker-related] files that . . . have accumulated."⁸¹ Following this discarding of documents, it is possible that the government could sue a defendant claiming that the defendant did not advise it of the specific information that the government had previously possessed, but destroyed. Simply stated, the government may keep an investigation under seal while (perhaps inadvertently) ordering the destruction of exculpatory evidence that directly refutes its allegations.

Medicare peer review organizations ("PROs"), or quality improvement organizations ("QIOs"), which are under contract with the government, review procedures performed by Medicare providers to determine their medical necessity.⁸² PROs have the authority to refuse payment or require repayment if a procedure is not medically necessary.⁸³ In instances when a PRO or QIO specifically reviewed a claim and determined the item or service provided was medically necessary, it would strongly support the defendant if the government's or relator's allegation is that the defendant knowingly submitted claims for medically unnecessary items or services. However, the records of these medical necessity determinations are destroyed after six years, pursuant to government policy.⁸⁴ Therefore, if a case is under seal for a sufficient duration, it is possible that the records will be destroyed before the government has filed its Notice of Intervention.

78. *United States v. Watson*, 690 F.2d 15, 16 (2d Cir. 1979).

79. *United States v. Deglomini*, 111 F. Supp. 2d 198, 203 (E.D.N.Y. 2000).

80. *Id.*

81. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. 13-3, MEDICARE INTERMEDIARY MANUAL pt. 3, Transmittal No. 1730 (1997).

82. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. 100-10, QUALITY IMPROVEMENT ORGANIZATION MANUAL § 4125 (2003).

83. *Id.* § 1005.

84. *Id.* §§ 15720, 15750.

Case law abounds holding that a defendant cannot be found to have *knowingly* violated the FCA when such defendant can demonstrate that the government was fully advised of the action and paid the claim anyway.⁸⁵ In *Yale-New Haven Hospital, Inc. v. Thompson*,⁸⁶ a federal court held that “[t]he fact that the intermediaries continued to pay for these services for a period of eight years after the manual provision was disseminated could reasonably be interpreted by [the Hospital] that payment would continue to be made” and that such payment constituted “conflicting information” from the government.⁸⁷ The *Yale-New Haven Hospital* court determined that this, at a minimum, created an issue of fact for trial.⁸⁸ Thus, at least one court has determined that evidence of government awareness and tacit approval of a hospital’s conduct is potentially exculpatory. A gross delay by the government in intervening in a case years after its investigation was “substantially complete,” combined with its destruction of exculpatory records in its possession, deprives a defendant of the ability to defend itself, and is a classic deprivation of the very idea of due process.

(II) *Where a seal has been extended beyond the applicable limitations period, a showing of substantial prejudice may not be necessary*

The government’s decision to keep a case under seal must have a legitimate basis, or else it may constitute prejudice to the defendant per se. In *United States v. Deglomini*,⁸⁹ the court stated that “[w]here the government has no legitimate purpose served by keeping the indictment sealed beyond the expiration of the limitations period, the defendants need not show prejudice, even if the indictment was properly sealed.”⁹⁰ The *Deglomini* court considered the government’s argument that a defendant must demonstrate prejudice where there was an unreasonable delay in unsealing an indictment, concluding, “[T]he policies underlying the statute of limitations . . . suggest that no showing of prejudice ought to be required when the government unreasonably delays unsealing the indictment.”⁹¹ The court further reasoned:

85. See *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (citations omitted) (“In such a case, the government’s knowledge effectively negates the fraud or falsity required by the FCA.”); *United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 545 (7th Cir. 1999) (“The government’s prior knowledge of an allegedly false claim can vitiate a FCA action.”); *United States ex rel. Humphrey v. Franklin-Williamson Human Servs., Inc.*, 189 F. Supp. 2d 862, 867 (S.D. Ill. 2002) (“[T]he government’s knowledge effectively negates the fraud or falsity required by the FCA.”).

86. *Yale-New Haven Hosp., Inc. v. Thompson*, 162 F. Supp. 2d 54 (D. Conn. 2001).

87. *Id.* at 68.

88. *Id.*

89. *United States v. Deglomini*, 111 F. Supp. 2d 198 (E.D.N.Y. 2000).

90. *Id.* at 200.

91. *Id.* at 202.

Extending the prejudice requirement to the case sub judice, where the government unreasonably delayed unsealing the indictment and the limitations period consequently was not tolled, would undermine the statute of limitations. One of the primary purposes of statutes of limitations is 'to protect individuals from having to defend themselves against charges when the basic facts may have become obscured by the passage of time and to minimize the danger of official punishment because of acts in the far-distant past.' In recognition of this 'overwhelming concern,' courts liberally construe statutes of limitations in favor of repose. The danger in allowing the government free rein to toll the limitations period by sealing indictments was well-articulated in *United States v. Sherwood*.⁹²

In *United States v. Sherwood*,⁹³ the court found a thirteen-month delay in unsealing a criminal complaint unreasonable and prejudicial as a matter of law. The court stated:

The five-year criminal statute of limitations would have little or no meaning were the law to be construed otherwise. A person would never know with certainty that a sealed indictment might be lurking in undisclosed government files, held in abeyance for a year or years to satisfy the personal motives of a government official.⁹⁴

On this same issue, the *Deglomini* court opined:

Requiring a showing of actual prejudice to the defendant would give the government carte blanche, creating potential for abuse. At the theoretical extreme, even a patently unjustified delay of virtually limitless duration would toll the limitations period, so long as the defendant is unable to meet the burden of proving actual prejudice to his defense as a result of the delay.⁹⁵

92. *Id.* at 202-03 (citations omitted).

93. *United States v. Sherwood*, 38 F.R.D. 14 (D. Conn. 1964).

94. *Id.* at 20.

95. *Deglomini*, 111 F. Supp. 2d at 203.

6. *The Duty of Candor to the Court in Ex Parte Proceedings*

When the government seeks permission for an extension of the seal from a court, the government has an obligation to abide by the American Bar Association Model Rule of Professional Conduct 3.3(d), which states, "In an ex parte proceeding, a lawyer shall inform the tribunal of all material facts known to the lawyer that will enable the tribunal to make an informed decision, whether or not the facts are adverse."⁹⁶ The rule is explained in the comment section of the Model Rule: "The judge has an affirmative responsibility to accord the absent party just consideration. The lawyer for the represented party has the correlative duty to make disclosures of material facts known to the lawyer and that the lawyer reasonably believes are necessary to an informed decision."⁹⁷

This Model Rule and its commentary are relevant because it is critical to the protection of the due process rights of the defendant to ensure that the government's stated basis for the extension of the seal are legitimate.⁹⁸ In the hearing discussed above, the Senate Committee specifically found sixty days to be an adequate amount of time to allow government coordination, review, and decision-making and that good cause would not be established merely upon a showing that the government was overburdened and had not had an opportunity to address the complaint.⁹⁹ Further, the Senate Committee believed the government should not be allowed to unnecessarily delay lifting the seal from the civil complaint or processing the *qui tam* litigation.¹⁰⁰

The obligations of an ex parte litigant also obligate the government to advise the court of relevant law, even if it is contrary to the government's position.¹⁰¹ The *Costa* court noted that "[t]he sixty-day period during which the complaint would be sealed was intended as a compromise, allowing the government to formulate and adopt litigation strategy without seriously injuring the interests of the defendant."¹⁰² Query whether serious injury to the interests of a defendant would result from the government's prolonged, ex parte, unilateral participation in the development of a cause of action, during which the court is informed only of the law supporting the case against the defendant.

The seal provision, as described by Congress and in the legislative history, has a legitimate government purpose. The practical use of the seal,

96. MODEL RULES OF PROF'L CONDUCT R. 3.3(d) (2002).

97. *Id.* cmt. 14.

98. See discussion *supra* Part II.A.

99. S. REP. NO. 99-345, at 25 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5289-90.

100. *Id.*

101. MODEL RULES OF PROF'L CONDUCT R. 3.3(d) (2002) ("In an ex parte proceeding, a lawyer shall inform the tribunal of all material facts known to the lawyer that will enable the tribunal to make an informed decision, whether or not the facts are adverse.").

102. United States *ex rel.* *Costa v. Baker & Taylor, Inc.*, 955 F. Supp. 1188, 1189 (N.D. Cal. 1997) (citation omitted).

however, has in many cases crossed the line that separates legitimate from illegitimate purposes. By using the seal in a manner contrary to law, the government erodes the legitimacy of the seal itself. It may come to pass that Congress revisits the necessity of the seal, and could determine that, because of the history of improper use, the seal no longer promotes any legitimate government purpose.

B. Statute of Limitations

No FCA claim may be filed as of the latter of: (1) six years after the date the alleged FCA violation is committed or (2) three years after the date when the material facts of the claim should have been known, "but in no event more than [ten] years after the date on which the violation [was] committed."¹⁰³ This section creates a two-tiered statute of limitations period: a baseline six-year period, or an extended period, up to a total of ten years, calculated by adding up to three full years from the time the material facts were known or should have been known by the relevant government official.

The statute of limitations period in FCA cases is not tolled until the claim is filed in a forum in which the plaintiff has a good faith intention of proceeding.¹⁰⁴ In *Biby v. Kansas City Life Insurance Co.*, the plaintiffs filed a complaint in the Central District of California against two defendants, one a Missouri resident and the other an Arkansas resident.¹⁰⁵ The plaintiffs filed the complaint just days before the limitations period expired, and serious doubt existed as to whether the California court could exercise personal jurisdiction over the defendants.¹⁰⁶ The plaintiffs did not attempt to serve the defendants, but instead, sought and obtained an ex parte order transferring the case to the Eastern District of Arkansas ten days after filing the complaint.¹⁰⁷

On appeal, the Eighth Circuit held that the statute of limitations period was not tolled by the filing of the suit in California.¹⁰⁸ In affirming the district court's dismissal, the Eighth Circuit explained that "[s]ome measure of good faith expectation of proceeding in the court in which the complaint is filed is essential to tolling the statute of limitations. A filing of a complaint which is merely a procedural ploy will not suffice."¹⁰⁹ The court in *United States v. St.*

103. 31 U.S.C. § 3731(b) (2003).

104. *Biby v. Kan. City Life Ins. Co.*, 629 F.2d 1289, 1294 (8th Cir. 1980); *United States v. St. Joseph's Reg'l Health Ctr.*, 240 F. Supp. 2d 882, 892 (W.D. Ark. 2002).

105. *Biby*, 629 F.2d at 1290.

106. *Id.* at 1292.

107. *Id.*

108. *Id.* at 1294.

109. *Id.* (citations omitted); *see also* *Chandler v. Roy*, 272 F.3d 1057, 1059 (8th Cir. 2001) (affirming the holding in *Biby* but distinguishing the facts and stating, "The reasonableness of a party's decision to select a forum is not dispositive; our focus instead is on the party's intent to proceed in that forum.").

Joseph's Regional Health Center,¹¹⁰ a case in which a relator filed suit in the Eastern District of Pennsylvania against one hundred hospitals from around the country alleging violations of the FCA, found the holding in *Biby* controlling and dispositive. In *St. Joseph's*, the relator alleged that venue was proper because some of the defendants were Pennsylvania hospitals.¹¹¹ The *St. Joseph's* relator, however, did not allege any "conspiracy or concert of action or joint and several liability between the defendants."¹¹²

The *St. Joseph's* complaint was filed under seal and no attempt was made to serve the hospital while the case was pending in Pennsylvania. Instead, the government sought repeated extensions of the seal and its time to elect to intervene, causing the case to remain under seal for more than five years.¹¹³ Before it intervened in the case, the government sought and obtained an ex parte order severing the claims against the out-of-state hospitals and transferring them to districts where jurisdiction and venue were proper.¹¹⁴ The claims against *St. Joseph's* were transferred to the Western District of Arkansas, where *St. Joseph's* finally had an opportunity to object to transfer, albeit after the fact.¹¹⁵

The Western District of Arkansas dismissed the claims against *St. Joseph's* as time barred.¹¹⁶ The government argued that the relator's original Pennsylvania action provided the relative date for statute of limitations purposes.¹¹⁷ In rejecting the government's argument, the *St. Joseph's* court held that "abuse of the [FCA] procedure cannot justify the tolling of the statutes of limitations."¹¹⁸ The *St. Joseph's* court noted that the relator's position on venue "was predicated on a misjoinder of parties."¹¹⁹ The court also noted many other "procedural irregularities," including the government's failure to serve *St. Joseph's* in the Pennsylvania proceeding and the ex parte severance and transfer of the claims against *St. Joseph's*.¹²⁰

The *St. Joseph's* court affirmed its prior dismissal and rejected the government's arguments, reiterating that *Biby* remains good law, and noting that the Eighth Circuit cited *Biby* as recently as 2001 in *Chandler*.¹²¹ The *St. Joseph's* court explained:

110. *United States v. St. Joseph's Reg'l Health Ctr.*, 240 F. Supp. 2d 882 (W.D. Ark. 2002).

111. *Id.* at 886.

112. *Id.*

113. *Id.* at 888.

114. *Id.* at 887.

115. *Id.* at 888.

116. *St. Joseph's Reg'l Health Ctr.*, 240 F. Supp. 2d at 888-89.

117. *Id.* at 888.

118. *Id.*

119. *Id.* at 886.

120. *Id.* at 888.

121. *Id.* at 891 (citing *Chandler v. Roy*, 272 F.3d 1057 (8th Cir. 2001)).

[W]here a plaintiff deliberately selects an improper forum; makes no effort to serve the defendant in that forum so that the defendant cannot seek to correct the error; makes the transfer request itself—*ex parte*—for its own purposes; and never had any intention of prosecuting the claim in the forum of filing, there is no analytical basis for the filing to toll the statute of limitations.¹²²

As *Biby* and *St. Joseph's* demonstrate, for a transferred case to relate back to an earlier filing, the government must demonstrate that the earlier filing was made in a forum that was proper or in which the plaintiff had a good faith expectation of proceeding.

Claims under the FCA may be filed “in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by [31 U.S.C. §] 3729 occurred.”¹²³ In a claim with multiple defendants, venue is properly laid if any one defendant “can be found, resides, transacts business, or [performs any act proscribed by 31 U.S.C. § 3729]” in the district, but only if the defendants are properly joined under Rule 20 of the Federal Rules of Civil Procedure, which permits joinder only if the defendants are jointly or severally liable or if the claims against them arose from the same transaction or occurrence.¹²⁴

III. FALSE CLAIMS ACT & STARK

Recent case law and current litigation matters reflect a development in FCA complaints: allegedly false claims predicated on a violation of the federal self-referral prohibitions of the Stark Law.¹²⁵ A self-referral that is not exempt from the Stark Law or that does not qualify for an exception to its prohibitions is unlawful.¹²⁶ Relators have alleged that a claim submitted in violation of the Stark Law gives rise to FCA violations, because the claim is automatically “false” given the strict liability nature of the statute. The

122. *St. Joseph's Reg'l Health Ctr.*, 240 F. Supp. 2d at 891-92 (footnotes omitted).

123. 31 U.S.C. § 3732(a) (2003).

124. JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 5.06(A)(1) (2d ed. 2002) (“[I]f venue is proper as to one defendant in a jurisdiction, it is proper for all other defendants in the same proceeding who are involved in the same false claims. This does not mean, however, that defendants who are accused of similar, but unrelated, conduct may all be sued in the same district.”). Rule 20 provides, “All persons . . . may be joined in one action as defendants if there is asserted against them . . . any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action.” Fed. R. Civ. P. 20(a).

125. 42 U.S.C. § 1395nn (2003).

126. *Id.* § 1395nn(a).

conclusion is, however, a non sequitur because a Stark Law violation does not require a "knowing" submission of a false claim.

The FCA requires that the allegedly false claim must have been submitted "knowingly."¹²⁷ Under the FCA, a false claim is submitted "knowingly" if it is submitted despite actual knowledge of the falsity of the information; in deliberate ignorance of the truth or falsity of the information; or with reckless disregard of the truth or falsity of the information.¹²⁸ The Stark Law, however, has no such knowledge requirement.¹²⁹ A claim submitted in violation of the Stark Law is a violation without regard to intent, so the Stark Law is essentially a strict liability statute. Thus the FCA and the Stark Law have dichotomous scienter criteria.

A brief history of the Stark Law is necessary to put context to the interplay between the Stark Law and the FCA.

A. Stark Law

The Stark Law, which first became effective on January 1, 1992 (Stark I), prohibited referrals to a clinical laboratory with which the referring physician had a non-exempt "financial relationship."¹³⁰ Congress amended the Stark Law in 1993 to have a delayed effective date, except with respect to clinical laboratory services, until "after December 31, 1994," so that the Secretary of HHS could promulgate regulations pursuant to 42 U.S.C. § 1395nn(g)(6)(C).¹³¹ After the 1993 amendment, the statute was known as Stark II and was significantly expanded in scope to apply to a much wider range of items and services.¹³²

The Secretary did not promulgate any proposed regulations under Stark II until January 1998.¹³³ In response to that delay, the House Ways and Means Subcommittee on Health held hearings on "the Health Care Finance Administration's (HCFA) implementation of the Medicare self-referral laws and its impact on the health care marketplace," beginning May 13, 1999.¹³⁴ At these hearings, representatives of HCFA assured Congress that final regulations

127. 31 U.S.C. § 3729(a) (2003).

128. *Id.* § 3729(b).

129. *See* 42 U.S.C. § 1395nn.

130. *Id.* § 1395nn(a)(1)(A).

131. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, 107 Stat. 312, 604-05 (1993).

132. *Id.* § 13562, 107 Stat. at 596-605.

133. Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659 (proposed Jan. 9, 1998).

134. *Medicare Self-Referral Laws: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means*, 106th Cong. 2 (1999); *see* *Ab-Tech Const., Inc. v. United States*, 31 Fed. Cl. 429, 433-35 (Fed. Cl. 1994) (discussing the damages incurred by the government in a false claims case), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995). HCFA has since been renamed Centers for Medicare & Medicaid Services (CMS). This article will refer to the agency alternately as CMS and HCFA, based on the time frame being discussed herein.

would be completed in a reasonable period of time. However, HCFA did not issue the first “phase” of final regulations until January 4, 2001, to become effective January 4, 2002.¹³⁵ On January 20, 2001, the White House issued a memorandum to the acting heads of executive departments and agencies, “temporarily postpon[ing] the effective date of the regulations for [sixty] days” for all published, but not yet effective, regulations.¹³⁶ Therefore, the effective date of the finalized Stark II regulation became March 5, 2002.

B. Stark and the False Claims Act

Since the 1986 amendment to the FCA, relators have attempted on many occasions to bring suits based on violations of Stark II.¹³⁷ The applicability of Stark II has been considered in light of the plain language of the statute, and cases predicated upon Stark II have been decided based on specific facts and circumstances.¹³⁸ None of the reported cases, however, demonstrates a challenge to the use of Stark II in FCA cases based on its legislative and regulatory history. A review of the history of Stark II since its codification, at least until the effective date of Phase I of the final regulations, will demonstrate that a *qui tam* relator cannot show that a health care provider knowingly violated Stark II or that Medicare would have withheld payment based on alleged Stark II violations.

The essence of a Stark II-based FCA suit is that a claim, while factually accurate, must have been the product of a referral for a designated health service from a physician with a non-exempt financial relationship with the entity to whom the referral is made.¹³⁹ Such a claim is purportedly rendered false because it contains, either explicitly or implicitly, a certification that the provider complied with all applicable statutes and regulations. If “certification of such compliance is a condition to *payment*,” a false claim could be

135. Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (codified at 42 C.F.R. pts. 411, 424).

136. Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7702 (Jan. 24, 2001).

137. See, e.g., *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

138. See, e.g., *United States ex rel. Willard v. Humana Health Plan of Tex.*, 336 F.3d 375, 381-83 (5th Cir. 2003); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 n.8 (4th Cir. 1999); *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1164 n.8 (10th Cir. 1999); *United States ex rel. Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 867 (C.D. Ill. 2003).

139. 42 U.S.C. § 1395nn(a)(1) (2003); see, e.g., *Perales*, 243 F. Supp. 2d at 843; *United States ex rel. Goodstein v. McLaren Reg'l Med. Ctr.*, No. 97-CV-72992-DT, 2001 U.S. Dist. LEXIS 2917 (E.D. Mich. Jan. 3, 2001).

alleged.¹⁴⁰ However, the historical application of Stark II, since its codification in 1993, reveals that compliance was not a condition of payment.

I. The Stark Law Was Not a Condition of Payment Prior to March 5, 2002

Stark I provided, and Stark II provides, that the entity to which a prohibited referral is made may not bill the Medicare program for such service.¹⁴¹ As explained below, however, the government agency charged with interpreting Stark II and paying Medicare claims stated that it would not enforce the statute.

On May 4, 1999, the House Ways and Means Subcommittee on Health held a hearing on the implementation of Stark II.¹⁴² The purpose of this hearing, as announced on May 4, 1999, was to “focus on implementation of existing self-referral statutes and on areas for reform.”¹⁴³ The hearing was required because, as Chairman Bill Thomas noted in announcing the hearing:

Physicians and hospitals are subject to a bewildering array of overlapping State and Federal statutes. Many of the steps physicians and hospitals take to integrate their practices are subject to a multitude of laws, including self-referral law, anti-kickback law, Federal tax law regulating the conduct of tax-exempt organizations, State referral bans, corporate practice of medicine prohibition and the Federal [FCA]. The fact that it has taken the HCFA more than 6 years to put out a final rule is further evidence that these laws are in need of an overhaul.¹⁴⁴

Even after Chairman Thomas made these comments, HCFA continued delaying promulgation of final rules for another three years.

At the hearing, the first witness to testify before the Committee was Kathleen A. Buto, Deputy Director of the Center for Health Plans and Providers, HCFA. Ms. Buto testified that HCFA was struggling with proposed Stark rules, describing the identification and definition of appropriate exceptions to “‘protect beneficiaries’ access to care and to take into account the many detailed financial arrangements” in modern health care to be a “daunting task.”¹⁴⁵ Ms. Buto testified that, at that time, HCFA was undertaking “[n]o

140. United States *ex rel.* Joslin v. Cmty. Home Health of Md., Inc., 984 F. Supp. 374, 385 (D. Md. 1997) (emphasis in original).

141. 42 U.S.C. § 1395nn(a).

142. *Medicare Self-Referral Laws*, *supra* note 135, at 2.

143. *Id.* at 3.

144. *Id.* at 2-3.

145. *Id.* at 13.

other type of enforcement actions [other than spot checks and complaint investigations] until outstanding questions [were] resolved and a final rule [was] published.”¹⁴⁶ According to HCFA, the agency tasked with paying Medicare claims, Stark II was not being enforced in 1998 and would not be enforced for several more years.

Ms. Buto’s testimony regarding HCFA’s refusal to enforce Stark II was supported by other testimony before the committee. Chairman Thomas began the hearing by observing that “not a single case has been prosecuted under the [Stark] self-referral laws.”¹⁴⁷ He went on to state that “since Federal investigators use the self-referral law to threaten physicians and hospitals, even though the status of the law is unclear, that seems to me a tacit admission that compliance is virtually impossible and that it only serves as a means to bully providers.”¹⁴⁸

HCFA did not enforce Stark II between the effective date of the statutory amendment and the effective date of Phase I of the final regulations, March 5, 2002. Compliance with Stark II, therefore, was not a Medicare condition of payment for a claim for health care services, so the elements of the false certification theory that make such certification a false claim cannot be met. Any FCA actions brought prior to March 5, 2002 for claims allegedly submitted in violation of Stark II should be defeated on summary judgment because compliance with the Stark Law was not a condition of payment until it was enforced.

2. A Violation of the Stark Law Cannot be a “Knowing” Violation

An essential element of a suit brought under the FCA is that the defendant “knowingly” submitted a false claim.¹⁴⁹ “Knowing” is defined as (1) actual knowledge of the information; (2) deliberate ignorance of the truth or falsity of the information; or (3) reckless disregard of the truth or falsity of the information.¹⁵⁰ A false certification can only be the basis of a FCA suit when it involves a knowingly false certification of compliance with a statute or regulation.¹⁵¹ Simply stated, nobody could have knowingly submitted a false certification of Stark II compliance because, prior to the issuance of final rules, nobody knew what the statute meant.

146. *Id.*

147. *Id.* at 4.

148. *Medicare Self-Referral Laws*, *supra* note 135, at 5.

149. 31 U.S.C. § 3729(a) (2003).

150. *Id.* § 3729(b).

151. *United States v. Southland Mgmt. Corp.*, 288 F.3d 665, 678 (5th Cir. 2002); *see also United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 416 (6th Cir. 2002); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1049 (N.D. Ill. 1998); *United States ex rel. Joslin v. Cmty. Home Health of Md., Inc.*, 984 F. Supp. 374, 383 (D. Md. 1997).

Chairman Thomas quoted Sir Thomas More's *Utopia* in his opening remarks, stating, "It is unjust to bind the people by a set of laws that are too many to be read and too obscure to be understood."¹⁵² He noted that "we are further from clarity in this area of the law than probably any other area of health policy."¹⁵³ The sponsor of the law, Fortney "Pete" Stark, Representative, observed that "the complexity of the law has been an embarrassment,"¹⁵⁴ and wrote in a letter introduced at the hearing that "the controversy drags on and many providers who seek to do the right thing find themselves caught in uncertainty."¹⁵⁵ Nancy L. Johnson, Representative, stated, "I am appalled that we, in the government, could pass a law and not tell people what we mean by it for [six] 6 years."¹⁵⁶

Ms. Buto, the aforementioned HCFA Deputy Director, testified that HCFA was trying "to clarify the law and create appropriate flexibility."¹⁵⁷ She told the committee, "We continue to evaluate the 12,800 comments we have received on the [1998] proposed rules and are open to ideas to further simplify the regulations and the law itself in ways that do not undermine its intent."¹⁵⁸

D. McCarty Thornton, Former Chief Counsel to the Inspector General, Office of the Inspector General, HHS, stated that the law had "been subject to considerable criticism, resulting from ambiguity in how the law applies to certain particular types of business arrangements among physicians and other health providers."¹⁵⁹ The concerns of the committee members and enforcement agencies were supported by testimony from representatives of the health care industry. One witness, Sanford Teplitzky, past president of the National Health Lawyers Association, testified:

I have appeared on numerous panels with representatives of HCFA and the OIG during which this legislation has been discussed. Those individuals have been quite honest and candid in responding to questions. However, their responses have not constituted for the most part, answers. Rather, they respond with their own questions, assumptions, and predictions of what the final regulations might look like. This is simply unacceptable to the great majority of providers who want, need, and deserve answers. I cannot provide definitive guidance to my clients.¹⁶⁰

152. *Medicare Self-Referral Laws*, *supra* note 135, at 4.

153. *Id.*

154. *Id.* at 10.

155. *Id.* at 9.

156. *Id.* at 31.

157. *Id.* at 13.

158. *Medicare Self-Referral Laws*, *supra* note 135, at 13.

159. *Id.* at 18.

160. *Id.* at 59.

C. David Morehead, M.D., President, Scott & White Health Plans, testifying on behalf of the American Medical Group Association, stated:

It is only fair, however, that we KNOW WHAT THE LAW MEANS AND WHAT THE RULES ARE before we are held accountable for them. The original version of this law is now almost ten years old, and we still don't know how to apply them to deliver medical care in our communities.¹⁶¹

The written statement of the Stark Law Coalition, who also testified at the hearings, was that, given "the ambiguity of the statutory language, it would be manifestly unjust for HCFA to enforce this statute before adopting legally binding regulations."¹⁶²

Prior to the effective date of Phase I of the Stark II regulations, nobody knew how to interpret or implement 42 U.S.C. § 1395nn. Providers did not know how to comply and their attorneys could not furnish bright-line advice. Neither the HCFA nor the OIG posed anything more than questions and predictions of their own. Not even Congress could tell people the meaning of the law they wrote. Fortney Stark, the aforementioned sponsor of the legislation that bears his name, decried the uncertainty for providers trying to meet the strictures of the law he described as an embarrassment.¹⁶³ Health care providers could have known of, been deliberately ignorant of, or have recklessly disregarded a Stark II violation in certifying a claim to Medicare, because the law was literally unknowable prior to the date the final regulations became effective on March 15, 2002.¹⁶⁴

Stark II was passed in 1993, but did not take effect until 1995. This delay was written into the statute to give HCFA time to draft rules to interpret and enforce the statute. Because no regulations under the statute took effect until March 2002, and because HCFA refused to enforce the statute until the rules were in place, an allegation that a claim violated Stark II and thus gave rise to a case brought under the FCA certification theory should be unsustainable for pre-March 2002 claims. Such a relator could not prove that compliance with the statute was a condition of payment or that a provider knew of a violation to the statute. These arguments would not be terribly effective, however, for claims filed on or after March 2002, and defendants must find other grounds to refute the new breed of FCA claims of false certification.

161. *Id.* at 71 (emphasis in original).

162. *Id.* at 148.

163. *Id.* at 10.

164. Certain Stark Law violations are not subject to the finer points of the Stark Law, and this Article does not suggest that any prohibited referral prior to Phase I would have been innocent. To the contrary, many aspects of the Stark Law are straightforward. Where the analysis goes beyond the basics of the Stark Law, however, comprehensibility quickly devolves.

IV. LIMITING THE BREADTH OF QUI TAM RELATORS' DISCOVERY

Counsel for FCA plaintiffs have been creative in crafting novel causes of action under the FCA.¹⁶⁵ Two federal district courts have limited such lawsuits by ruling that a case under the FCA does not grant the plaintiff unfettered access to a defendant's business records through the discovery process.¹⁶⁶ These decisions, perhaps pioneering a trend in judicial limitation of FCA discovery, portend relief for health care providers from onerous and overreaching discovery requests.

One of the most disturbing trends in false claims law for health care providers has been the filing of general allegations by qui tam relators who hope to create a case through the discovery process. Discovery in a qui tam case, which can include every claim submitted to Medicare or Medicaid over a six-year period, is extraordinarily onerous.¹⁶⁷ Courts have rejected FCA complaints without specific factual examples to support a relator's general allegations, however, based on the requirement in Rule 9(b) of the Federal Rules of Civil Procedure¹⁶⁸ that such cases be pled in greater detail than usual civil actions.¹⁶⁹ More specifically, Rule 9(b) requires that the circumstances—who, what, when, where, and how—constituting the alleged fraud be stated in the relator's complaint.¹⁷⁰ Rule 9(b) has been applied to the FCA to require specificity in pleadings thereunder.¹⁷¹

The plaintiffs' bar responded to the application of Rule 9(b) to FCA complaints by filing qui tam actions alleging "tens of thousands" of violations, but including at least one specific example of the alleged fraud. Courts have accepted such pleadings by example to be adequate under the Federal Rules

165. 31 U.S.C. §§ 3729-33 (2003).

166. *United States ex rel. Grandeau v. Cancer Treatment Ctrs. of Am.*, No. Civ.A.99-C8287, 2003 WL 21504998, at *2-3 (N.D. Ill. June 30, 2003); *United States ex rel. Stewart v. La. Clinic*, No. Civ.A.99-1767, 2003 WL 21283994 (E.D. La. June 4, 2003).

167. *See, e.g., Grandeau*, 2003 WL 21504998, at *3.

168. Rule 9(b), regarding Pleading Special Matters, states in its entirety: "(b) FRAUD, MISTAKE, CONDITION OF THE MIND. In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." FED. R. CIV. P. 9(b).

169. *See, e.g., Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999); *United States ex rel. Robinson v. Northrop Corp.*, 149 F.R.D. 142, 145 (N.D. Ill. 1993).

170. *Ackerman*, 172 F.3d at 469; *Robinson*, 149 F.R.D. at 145.

171. *See, e.g., United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1320-21 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003); *United States ex rel. Branhan v. Mercy Health Sys. of Southwest Ohio*, No. 9803127, 1999 U.S.App. LEXIS 18509, at *7 (6th Cir. Aug. 5, 1999) (unpublished table decision); *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 568 (11th Cir. 1994); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001); *United States ex rel. Drake v. Norden Sys., Inc.*, No. Civ.A.3:94-CU-963, 2000 WL 1336497, at *5 (D. Conn. Aug. 24, 2000); *United States ex rel. Gublo v. Novacare, Inc.*, 62 F. Supp. 2d 347, 354 (D. Mass. 1999).

of Civil Procedure.¹⁷² Thus, in a claim under the FCA, the relator must plead with particularity the identity of the person who made the alleged false claim, the time, place, and content of the alleged false claim, and the method by which the alleged false claim was communicated to the government.

Once a pleading is accepted by the court as having been pled with sufficient particularity, discovery may begin. The court must simply decide how much discovery to permit. The initial query is whether the pleading of only a single claim should lead to discovery on only that claim, or should give a plaintiff the “keys to the kingdom” by allowing discovery as to all of the defendant’s claims and related records and files. Two courts, one in Louisiana and one in Illinois, have recently answered that question in favor of the health care provider.¹⁷³ The reasoning in each case, that discovery should be limited to only those claims pled with particularity but not those merely generally alleged, provides a cogent analysis of the issue.

A. *United States ex rel. Stewart v. Louisiana Clinic*

On June 4, 2003, the U.S. District Court for the Eastern District of Louisiana limited the scope of a relator’s discovery to the time period and patients enumerated in her complaint.¹⁷⁴ The magistrate who issued the opinion followed the direction of the district court judge who ordered, “[R]elators should not view this ruling as carte blanche to conduct a fishing expedition. Although allowing relators to proceed with this ‘bare minimum’ pleading, this [c]ourt will remain guided through discovery by the principles behind Rule 9(b).”¹⁷⁵ This ruling was part of the district court’s caution “against ‘fishing’ for additional claims” and was based upon its observation “that the right of action granted to private citizens is quite limited, *i.e.*, the right to proceed on behalf of the United States is limited to those citizens who ‘have independently obtained knowledge of the fraud.’”¹⁷⁶

The *Stewart* court also specifically addressed whether an allegation of conspiracy may allow a relator greater depth of discovery. The relator in *Stewart* alleged conspiracy to commit false claims, but the court found the circumstances of a conspiracy conspicuously absent from her pleadings.¹⁷⁷ “The issue of a menacing scheme or conspiracy is wholly absent in this case and all claims against The Louisiana Clinic have been dismissed.”¹⁷⁸ The

172. See, e.g., *United States ex rel. Regan v. Medtronic, Inc.*, No. CIV.A.95-1236-MLB, 2000 WL 1478476 (D. Kan. July 13, 2000).

173. *United States ex rel. Grandeau v. Cancer Treatment Ctrs. of Am.*, No. Civ.A.99-C8287, 96-1309-MLB, 2003 WL 21504998 (N.D. Ill. June 30, 2003); *United States ex rel. Stewart v. La. Clinic*, No. Civ.A.99-1767, 2003 WL 21283944 (E.D. La. June 4, 2003).

174. *Stewart*, 2003 WL 21283944, at *8-12.

175. *Id.* at *9.

176. *Id.* at *8 (citation omitted).

177. *Id.*

178. *Id.* at *9.

district judge, in granting the relator limited discovery as to counts other than the conspiracy allegations, “specifically held that relators had been given ample opportunity to identify fraud, noted that the balance of the equities in this case weigh against further leave to amend, [and] proscribed further proceedings bent on ‘finding fraud during the discovery process.’”¹⁷⁹ The court then found that the FCA is concerned not with a “menacing underlying scheme,” but with the submission of a claim alleged to be false.¹⁸⁰

The court did state, however, that conspiracies or continuing patterns of wrongful conduct may require a more expansive scope for discovery, when the necessary facts are pled with particularity as required by Rule 9(b).¹⁸¹ The court was not persuaded by the relator’s arguments in favor of more expansive discovery and determined that the burden of responding to factual allegations outside the scope of the complaint far outweighed the possible relevance of such evidence.¹⁸² The relator in *Stewart* cited a case to support her request that the court grant greater discovery authority in which the court held that the relator sought to use “a broadsword where a scalpel would suffice.”¹⁸³ The *Stewart* court, addressing the relator’s request to be permitted expansive discovery beyond the scope of that related to the claims plead with particularity, indicated that evidence of a conspiracy must be sufficiently significant as to outweigh the burden of production.¹⁸⁴

B. United States ex rel. Grandeau v. Cancer Treatment Centers of America

On June 30, 2003, the U.S. District Court for the Northern District of Illinois decided *United States ex rel. Grandeau v. Cancer Treatment Centers of America*.¹⁸⁵ In that case, the relator alleged “some specific circumstances of the alleged fraud,” including explicitly naming some patients.¹⁸⁶ The defendants in that case provided discovery related to the named patients only. The relator made additional discovery requests, which the defendants estimated

179. *Id.*

180. *Stewart*, 2003 WL 21283944, at *9.

181. *Id.* at *10.

182. *Id.*

183. *Id.* at *11 (citing *United States ex rel. Regan v. Medtronic, Inc.*, No. Civ. A. 95-1236-MLB, 96-1309-MLB, 2000 WL 14784767 (D. Kan. July 13, 2000)).

184. *Id.* at *12.

[D]efendants in the case at bar have sufficiently demonstrated that compliance with temporally and topically overly broad discovery requests would threaten the normal operation of their respective businesses and that the result of such a costly exercise would likely yield voluminous data of no significance to the alleged false claims.

Id.

185. *United States ex rel. Grandeau v. Cancer Treatment Ctrs. of Am.*, No. Civ.A.99-C8287, 2003 WL 21504998, at*9 (N.D. Ill. June 30, 2003).

186. *Id.*

would have required production of approximately two million pages.¹⁸⁷ The court considered the balance of interests, the conflict between the stringent pleading requirements in fraud cases, and the onerous burden such a discovery would create.¹⁸⁸ The court's analysis is reproduced here in its entirety:

This case well represents a continuing conundrum in *qui tam* cases. The relator is supposed to be an insider, one who advances claims she knows about because of her unique position that the government does not know. And fraud must be pleaded with particularity. But the breadth of the claims may be such that alleging all the "who, what, when and where" of the claims would lead, ultimately, to an extremely long, complex and incomprehensible complaint. Still, a *qui tam* action is not a roving commission to investigate all the financial dealings of the defendants.

Here the relator has alleged some specific examples. That saves the complaint from total dismissal. In other allegations there are no specific examples, or the examples alleged are somewhat general or lack the who or the when. Relator contends she can add details as necessary and talks about filing another amended complaint. We think the better way to proceed is by tailoring discovery to the specificity of the claims, as we previously attempted to do until discovery on the *qui tam* claims was stayed pending ruling on these motions. Judge Ashman can, then, permit discovery as the relator provides an adequate foundation for it.¹⁸⁹

The effect of the court's ruling in *Grandeau* was to permit the relator to proceed with discovery in a suit brought under the FCA only so far as fraud was pled with particularity. In other words, the complaint, pled in general with some specific examples, was treated as a complaint alleging only those examples.

C. Lessons Learned from *Grandeau* and *Stewart*

Grandeau and *Stewart* stand for the proposition that a *qui tam* case pled with the minimum particularity to survive scrutiny will yield only a minimum of discovery. These cases suggest that health care providers will be able to limit discovery, which in a FCA claim is extraordinarily voluminous, expensive, and time-consuming, when a relator's complaint is based on isolated

187. *Id.* at *2.

188. *Id.*

189. *Id.* at *2 (citation omitted).

allegations of billing irregularities. The FCA requires more than a technical error to serve as a foot in the door allowing relators to force open discovery and conduct an open-ended, court-authorized fishing expedition in the defendant's records in anticipation of finding a case brought under the FCA. If *Grandeau* and *Stewart*, both decided by federal district courts, represent the future of FCA discovery, relators will no longer be able to use the threat of unwieldy discovery requests to coerce settlements that a defendant would otherwise reject.

V. PROVIDER BACKLASH AGAINST ABUSIVE ENFORCEMENT

A. *The OIG's Former Chief Counsel's Attack on the "Backlash"*

In 1999, former Chief Counsel to the Inspector General for HHS, McCarty D. Thornton, claimed federal enforcement efforts created the beneficial "sentinel event" of increased health care provider concern for compliance with Medicare billing requirements.¹⁹⁰ Mr. Thornton complimented the health care industry for cooperating with the overall effort to promote compliance and for the reduction in the payment error rate associated with the submission of Medicare claims.¹⁹¹ He also noted the assistance provided by the Office of the Inspector General in developing model compliance plans and issuing advisory opinions directed at making rules more clear for providers.¹⁹²

However, Mr. Thornton criticized the health care industry for alleged hyperbole and for "inaccurate, excessive rhetoric" associated with provider "backlash" against the fraud enforcement efforts, and he discounted any provider concerns that the government is (or has been) over-zealous in its fraud enforcement effort.¹⁹³ In his article, Mr. Thornton represented the OIG, and other federal enforcement agencies, as understanding and beneficent entities that only invoke powerful statutory tools, such as the FCA, when clearly justified.¹⁹⁴ He also claimed that the OIG "does not disparage medical professionals or medical enterprises," understands that "the great majority of them are working ethically," and is "mindful of the differences between negligent errors and mistakes . . . and reckless or intentional conduct."¹⁹⁵ Thornton dismissed as unreasonable provider fears that they would be "prosecuted for some trivial offense."¹⁹⁶

190. McCarty D. Thornton, "*Sentinel Effect*" Shows Fraud Control Effort Works, 32 J. HEALTH L. 493 (1999).

191. *Id.* ("Many providers have reacted to the enforcement effort in a healthy way by devoting significant resources to compliance efforts.")

192. *Id.* at 497-98.

193. *Id.* at 494, 499.

194. *Id.* at 498-99.

195. *Id.*

196. Thornton, *supra* note 191, at 498-99.

Mr. Thornton's portrayal of the government's approach is difficult to reconcile with the many examples of the government's zealous enforcement initiatives. Numerous providers have been snared by a net cast widely over the industry. A common provider concern is that the government fails to give sufficient consideration to the complex and often vague nature of the rules. Providers believe government fraud enforcers act on interpretations of the rules that are not apparent on the face of the rules and impose those interpretations in a retroactive fashion. These provider concerns are supported by court decisions that are highly critical of the government's tactics and by some of the government's own documents and representations.

B. The Courts Have Criticized Government Abuses

Some of the most targeted criticism against the government's actions has come, not from the industry, but from the federal courts. In *United States v. Krizek*,¹⁹⁷ the judge described the government's treatment of health care providers under the FCA as "plainly unfair and unjustified," and the court refused to impose liability under the FCA based on the government's "strained interpretation of the CPT [billing] codes."¹⁹⁸ The court chastised the government for failing to provide "clear guidance as to what services are reimbursable."¹⁹⁹ When the government continued to pursue its prosecution of Dr. Krizek, even after this unusually strong condemnation of its actions by a federal court, a clearly exasperated Judge Sporkin, in a subsequent decision, stated that "[t]he [g]overnment insists on pursuing a case that should long have been over."²⁰⁰ Judge Sporkin wrote, "The [g]overnment's pursuit of Dr. Krizek is reminiscent of Inspector Javert's quest to capture Jean Valjean in Victor Hugo's *Les Miserables* . . . there comes a point when a civilized society must say enough is enough."²⁰¹ Judge Sporkin went on to cite in a footnote "overzealous use of the [FCA]" as a basis for recent guidance from the U.S. Deputy Attorney General to use the statute more carefully and congressional "consideration of a bill that would set limitations on the use of this statute."²⁰²

One of the government fraud enforcement initiatives most criticized by the health care industry is associated with the National Outpatient Laboratory Billing Initiative named "Operation Bad Bundle" by the government.²⁰³ This

197. *United States v. Krizek*, 859 F. Supp. 5, 10 (D.D.C. 1994).

198. *Id.* at 10.

199. *Id.*

200. *United States v. Krizek*, 7 F. Supp. 2d 56, 60 (D.D.C. 1998).

201. *Id.*

202. *Id.* at 60 n.4.

203. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., SEMI-ANNUAL REPORT OCTOBER 1, 1997 - MARCH 31, 1998, at 7 (1998).

initiative accused hospitals of “unbundling”²⁰⁴ outpatient laboratory claims for multi-channel chemistry services and for improperly billing “additional indices” in violation of the FCA. The Laboratory Billing Initiative was the subject of two court decisions in which the Ohio Hospital Association and the American Hospital Association sued for injunctive and declaratory relief against the Initiative.²⁰⁵ These two decisions present compelling evidence of judicial criticism for overly aggressive government tactics and strained legal interpretations.

In the first decision, the trial court dismissed the suit against the government on technical jurisdictional grounds.²⁰⁶ However, this was a rather hollow victory for the government as the trial court took the unusual step of going out of its way to comment on some of the substantive issues. The court repeatedly called the government’s tactics “heavy handed” and stated that there was a “very real possibility that the Secretary’s position regarding the hospitals’ billing practices is wrong.”²⁰⁷ The court even went so far as to suggest that the government’s approach of threatening FCA prosecution for these issues danced on the edge of attorney ethical violations.²⁰⁸

The Ohio Hospital Association appealed the dismissal of its case to the Sixth Circuit Court of Appeals. On December 29, 1999, the court of appeals reversed the dismissal and released a decision that again validated the concern of health care providers regarding the government’s tactics and legal position.²⁰⁹ The court of appeals stated:

The Secretary has never initiated a rulemaking proceeding under the Administrative Procedure Act to formalize the billing standards she now espouses. Neither has she initiated administrative proceedings to recoup the alleged overpay-

204. “Unbundling” is the process of billing separate components of tests performed as a single panel that can be billed at a single panel or global rate. *See* DEP’T OF JUSTICE, HEALTHCARE FRAUD REPORT--FISCAL YEARS 1995-1996 (1997), *reprinted in* Healthcare Compliance Rep. (CCH) ¶ 350,001 (Aug. 13, 1997).

205. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., *supra* note 204, at 7.

206. *Ohio Hosp. Ass’n v. Shalala*, 978 F. Supp. 735, 742 (E.D. Ohio 1997).

207. *Id.*

208. “[I]f the Attorney General’s threatened [FCA] prosecution was criminal in nature, the actions of government counsel could be in breach of the mandatory ethical standards contained in the Ohio Code of Professional Responsibility.” *Id.* at 738 n.3. It is notable that while the [FCA] is technically civil in nature, a Supreme Court interpretation in effect at the time the Judge made this comment regarded the harsh financial penalties under the [FCA] as so punitive that they were treated as criminal in nature for purposes of Constitutional Double Jeopardy Clause evaluation. *See United States v. Halper*, 490 U.S. 435, 450-51 (1989). This interpretation was later reversed by the Supreme Court in *Hudson v. United States*, 522 U.S. 93 (1997). However, even in *Hudson*, the Court stated that the excessive fines provision of the Eighth Amendment applies to the FCA. *Id.* at 103.

209. *Ohio Hosp. Ass’n v. Shalala*, 201 F.3d 418, 419 (6th Cir. 1999).

ments. Instead, as part of a sweeping investigation . . . the Secretary has allegedly used . . . elements of the Department of Justice to coerce the hospitals into retroactively accepting revised standards and paying the Secretary large sums of money under threat of having to pay much more if the hospitals decline to enter into settlement agreements. . . .²¹⁰

When placed in the context of well-established law requiring that any legally binding substantive rules be promulgated under the Administrative Procedures Act,²¹¹ this statement by the court of appeals is compelling. The description by the court of appeals that the Secretary's actions are "to coerce the hospitals into retroactively accepting revised standards"²¹² clearly suggests the Secretary's actions have no legal basis and validates the exact concerns raised by the health care industry regarding this matter. The government appealed the decision to the U.S. Supreme Court, but the Supreme Court refused the government's request to hear the appeal.²¹³

Any claims that the government has reformed its practices cannot be sustained in light of the fact that government continues to "coerce hospitals into retroactively accepting revised standards" in Operation Bad Bundle initiatives that continue in many states to this day, even after these court decisions.

C. The Government's Own Documents Prove Abuse of the Law

Operation Bad Bundle represented a clear case of government fraud enforcers acting on interpretations of guidelines not apparent on the face of the guidelines. Perhaps the strongest evidence of this comes from three separate *Red Book Reports* from the OIG. The "Red Books" are a collection of cost savings *recommendations* from the OIG that have not been implemented.²¹⁴ Three separate *Red Book Reports* for 1995, 1996, and 1997-1998 recommended that HCFA implement a rule requiring bundling of panel tests because no such rule existed.

210. *Id.*

211. See *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995) (holding that policies issued without the benefit of notice and comment under the Administrative Procedures Act "do not have the force of law and are not accorded that weight in the adjudicatory process").

212. *Ohio Hosp. Ass'n*, 201 F.3d at 419.

213. *Shalala v. Ohio Hosp. Ass'n*, 531 U.S. 1071, 1071 (2001).

214. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., THE 1996 RED BOOK 40 (1996) (emphasis added). All three *Red Books* from 1995, 1996, and 1997-1998 contained identical language recommending implementation of a bundling requirement, because no such requirement existed. *Id.* For additional information substantiating the lack of legal basis for this initiative see also the *Special Report to the American Hospital Association: Development of Government Guidelines for Hospital Outpatient Laboratory Reimbursement*, Prepared by Jones, Davis, Reavis & Pogue (Mar. 1998).

Medicare policies are not sufficient to control the billing of profile tests because there is no requirement that tests ordered as a panel by the physician be billed only as a panel. The *HCFA's guidelines do not address the problem . . . of the industry billing the contents of the panels individually.*²¹⁵

In short, the government has accused health care providers of violating a rule that its own reports say never existed.

D. The Three-Day Window Rule Investigation is Another Example of Abuse

Another example of an initiative supporting provider concerns that the government is not acting fairly is the "3-Day Window Rule" initiative.²¹⁶ In this initiative, the government threatened hospitals with FCA lawsuits for alleged failures to catch circumstances where outpatient diagnostic services were furnished within three days prior to an inpatient admission.²¹⁷ While Mr. Thornton claimed the OIG understands "the great majority" of health care providers are "working ethically," this enforcement initiative was directed at the vast majority of acute care hospitals in the United States.²¹⁸ In some states every acute care hospital received a letter from the U.S. Attorney for the Middle District of Pennsylvania claiming that "it has been determined that your institution should be civilly prosecuted pursuant to this [FCA]."²¹⁹ Thus,

215. *Id.*

216. The law establishes that most outpatient services furnished by a hospital (or any wholly owned or operated entity of the hospital) within three days prior to an inpatient admission to the hospital are regarded as paid for in the prospective payment system (or DRG) payment to the hospital. 42 U.S.C. § 1395ww(a)(4) (2002).

217. *Id.*

218. A 1995 OIG Report identified 4,660 hospitals nationwide to be targeted with allegations that they violated the FCA in regard to the 3-Day Window Rule. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF THE INSPECTOR GEN., REPORT NO. A-03-94-00021, STATUS REPORT—OFFICE OF THE INSPECTOR GENERAL/DEPARTMENT OF JUSTICE JOINT PROJECT—MEDICARE NONPHYSICIAN OUTPATIENT BILLS SUBMITTED BY HOSPITALS 2 (1995). This represents almost every acute care hospital in the nation. The OIG Report openly admitted there would be no validations of the specific claims or allegations for the 4,660 hospitals involved, because "of the resources required to conduct validations" and because the government's proposed settlement was so much "more generous than the penalties under the [FCA]." *Id.* at 6. Of course this means the government simply presumed the hospital's conduct violated the FCA to begin with, and proves the government's willingness to accuse hospitals of violating the FCA without validating its information on an individual hospital basis. The OIG Report also made clear that it would impose a single "model settlement agreement with all 4,660 hospitals included in the project." *Id.*

219. For example, this exact language appeared in all 113 letters sent to every acute care hospital in Indiana. The highly threatening letters went so far as to calculate the potential liability under the FCA (of treble damages and \$5,000 per claim). Because of the frequently

the OIG's platitude that it believes that "the great majority" of health care providers are "working ethically" is not consistent with the *reality* of the government claiming "the great majority" of hospitals in the nation should be prosecuted or required to accept settlements for "knowingly" submitting false claims to the government.²²⁰

Mr. Thornton claimed that providers have no basis for any "fear of being prosecuted for some trivial offense," but again, real examples associated with the 3-Day Window Rule investigation suggest otherwise.²²¹ The government sent highly threatening letters without regard for the materiality of the offense.²²² These letters asserted specific false claims spanning a four-year period from 1990 to 1994.²²³

A particularly egregious example of how the government's approach was devoid of specific fact evaluation involves an Indiana hospital that received a letter informing the hospital that its case had been referred for prosecution under the FCA.²²⁴ For the entire four-year period reviewed, the hospital had but a single alleged erroneous claim totaling \$60.07, the recovery of which supposedly justified the government's claim that the hospital had "knowingly" submitted false claims to the government.²²⁵

large numbers of claims involved, this was an extraordinarily high level of damages, completely disproportionate to the conduct alleged and was highly intimidating to the hospitals receiving the letters. For example, for the 113 Indiana hospitals involved, the government's total assertion of overpayments was only \$2,251,102. Thus, the government claimed all 113 hospitals knowingly submitted false claims to increase their income by an average of \$5,000 per year for each hospital. The government noted that the liability of the 113 hospitals under the FCA was \$192,162,736. In short, the government threatened hospitals with a damage multiplier of nearly 100 times actual damages if they did not settle the case. See *id.* at 7 for a chart stating the number of hospitals targeted in the first seven states under the initiative with estimates of liability under the FCA if the hospitals did not settle.

220. The FCA allows liability only when the defendant "knowingly presents, or causes to be presented . . . a false or fraudulent claim for approval." 31 U.S.C. § 3729(a) (2002). The FCA defines "knowingly" as actual knowledge, deliberate ignorance, or reckless disregard for the falsity of the claim. *Id.* § 3729(b).

221. Thornton, *supra* note 191.

222. See, e.g., Letter from United States Department of Health and Human Services, Office of Inspector General, Baltimore, Md., to all Hospitals in United States (various dates, 1996) (on file with authors).

223. *Id.*

224. *Id.*

225. During negotiations on this matter, the government's explanation for this hospital's treatment was that the letter was issued by a computer generated mail merge system that simply sent such letters without any regard for the specific circumstances of any hospital. This only proves how completely devoid of any factual investigation the government's allegations were. In short, it was character assassination by mail merge. The government still required the hospital to sign a settlement and pay the \$60.07. No apology for the heavy-handed threat of FCA violations was ever offered to the people who work for and administer the hospital.

E. Government Responses to the "Backlash" Admit Abuse

The government's efforts to address the "backlash" contradict Mr. Thornton's claim that provider concerns are baseless. In response to strong complaints from the health care industry, on June 3, 1998, the DOJ released guidance for DOJ use of the FCA.²²⁶ In a June 5, 1998 cover letter forwarding the new guidance to the American Hospital Association, John T. Bentivoglio claimed the guidance was issued to address "*legitimate concerns* that have been raised [regarding] our efforts."²²⁷ In a speech on February 1, 1999 to the American Hospital Association, Deputy U.S. Attorney General Eric Holder admitted that there had "been understandable concern within the industry" for what "have been, at times, heavy-handed treatment by the government."²²⁸

The DOJ claims that the guidelines were implemented and have ended government excesses related to the FCA.²²⁹ Not only do many of the recent examples of abuse in the prior sections of this Article contradict that claim, but also the government's own reports reject the DOJ's conclusion.²³⁰ On February 3, 1999, Deputy Attorney General Eric Holder released the results of a DOJ sixth-month *self-evaluation* that, not surprisingly, found the guidance had "been extremely effective" in addressing earlier problems.²³¹ However, *independent* government reviews contradict the DOJ's conclusions. The United States General Accounting Office ("GAO"), in a review of the "DOJ's Implementation of False Claims Act Guidance," described the DOJ's oversight of its subordinate U.S. Attorneys' Offices' compliance with the guidance as "superficial."²³² The Report also noted that at the time FCA allegations related to the Laboratory Billing Initiative were made, "most offices had not adequately analyzed the data to determine if the apparent errors were sufficient to warrant a false claims violation" and that "these

226. Memorandum from Eric Holder, Deputy Attorney General, to all United States Attorneys (June 3, 1998), *reprinted in* Healthcare Compliance Guide (CCH) Attachment II-3-A, available at <http://www.usdoj.gov/d4foia/readingrooms/chem.htm>.

227. Letter from John T. Bentivoglio, Special Counsel for Health Care Fraud, U.S. Department of Justice, Office of the Attorney General, to Richard Davidson, President of the American Hospital Association (June 5, 1998) (on file with authors).

228. Eric H. Holder, Jr., Remarks to the American Hospital Association (Feb. 1, 1999), *reprinted in* Healthcare Compliance Rep. (CCH) ¶ 444,005, available at <http://www.usdoj.gov/archive/dag/speech/holderahaspeech.htm>.

229. *Id.*

230. See U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-99-170, MEDICARE FRAUD AND ABUSE: DOJ'S IMPLEMENTATION OF FALSE CLAIMS ACT GUIDANCE IN NATIONAL INITIATIVES VARIES 4 (Aug. 6, 1999).

231. Memorandum from Eric H. Holder, Jr., Deputy Attorney General, to all United States Attorneys (Feb. 3, 1999), *reprinted in* Healthcare Compliance Rep. (CCH) ¶ 350,002, available at <http://health.cch.com/primesrc/bin/highwire.dll?a=dd&AVal=CCHDOC28&BRSL=7968>.

232. U.S. GEN. ACCOUNTING OFFICE, *supra* note 231, at 18.

offices lacked evidence that each of the hospitals had knowingly submitted false claims.”²³³

Critical as this GAO Report may seem, it actually gave every benefit of the doubt to the DOJ. The GAO sought input from state hospital associations regarding their perceptions of the DOJ’s implementation of its FCA Guidance.²³⁴ The GAO admitted that almost all negative responses “related to the Laboratory Unbundling initiative” and that “[t]he most often voiced criticism was that this initiative lacked a legal basis.”²³⁵ Yet, even though this was the most serious concern, the GAO admits that it “did not evaluate the legal merits of any of the DOJ’s national initiatives.”²³⁶ The GAO only verified that the DOJ performed its own legal analysis.

In short, there has been no oversight of the DOJ for the crucial question of the legal sufficiency of the DOJ’s arguments in the Laboratory Unbundling initiative, even though the GAO admits that this is the most serious concern of the provider community. Since the DOJ Guidance requires an evaluation of the “legal predicates” for any national initiative, the failure of the GAO to address this concern means that there has been no independent review of whether the DOJ conducted a meaningful evaluation of the “legal predicates” for the laboratory unbundling initiative.

F. The Costs of Abuse to the Health Care System

The government’s abusive investigation practices do not have small consequences. They disrupt the provision of health care services by forcing providers to divert often-substantial resources, time, and human capital to respond.²³⁷ In addition, the government routinely uses the threat of the draconian penalties under the FCA to coerce unjust settlements that often include payment of penalties that further divert resources from the provision of health care.²³⁸ Not for profit health care organizations, dedicated to charitable care, are often included in the target list of broad sweeping health care fraud initiatives. The penalties paid by these organizations can only be viewed as directly penalizing the most vulnerable in our society in their need for health care services. Payment of such penalties might be justified if the

233. *Id.* at 18.

234. *Id.* at 3, 5, 16.

235. *Id.* at 16.

236. *Id.* at 16 n.9.

237. See generally Pamela H. Bucy, *The Path from Regulator to Hunter: The Exercise of Prosecutorial Discretion in the Investigation of Physicians at Teaching Hospitals*, 44 ST. LOUIS L.J. 3 (2000). Responding to a fraud investigation can be enormously burdensome, and the government generally requires the hospital to prove its innocence. This often requires sorting through and producing enormous amounts of documents. Often extensive and expensive consultation with legal counsel is also required.

238. *Id.* at 41, 46.

government initiatives clearly targeted actual cases of fraud. However, as discussed in this Article, this is simply not always the case.

It is true that the “great majority” of health care providers are “working ethically.”²³⁹ Had the government consistently treated health care providers with this kind of assumption, the “backlash” would be less of an issue. However, the government has assumed, and continues to assume, that providers are guilty of “knowingly” submitting false claims (until they prove themselves innocent) in all too many cases where the government’s post hoc interpretation of vague rules and guidelines determines providers submitted claims in error.

VI. CONCLUSION

Health care fraud is, without question, a significant problem in the United States today. The remedies employed against this problem, however, may cause more harm than good. The use of the FCA has devolved from a tool for fraud prevention to a tool for virtual extortion. It is clear that FCA plaintiffs, both the government and its relators, use the significant weight of a FCA lawsuit to lean on health care providers in an illegitimate attempt to gain rewards, either economic or egoistic, in a manner inconsistent with the intent of the law. A relator’s desire to receive a percentage of the recovery or of a government official to gain media exposure, however, does not justify the strong-arming of health care providers. The FCA is too potent a weapon to be used indiscriminately, and it is incumbent upon the federal judiciary to reign in abuses, Congress to assess the necessity of a statutory correction, and the administrative enforcement bodies to develop the necessary restraint to stop the abuse and misuse of the FCA.

239. Thornton, *supra* note 191, at 498-99. *See also*, Hearing Before the Subcomm. on Health of the Comm. on Ways and Means, House of Rep., 106th Cong. 34 (1999) (regarding physicians’ compliance with the Stark Law) (statement of Rep. McCrery) (stating that “Maybe we should . . . not assum[e] that all physicians . . . are crooks”); *id.* at 54 (statement of K. Buto, Dep. Dir., Ctr. for Health Plans & Providers, Health Care Fin. Admin.) (“We are assuming that the providers are complying with the [Stark] statute.”).

