

**THE UBIQUITOUS FALSE CLAIMS ACT: THE INCONGRUOUS
RELATIONSHIP BETWEEN A CIVIL WAR ERA FRAUD STATUTE AND
THE MODERN ADMINISTRATIVE STATE**

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I. INTRODUCTION

On March 2, 1863, Congress enacted the False Claims Act (FCA).¹ The FCA provides penalties and creates a damages remedy for “false or fraudulent” claims submitted to the United States.² The FCA includes a qui tam provision authorizing private individuals to sue for damages and penalties in the name of, and on behalf of, the United States.³

In the nearly century and a half since Congress enacted the FCA, the federal government’s structure has changed substantially. In addition, the federal government’s role in national economic life has grown exponentially.⁴ These changes have resulted in a restructuring of the relationship between the federal government and the private entities with which it contracts.⁵

In 1863, when the FCA was adopted, government contracts were purchase and sale agreements that specified the goods to be delivered and the price to be paid.⁶ Now, however, the federal government contracts with private entities to administer massive social welfare programs and provide benefits subject to pervasive and extensive federal agency regulation and oversight.⁷ From the mid-nineteenth century through the early twentieth century, federal regulation, to the extent it existed at all, addressed economic issues—the prices at which goods and services could be sold.⁸ Today, the federal government, through its administrative agencies, also oversees and regulates government contractors’ production processes and often dictates the methods that contractors must use to produce the goods or services for which the government contracts.⁹

1. See An Act to Prevent and Punish Frauds Upon the Government of the U.S., ch. LXVII, § 1, 12 Stat. 696 (1863) (codified as amended at 31 U.S.C. §§ 3729-3733 (2000)).

2. *Id.*; see also JAMES F. NAGLE, A HISTORY OF GOVERNMENT CONTRACTING 202-04 (1st ed. 1992) (detailing the abuses that led to adoption of the FCA, known as “The Abraham Lincoln Law”)

3. 31 U.S.C. § 3730.

4. See generally 1 JACOB A. STEIN ET AL., ADMINISTRATIVE LAW §1.01[4], at 1-25 to -32 (Matthew Bender & Co., Inc., 2007) (detailing various reports addressing the increased role of the federal government in “regulating the entire economy”).

5. See NAGLE, *supra* note 2, at 1 (stating that the country’s government contracting needs changed based on exploration of the West, national defense, transportation, and mail delivery).

6. See *id.* at 7-8.

7. See, e.g., *infra* Part II.A.2 (discussing the extensive regulation of provider-contractors under the Medicare Act).

8. See generally 1 STEIN ET AL., *supra* note 4, at 1-17 to -24 (detailing various federal regulatory functions beginning with the Interstate Commerce Commission in 1887 and ending with the United States Maritime Commission in 1936).

9. See NAGLE, *supra* note 2, at 9; see also 1 STEIN ET AL., *supra* note 4, § 1.01[2], at 1-7 to 1-8.

Federal appellate and trial courts have struggled to apply the FCA in light of these changed circumstances. Recent cases evidence the difficulties experienced by courts and foreshadow even greater difficulties if the tension between the Civil War era FCA and the modern administrative state is not addressed and resolved.

II. BACKGROUND

A. *The Disconnect Between the FCA and the Modern Administrative State*

1. The Ninth Circuit and the Department of Education or “Who’s In Charge Here?”

In *United States ex rel. Hendow v. University of Phoenix*,¹⁰ the Ninth Circuit reversed the district court’s order dismissing the case and permitted an FCA qui tam action to proceed. The court of appeals adopted a sweeping interpretation of “false or fraudulent” that effectively nullified the Department of Education’s (DOE) discretionary decision to treat alleged statutory and regulatory infractions as administrative enforcement matters, not as fraud upon the government.¹¹ In place of weighing policy options and balancing competing interests, as is required of an agency administering a government benefits program, *Hendow* permits courts to decide whether a claim is false or fraudulent based on whether a contractor was in compliance with administrative requirements when it claimed payment from the government.¹² In contrast to the range of discretionary sanctions an administrative agency can use in a regulatory enforcement action, the FCA mandates that a court, upon determining a claim is false or fraudulent, impose per claim penalties and multiple damages.¹³

Remarkably, the Ninth Circuit permitted FCA damages and penalties for the University of Phoenix’s (UOP) violation of the DOE’s requirements, even though the DOE had concluded that such violations did “not result[] in monetary loss to the Department.”¹⁴ Moreover, the DOE already had acted

10. 461 F.3d 1166, 1177-78 (9th Cir. 2006), *cert. denied*, 127 S. Ct. 2099 (2007).

11. *Id.* at 1170-71.

12. *Id.* at 1171.

13. 31 U.S.C. § 3729 (2000).

14. Memorandum from William D. Hansen, Deputy Sec’y, U.S. Dep’t of Educ., to Terri Shaw, Chief Operating Officer, Fed. Student Aid, Subject: Enforcement policy for violations of incentive compensation prohibition by institutions participating in student aid programs (October 30, 2002), *attached to* Petition for Writ of Certiorari at 51a, *Hendow*, 127 S. Ct. 2099 (2007) (No. 06-1006), 2007 WL 160712 [hereinafter DOE Memorandum]. The policy applied by the DOE to UOP regarding Federal Student Aid states that the purpose of the memorandum “is to provide direction with regard to the Department’s response to violations

pursuant to the agency's published policy, imposing administrative penalties for the alleged noncompliance at issue in the court case, but neither recouping past payments nor terminating future payments to UOP.¹⁵ Furthering the paradox, *Hendow* also permits a private individual to seek damages and penalties on behalf of the United States despite refusal by the DOE, the agency authorized to administer the program for the United States, to do so.¹⁶

2. The Tug of War Between the FCA and the Medicare Act

(a) The Long Term Care Survey and Enforcement Process

The disconnect between the FCA, especially its *qui tam* provisions, and the modern administrative state is perhaps most evident in the context of government-run healthcare benefits programs, such as the Medicare and Medicaid Programs. Although any number of Medicare regulatory and enforcement programs could be utilized to illustrate the inherent tension between administrative oversight of government contractors and the FCA, the long term care survey and enforcement process is a paradigm.

The current long term care survey and enforcement process, adopted by Congress in 1987,¹⁷ includes a plethora of substantive performance standards governing both the process of delivering care and the outcome of

of section 487(a)(20) of the Higher Education Act" prohibiting incentive payments to student recruiters. *Id.* The memorandum states:

The Department has in the past measured the damages resulting from a violation as the total amount of student aid provided to each improperly recruited student. After further analysis, I have concluded that the preferable approach is to view a violation of the incentive compensation prohibition as not resulting in monetary loss to the Department. Improper recruiting does not render a recruited student ineligible to receive student aid funds for attendance at the institution on whose behalf the recruiting is conducted. Accordingly, the Department should treat a violation of the law as a compliance matter for which remedial or punitive sanctions should be considered.

Id. at 52a. The memorandum then goes on to identify the facts that should be considered in assessing the appropriate sanction, including whether the law was knowingly violated "as would be evidenced, for example, by attempts to disguise its compensation plan and by other aggravating factors." *Id.*

15. *Id.* at 52a.

16. See *Hendow*, 461 F.3d at 1174-75 (relators, former enrollment counselors, sued University of Phoenix on behalf of the United States under the FCA); see also U.S. *ex. rel.* Hopper v. Anton, 91 F.3d 1261, 1266 n.7 (9th Cir. 1996) (discussing the ability of private individuals to "bring an action on behalf of the U.S. government" against anyone who "knowingly presented" a "false or fraudulent claim to the U.S. government").

17. Changes to long term care facility quality standards, survey procedures, and enforcement processes were enacted as part of the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330.

care.¹⁸ The Medicare and Medicaid Acts also specify processes and protocols that must be used to evaluate compliance with program standards,¹⁹ as well as who may conduct the assessment.²⁰

One of the principal reasons that the current survey and enforcement process was adopted was to provide a menu of discretionary, intermediate sanctions that could be used to address alleged noncompliance with program standards.²¹ The discretion to utilize intermediate sanctions was conferred on the Secretary of Health and Human Services (the Secretary) to provide a means of encouraging nursing facility compliance so that termination of Medicare payments, which often resulted in closure of the facility and traumatic displacement of residents, could be avoided.²² In order to allow intermediate sanctions to function, the survey and enforcement process also provides that payment may continue to be made, even to seriously noncompliant providers.²³

(b) The Medicare Part D Prescription Drug Benefit

The recent creation and implementation of the Medicare prescription drug benefit, known as Part D, portends even more tension between the FCA and the modern administrative state. Part D,²⁴ which was adopted by Congress in 2003 and first implemented by the Centers for Medicare and

18. See 42 U.S.C. §§ 1395i-3, 1396r (2000); see also 42 C.F.R. pt. 488 (2007) (implementing the statute's survey and enforcement process).

19. 42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C) (Medicare and Medicaid, respectively); 42 C.F.R. § 488.300-335; see also Robert Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 151 (1999) (noting that quality of care requirements "are enforced through a complex enforcement process which includes frequent on-site inspections").

20. 42 U.S.C. §§ 1395i-3(g)(2)(E), 1396r(g)(2)(E); 42 C.F.R. § 488.314(a) (2007).

21. See generally 42 U.S.C. § 1395i-3(h)(3)(c); 42 U.S.C. § 1396r(h)(3)(c) (remedies listed are sanctions for substandard performance).

22. See, e.g., Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. 56,116, 56,221 (Nov. 10, 1994); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 22 (2000) (noting that "terminations from the program are rare and generally reserved for the most egregious recidivist institutions" (quoting the reply brief of the Secretary of Health and Human Services)).

23. See 42 U.S.C. § 1395i-3(h)(2)(C) (2000); 42 C.F.R. § 489.55; cf. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 676 (5th Cir. 2003) (en banc) (continued government payments despite known noncompliance reflected policy choice that payments were needed to fund improvements and negated argument that claims were false or fraudulent under the FCA).

24. 42 U.S.C. § 1395w-101 – 152 (Supp. IV 2004).

Medicaid Services (CMS) in 2005, created, virtually overnight, an unprecedented benefit program that over 35 million people use.²⁵

The Part D program provides benefits through private sector prescription drug plans. The plans bid for the right to participate in Part D.²⁶ If the bid is successful, the plan is authorized to provide prescription drugs to Medicare beneficiaries and submit claims for government reimbursement for such drugs.²⁷ Part D imposes extensive reporting requirements on the pharmacy plans, both with respect to the initial application and with respect to the submission of claims for payment.²⁸

Like the long term care survey and enforcement process, Part D provides CMS with a menu of remedies for noncompliance with program requirements. The options available to CMS range from civil money penalties of up to \$100,000 to termination of a plan's contract.²⁹ The Part D remedies are discretionary and CMS has stated that, as a matter of policy, it will limit enforcement to "large, repeat and/or egregious" violations of Part D requirements.³⁰ Also for policy reasons, CMS has disavowed intent to publicize enforcement actions directed at noncompliant plans.³¹

Arguably, CMS's Part D enforcement policy decisions—which reflect policy choices similar to those made in the 1960s and early 1970s to encourage development of sufficient long term care facilities to provide that

25. See Press Release, U.S. Dep't. of Health & Human Servs., *Over 38 Million People With Medicare Now Receiving Prescription Drug Coverage* (June 14, 2006), available at www.hhs.gov/news/press/2006pres/20060614.html (last visited Jan 31, 2008) (showing where Medicare beneficiaries are receiving drug coverage, including coverage implemented by Part D).

26. Toby S. Edelman, HENRY J. KAISER FAMILY FOUND., *Oversight and Enforcement of Medicare Part D Plan Requirements: Federal Role And Responsibilities 5* (2006), available at www.kff.org/medicare/upload/7558.pdf (last visited Oct. 14, 2007).

27. *Id.*

28. See 42 U.S.C. § 1395w-111.

29. 42 C.F.R. §§ 423.750(a)(1), 423.756(e) (2007); see also 42 C.F.R. § 423.756(f) (2007) (The Department of Health and Human Services Office of Inspector General also may impose sanctions instead of, or in addition to, CMS.).

30. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T. OF HEALTH & HUMAN SERVS., *PART D OVERSIGHT STRATEGY FOR CONTRACTORS/INDUSTRY 2* (Oct. 24, 2005), available at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/OversightStrategy_10.24.05.pdf (last visited Oct. 25, 2007).

31. Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4367 (Jan. 28, 2005). CMS stated that it takes this position because:

Some organizations that have received sanctions have later become solid examples of compliant contract administration. We believe that a public listing of sanctioned Part D Plans may not portray the current level of compliance by contracted organizations and could unfairly impede business opportunities for fully compliant contractors that were sanctioned in prior years. . . . Sanction authority is not designed to be punitive.

Id.

newly created benefit—also reflect the need to attract sufficient contractors to provide the entirely new benefit.³² Yet, CMS's policy choices regarding appropriate enforcement policy, whether with respect to nursing facility compliance, violation of Part D standards, or compliance with other Medicare program requirements, do not prevent, or, under *Hendow*, even inhibit prosecution of an FCA action based on the same or similar regulatory violations that program administrators have elected to address through other means. Indeed, such an action may be initiated and prosecuted, even when the government refuses to participate, by a private individual. Moreover, in contrast to the agency's responsibility to consider public policy goals as well as the potential adverse impact on private interests when selecting, and before imposing, a sanction for noncompliance, neither a qui tam relator nor the Department of Justice (DOJ) are bound to consider the larger consequences before initiating an action under the FCA.³³ The potential for conflict between administrative and judicial goals and enforcement of regulatory programs is obvious.

III. DISCUSSION

A. *The Historical Origins of the FCA*

The FCA is a Civil War era statute that, in significant respects, has remained substantively unchanged since its original 1863 enactment.³⁴ The statute was adopted "following a series of sensational congressional investigations into the sale of provisions and munitions to the War Department."³⁵ To combat Civil War era military contracting abuses, Congress created a damages cause of action that could be brought directly by the United States or on its behalf by private persons in a qui tam action.³⁶

The original FCA authorized suit against "any person . . . who shall make or procure to be made . . . any claim against . . . the Government of the United States . . . [knowing such claim to be] *false, fraudulent, or*

32. In its landmark study, the Institute of Medicine notes that early long term care enforcement policy focused on encouraging compliance and entry into the market because there were insufficient nursing facilities to meet the demand created by the newly adopted Medicare and Medicaid Acts. COMM'N ON NURSING HOME REGULATION, INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES 13-14 (1986).

33. *Cf.* U.S. *ex rel.* Marcus v. Hess, 317 U.S. 537, 542 n.5 (1943) (Qui tam relators often act "under the strong stimulus of personal ill will or the hope of gain." (quoting United States v. Griswold, 24 F. 361, 366 (D. Or. 1885))).

34. *Compare* An Act to Prevent and Punish Frauds Upon the Government of the U.S., ch. LXVII, § 1, 12 Stat. 696 (1863) with 31 U.S.C. §§ 3729-3733 (2000).

35. United States v. McNinch, 356 U.S. 595, 599 (1958); *see also* NAGLE, *supra* note 2, at 202-205 (describing passage of original FCA).

36. An Act to Prevent and Punish Frauds Upon the Government of the U.S., ch. LXVII, § 1.

fictitious.”³⁷ It also authorized suit against any person “who shall, for the purpose of obtaining . . . the approval or payment of such claim, make, use, or cause to be made or used, any false bill, receipt, voucher, entry, roll, account, claim, statement, certificate, affidavit, or deposition, knowing the same to contain any *false or fraudulent* statement.”³⁸

Congress recodified the FCA in 1982 and, at that time, eliminated the word “fictitious” from the 1863 proscription of “false, fictitious, or fraudulent” claims.³⁹ However, this minor textual change was designed only to “eliminate unnecessary words” and provide “consistency,” rather than to effect any substantive change.⁴⁰ The FCA was amended again in 1986.⁴¹ However, the terms “false or fraudulent” have never been changed, nor has Congress ever defined the terms.

The current version of the FCA allows suit against any person who “knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a *false or fraudulent* claim for payment or approval.”⁴² A second provision allows suit against any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a *false or fraudulent* claim paid or approved by the Government.”⁴³

B. The Civil War Era FCA Was Not Designed to Apply to Claims Made upon the Modern Administrative State

The threshold question in most FCA actions is whether the claim is false or fraudulent.⁴⁴ In making that determination, the courts’ obligation is to apply Congress’s acts as written, not to expand or contract a statute’s reach to effect the court’s view of wise policy necessitated by changed or unanticipated circumstances.⁴⁵ Thus, whether a claim is false or fraudulent

37. *Id.* (emphasis added); see also *id.* § 3 (making § 1 applicable to non-military members).

38. *Id.* § 1 (emphasis added).

39. Money and Finance, Pub. L. No. 97-258, § 3729, 96 Stat. 877, 978 (1982); H.R. REP. NO. 97-651, at 143 (1982), reprinted in 1982 U.S.C.C.A.N. 1895, 2037.

40. H.R. REP. NO. 97-651, at 143.

41. False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153.

42. 31 U.S.C. § 3729(a)(1) (2000) (emphasis added).

43. *Id.* § 3729(a)(2) (emphasis added).

44. See, e.g., U.S. *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1171 (9th Cir. 2006), cert. denied, 127 S. Ct. 2099 (2007) (stating that the district court had rejected relators’ theories that the University submitted “false or fraudulent claims . . . under the ‘false certification’ theory”) (citing U.S. *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996)).

45. See, e.g., Alexander v. Sandoval, 532 U.S. 275, 286-87 (2001) (noting that the “judicial task is to interpret the statute Congress has passed” to determine whether it creates a cause of action; “[s]tatutory intent . . . is determinative . . . [C]ourts may not create [a cause

under the FCA because a government contractor allegedly violated regulatory requirements necessitates determining the meaning that the 1863 Congress ascribed to “false or fraudulent.”⁴⁶

When Congress enacted the FCA in 1863, the majority of federal government contracts involved services and products to be delivered directly to the government on its own account, not contracts entered in order to obtain federal payment for goods or services delivered to third parties.⁴⁷ Moreover, the types of government benefit, entitlement, and welfare programs run by agencies such as the Department of Health and Human Services (HHS) and the DOE were not only unknown in 1863, they were the type of programs that were not seen as any part of the federal government’s business.⁴⁸ Simply put, federal programs providing—and paying for—governmental benefits delivered to third parties by private sector contractors simply did not exist when the FCA was adopted.⁴⁹

of action] no matter how desirable that might be as a policy matter, or how compatible with the statute”).

46. See generally *Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 781-88 (2000) (holding that the FCA’s terms adopted in 1863 should be given the meaning ascribed to them by authors of the Act at the time the Act was adopted); see also *Touche Ross & Co. v. Redington*, 442 U.S. 560, 568 (1979) (“The question of the existence of a statutory cause of action is, of course, one of statutory construction . . . [and the court’s] analysis must begin with the language of the statute itself.”); *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (although the issue at hand had not been previously considered by the Supreme Court, “the history and language of the False Claims Act . . . indicate the answer to our present inquiry”); *United States v. McNinch*, 356 U.S. 595, 599 (1958) (discussing the circumstances surrounding passage of the False Claims Act, notably how “the United States had been billed for nonexistent or worthless goods”).

47. See generally NAGLE, *supra* note 2, at 181-220 (describing federal contracting during the Civil War period).

48. LAWRENCE M. FRIEDMAN, *A HISTORY OF AMERICAN LAW* 213 (1985) (“*A fortiori* the federal government had nothing to do with the poor laws. It played a minute role in social welfare.”).

49. *Id.* at 439-441. Lawrence Friedman has noted that “[t]he period between 1850 and 1900 is considered the climax of *laissez-faire* – the age of social Darwinism” that eventually gave way as the middle class emerged and sought control over the “great aggregations” that minimized the individual’s ability to control the forces affecting daily life. *Id.* at 440-41. As Professor Friedman has summarized:

The cure was, at first, statewide control. When the states could not meet the demands of their constituents, these constituents embarked on a federal adventure. The process was repeated in many areas of law. In welfare, for example, first came local poor laws, run by country justices and squires of the community. When this system was felt to be obsolete, states centralized their welfare administration. When the states could no longer handle the job (much later, to be sure), the federal government stepped in.

This did not take place until the age of the New Deal, in the 1930s.

Id. at 441.

In 1863 the prevailing view of the role of the federal government was still dictated by the principles and philosophy of Jacksonian democracy. The Jacksonians, insofar as possible, sought to confine political power in state and local governments. Jacksonians abhorred centralized power of any type, and, especially, power consolidated in the federal government because such power was viewed as a threat to individual liberty.⁵⁰

To be sure, the Civil War, and the palpable consequences of the states' rights arguments that precipitated the War, caused many, particularly in the North, to begin to reconsider the appropriate role of the federal government.⁵¹ In addition, the years following the War saw "the emergence of vitally important economic problems demanding Federal rather than State regulation" because of their national scope.⁵²

However, a strong, dominant national government with the resources, the will, and the ability to protect its interests was still years in the future. Indeed, it would have been as difficult for the 1863 Congress to foresee the pervasive role and power that federal agencies wield today as it is for twenty-first century Americans to appreciate the federal government's almost insignificant role in the nation's economic life in 1863.

In 1863, the federal government was so lacking in resources that, without a *qui tam* provision authorizing private individuals to sue on behalf of the United States, the FCA may have been a dead letter. Enforcement of the FCA by the federal government in 1863 was not likely because the Department of Justice did not exist. The DOJ was not created and vested with power to protect the federal government's interests until 1870, seven years after the FCA was adopted.⁵³

In 1863, the Civil War Amendments to the Constitution, the bellwethers of a seismic shift in power from the states to the federal government, were

50. *See generally* JAMES F. SIMON, LINCOLN AND CHIEF JUSTICE TANEY: SLAVERY, SECESSION, AND THE PRESIDENT'S WAR POWERS 14-25 (2006) (discussing Jacksonian populism, opposition to "any special interests" and abhorrence of "concentrated and unaccountable" power in the context of the "Bank War" waged by Jackson and Roger B. Taney against the Second Bank of the United States); *see also* PAUL KENS, JUSTICE STEPHEN FIELD: SHAPING LIBERTY FROM THE GOLD RUSH TO THE GILDED AGE 187 (1997) (discussing Andrew Jackson's "concern for states' rights and opposition to the federal judiciary").

51. *See generally* NAGLE, *supra* note 2, at 185-189 (The federal government increased its arsenal by increasing domestic production, contracting with more private manufacturers, and purchasing arms from overseas. However, this caused the government to reevaluate its contracting methods because of corruption.).

52. 1 STEIN ET AL., *supra* note 4, at 1-17 to 1-18 n.71 (quoting THE PRESIDENT'S COMM. ON ADMIN. MGMT., REPORT OF THE COMMITTEE WITH STUDIES OF ADMINISTRATIVE MANAGEMENT IN THE FEDERAL GOVERNMENT (1937)).

53. *See* An Act to Establish the Department of Justice, ch. 150, 16 Stat. 162 (1870).

still years away.⁵⁴ Steven J. Field, the godfather of substantive due process and the constitutional liberty to contract—doctrines that, for fifty years, frustrated government regulation of business and invalidated social welfare legislation—had not even joined the Supreme Court.⁵⁵ Congress's discretion to spend in aid of the general welfare would not be confirmed for another seventy years.⁵⁶ *Helvering v. Davis*⁵⁷ and *Steward Machine Co. v. Davis*,⁵⁸ upholding the federal income tax, were almost seventy-five years in the future; the Social Security Act was almost seventy years from enactment;⁵⁹ and the Federal Administrative Procedure Act was not adopted for another eighty years.⁶⁰ Perhaps even more to the point, as late as 1918—fifty-five years after the FCA's adoption—the Supreme Court in *Hammer v. Dagenhart* held unconstitutional a federal statute designed to suppress the use of child labor in manufacturing.⁶¹

The Congress that adopted the FCA would find ludicrous the idea that the federal government could or should prescribe standards that businesses are required to meet in their daily operations or that the federal government should oversee such operations. Only in the late nineteenth century did the idea begin to emerge “that governmental regulation of business should not be confined to the enforcement of criminal penalties but should partake of continuous and not unfriendly supervision.”⁶² In short, the sorts of pervasive federal regulatory and oversight systems that characterize the modern administrative state—complete with their own systems to assess regulatory compliance, processes to adjudicate regulatory violations, standards to evaluate the significance of such violations, and administrative discretion to decide whether a remedy or sanction is appropriate—were unknown to the Congress that adopted the FCA.⁶³

54. See generally KENS, *supra* note 50, at 184-96 (detailing the history of cases limiting the federal government).

55. Bernard Schwartz, *Supreme Court Superstars: The Ten Greatest Justices*, 31 TULSA L.J. 93, 108-15 (1995).

56. See *United States v. Butler*, 297 U.S. 1, 65 (1936) (“public funds may be appropriated ‘to provide for the general welfare of the United States’”).

57. 301 U.S. 619 (1937).

58. 301 U.S. 548 (1937).

59. See COMM'N ON NURSING HOME REGULATION, INST. OF MED., *supra* note 32, at 238.

60. Administrative Procedure Act, ch. 324, 60 Stat. 238 (1946) (codified as amended at 5 U.S.C. § 500 (2000)).

61. 247 U.S. 251 (1918). Moreover, the case, known as the “Child Labor Case,” was not overruled for twenty-three years. See *United States v. Darby*, 312 U.S. 100 (1941).

62. 1 STEIN ET AL., *supra* note 4, at 1-17 to 1-18 (quoting THE PRESIDENT'S COMM. ON ADMIN. MGMT., REPORT OF THE COMMITTEE WITH STUDIES OF ADMINISTRATIVE MANAGEMENT IN THE FEDERAL GOVERNMENT (1937)).

63. NAGLE, *supra* note 2, at 181-220. Defects in performance of obligations imposed by government contracts were discovered by the government at the same time that any other

It was not until the

take-off decade of 1905-1915 [that] the regulatory component of statute law became . . . prominent and . . . brought a new type of statute law concerning organized relationships. The focus [of statutes] changed from enabling organized action to injecting more public management or supervision of affairs and providing more sustained, specialized means of defining and enforcing public policy. Symbolic of this turn of affairs were the statutes creating the modern federal and state administrative apparatus; typical was the shift from factory safety laws that simply commanded employers to provide safe work places to laws implemented by provision for administrative rule making and inspection.⁶⁴

But these changes occurred in statutes, not in regulations. Administrative agencies did not become prominent until the New Deal,⁶⁵ and rulemaking did not become the dominant form of regulation until the 1970s.⁶⁶

purchaser would have discovered that he did not get the benefit of his bargain—when the defective goods were delivered and put to use. One transaction between John Pierpoint Morgan and the government demonstrates that, at the time the FCA was adopted, the government, as contractor, stood in no different position than a private entity. Before the Civil War, the army condemned a cache of obsolete guns and ordered them auctioned. The guns sold for less than \$2.00 apiece. In May 1861, Mr. Morgan purchased the guns for \$3.50 each and, claiming that they were “new Carbines in perfect condition,” sold them back to the army for \$22.00 each. When soldiers attempted to use the “new carbines in perfect condition,” they often succeeded only in “shooting off their own thumbs.” *Id.* at 199. When the government refused to pay, Mr. Morgan sued and “won the full sum because, regardless of the wisdom of its bargain, the government still had signed the contract. Caveat emptor.” *Id.* at 200.

64. JAMES WILLARD HURST, *LAW AND SOCIAL ORDER IN THE UNITED STATES* 36 (1977).

65. RICHARD J. PIERCE JR. ET AL., *ADMINISTRATIVE LAW AND PROCESS* 29-31 (2nd ed. 1992).

66. RICHARD J. PIERCE JR., 1 *ADMINISTRATIVE LAW TREATISE* 23 (4th ed. 2002). Any argument that the Civil War era Congress could have conceptualized the scope and reach of the modern administrative agency is belied not only by the fact that the DOJ did not exist, but also by comparison of the number of civilians employed by the federal government at the time the FCA was adopted, in the years just prior to the New Deal, and in 1970 when administrative regulation of business was the rule, rather than the exception. The fact is that, at the time that the FCA was adopted, the federal government was so limited in scope that it could not possibly have engaged in the sort of pervasive regulation of business that is at the heart of many FCA cases today.

In 1861, for example, there were only 40,651 civilian jobs and, of those, almost 23,000 were in the Post Office. See PHILLIP SHAW PALUDAN, *THE PRESIDENCY OF ABRAHAM LINCOLN* 35-36 (1994). Moreover, in 1930, before administrative regulation of business became commonplace, the federal government employed only 601,000 civilians. In 1970, when administrative regulation of business began to reach its heyday, federal government employees had increased 500% over the 1930 level to 3,000,000. Charles Fried, *Domestic Affairs: American Programs and Priorities* by James Duffy, 92 *HARV. L. REV.* 1561, 1564 n.9 (1979) (book review); see also U.S. CENSUS BUREAU, NO. HS-50. *FEDERAL GOVERNMENT—EMPLOYMENT: 1901 TO 2002*, available at www.census.gov/statab/hist/HS-50.pdf (last visited

In addition, the idea that the power to make substantive law could be delegated by Congress to an executive agency also never would have occurred to the Civil War Congress. In fact, in 1935 the Supreme Court's inability to accept the notion that legislative power could be delegated to an administrative agency controlled by the Executive Department almost stopped the New Deal before it started.⁶⁷

The growth of the administrative state has revolutionized and restructured the relationship between the federal government and government contractors. The importance of this change is hard to overstate.⁶⁸ For example, in 1936 Justice Harlan Stone, later Chief Justice, commented that the rise of the administrative law system was the "most striking change in the common law of this country."⁶⁹ Similarly, Justice Jackson noted that the "rise of administrative bodies probably has been the most significant legal trend of the last century" and that agencies had become a "veritable fourth branch of the [g]overnment."⁷⁰ Professors Jaffe and Nathanson have observed that "the administrative process has been the characteristic instrument for redesigning the operation of our economic system and for effecting the required transfers of power."⁷¹ Others have noted that, with the growth of the administrative state, has come a concomitant increase in the federal government's "economic role in national life . . . and with it the opportunities for those receiving government funds" to violate one or more of the innumerable regulations governing entitlement to provide government benefits.⁷²

Because the "fourth branch of government" did not exist and, thus, was not a source of federal law in 1863 when the FCA was adopted, legitimate questions arise about whether or when a claim for payment can be "false

Feb. 13, 2008). It is inconceivable that a Senator or Congressman legislating in 1863 on behalf of a federal government with less than 20,000 non-postal civilian employees could have anticipated, or intended, that the FCA would become one of the principal enforcement tools of the modern administrative state.

67. See generally *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529-30 (1935) (discussing the issue of delegating legislative power); *Panama Refining Co. v. Ryan*, 293 U.S. 388, 248-49 (1935) (discussing the Constitution's assignment to Congress of "[a]ll legislative [p]owers herein granted"); see PIERCE, *supra* note 66, at 25-32 (Pierce argues that Congress' authority to "delegate to agencies the power to promulgate legislative rules that resolve fundamental policy issues" was not addressed until the 1980s.).

68. See LOUIS L. JAFFE & NATHANIEL L. NATHANSON, *ADMINISTRATIVE LAW* 8 (3rd ed. 1968).

69. Harlan F. Stone, *The Common Law in the United States*, 50 HARV. L. REV. 4, 16-18 (1936).

70. *Fed. Trade Comm'n v. Ruberoid Co.*, 343 U.S. 470, 487 (1952) (Jackson, J., dissenting).

71. JAFFE & NATHANSON, *supra* note 68, at 8.

72. 1 JOHN T. BOESE, *CIVIL FALSE CLAIMS AND QUI TAM ACTIONS* § 1.01[B], at 1-11 (3rd ed. 2007).

and fraudulent” under the FCA based on a government contractor’s failure to comply with administrative regulatory standards of a type unknown to the Civil War Congress (e.g., regulating the production process or quality). It is fair to say that the question whether violation of such a regulation makes a subsequent claim for payment false or fraudulent is a question that never would have occurred to the FCA’s authors.

Given a nineteenth century lawyer-legislator’s frame of reference, it is almost certain that the FCA’s authors considered a claim for payment false or fraudulent only when there was a complete failure to deliver on a contract. The Supreme Court, for example, has noted that “[t]he [FCA] was originally adopted” because Congress was outraged that “the United States had been billed for *nonexistent* or *worthless* goods . . . and generally robbed in purchasing the necessities of war.”⁷³ In other words, when a contractor billed the United States, but gave no value in return, the claim was false or fraudulent. Defective performance, including disputes about the value of performance, the relative quality of goods or the degree of compliance with the contract, might breach the contract, but did not make a payment claim false or fraudulent.⁷⁴ Moreover, whether the contractor adhered to appropriate or reasonable manufacturing standards would have been irrelevant to those who passed the FCA.⁷⁵

C. *The FCA and Modern Administrative Regulatory Programs*

If one views the FCA from the perspective of the 1863 Congress, reconciling this Civil War era Act to the modern administrative state is difficult because administrative agencies today:

- have been delegated the power to adopt substantive compliance standards;⁷⁶
- may use specialized investigative and fact-finding procedures and protocols and possess specialized expertise with respect to the entities that they regulate;⁷⁷

73. *United States v. McNinch*, 356 U.S. 595, 599 (1958) (emphasis added).

74. *See supra* note 63 (discussing how the government was treated like any other party to a contract would be treated).

75. Although the process changed somewhat over time, government contracts remained straightforward purchase and sale agreements. No attempt was made to regulate the means of production or the wages or working conditions of those producing the goods for which the government contracted. Generally, the government put a contract out for bid and contracted for the lowest price offered. NAGLE, *supra* note 2, at 181-220

76. *See, e.g.*, 42 U.S.C. §§ 1395i-3(d)(4)(A) (nursing facilities must “operate and provide services in compliance with all applicable Federal, State, and local laws and regulations”), 1396a(a)(28)(D) (2000); 42 C.F.R. §§ 483.1-483.206 (2007) (setting forth substantive requirements for certain healthcare facilities).

- make discretionary judgments regarding the degree and level of a contracting entity's compliance with complex statutory and regulatory standards;⁷⁸
- have discretion to determine what, if any, action to take in the face of noncompliance; and⁷⁹
- have authority to use a variety of remedial measures for noncompliance while allowing contract payments to continue.⁸⁰

In 1863, the development of the administrative system that occurred in the second half of the twentieth century could not have been foreseen.⁸¹ Nor could congressionally imposed limits on judicial review of administrative action have been anticipated.

1. The Medicare Act's Jurisdictional Provisions and the Federal Courts' Authority to Decide Questions Arising Under the Medicare Act

The Medicare Act, unlike most statutes, includes an explicit and comprehensive jurisdictional ban on judicial interference with the Secretary of HHS's discretion to administer the Medicare program. Specifically, Congress recognized the vital importance agency discretion would play in the program's proper administration by channeling any claim arising under the Medicare Act through the Secretary.⁸² Section 405(h) of the Medicare Act provides: "No findings of fact or decision of the [Secretary] shall be reviewed by *any* person, tribunal, or governmental agency," except as

77. *See, e.g.*, 42 U.S.C. §§ 1395i-3(g)(2), 1396r(g)(2) (2000) (setting out standards and procedures for forms, protocols, and surveys of skilled nursing facilities); 42 C.F.R. §§ 488.100-488.115 (2007) (describing detailed survey forms, protocols, and procedures).

78. 42 U.S.C. §§ 1395i-3(g)(2), 1396r(g)(2); 42 C.F.R. §§ 488.100-488.115; *see also*, *e.g.*, 42 C.F.R. §§ 488.404(b), 488.408(e), 488.410(a) (2007) (detailing factors to be used in determining compliance and appropriate sanctions for various degrees of violations).

79. *See, e.g.*, U.S. *ex rel.* Willard v. Humana Health Plan of Tex., Inc., 336 F.3d 375 (5th Cir. 2003); U.S. *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1267 (9th Cir. 1996) ("There are administrative and other remedies for regulatory violations.").

80. *See, e.g.*, 42 U.S.C. §§ 1395i-3(h)(2)(A)(i), (authorizing the Secretary to choose a remedy, taking into consideration whether the facility's deficiencies "immediately jeopardize the health or safety of its residents"), 1396r(h)(2) (2000); *see also* U.S. *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1087 (D. Kan. 2006) ("Denial of government payment is not the exclusive remedy of HHS in the event of a regulatory violation . . . [T]he Social Security Act provides . . . [CMS] with discretionary authority whether to impose sanctions in a particular case.").

81. Indeed, the American Bar Association and well-respected authorities continued to resist the development of pervasive and powerful administrative agencies even into and beyond the 1930s. *See* PIERCE, *supra* note 66, at 8-16.

82. *See* 42 U.S.C. § 1395ii (2000); *cross-referencing* 42 U.S.C. §§ 405(g), 405(h).

specifically authorized by Congress.⁸³ Yet, when regulatory violations are alleged, a claim for payment cannot be false under the FCA unless a court does precisely what the Supreme Court has said Section 405(h) permits only the Secretary to do—determine compliance with program standards.⁸⁴

It can be argued, indeed with some force, that Section 405(h) does not preclude jurisdiction in a case brought by or on behalf of the United States under the FCA.⁸⁵ Such an argument, however, ignores the facts: (1) that the statute has repeatedly been held to reflect Congress' intent and policy that *all* claims requiring application of the Medicare Act's provisions should be

83. 42 U.S.C. § 405(h) (emphasis added). The Administrative Procedure Act also provides that the Act's provisions authorizing judicial review of agency action apply "except to the extent that . . . agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2) (2000).

84. *Compare* *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (ruling that the section 405(h) jurisdictional bar applies irrespective of whether plaintiff challenges agency action on evidentiary, rule-related, statutory, constitutional, or other legal grounds), *with* U.S. *ex. rel.* *Body v. Blue Cross and Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1105 (11th Cir. 1998) ("Medicare rules and regulations clearly would be determinative of whether false claims were, in fact, submitted . . ."); U.S. *ex. rel.* *Woodruff v. Haw. Pac. Health*, No. 05-00521 JMS/LEK, 2007 WL 1500275, at *8 (D. Haw. May 21, 2007) (To state an FCA claim, plaintiffs "must allege that Defendants violated a statute, regulation, or other law upon which the government conditions payment of Medicare or Medicaid claims."); *United States v. Tenet Healthcare Corp.*, 343 F. Supp. 2d 922, 930 (C.D. Cal. 2004) ("[W]hether recovery was sought under the FCA or common law remedies, the fact finder must interpret Medicare reimbursement regulations to determine the propriety of the provider's claim."); *United States v. Rogers*, No. 1:97CV461, 2001 WL 818160, at *25 (E.D. Tenn. June 28, 2001) ("To determine whether the defendants submitted false and fraudulent claims . . . , this Court must necessarily look to and apply [CMS's] rules and regulations governing the reimbursement of . . . providers."). *But see* *United States v. Univ. of Mass. Mem'l Med. Ctr.*, 296 F. Supp. 2d 20 (D. Mass. 2003) (Medicare Act precludes court from determining regulatory compliance in common law recoupment action), *overruled by* *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 17-18 (1st Cir. 2005).

85. The argument rests on the third sentence of § 405(h) which, as codified, appears to apply only to proscribe an "action against the [U.S.] . . . to recover on [a] claim." 42 U.S.C. § 405(h) (2000). The viability of that limitation is subject to doubt. *See, e.g.*, *Bodimetric Health Servs., Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 488, 489 (7th Cir. 1990) (Section 405(h), as originally adopted, precluded jurisdiction under virtually "all of the grants of jurisdiction to the [U.S.] district courts under Title 28"; changes limiting the scope of section 405(h)'s third sentence were not authorized by Congress); *see also* *Ganem v. Heckler*, 746 F.2d 844, 850-52 (D.C. Cir. 1984).

Moreover, the second sentence of § 405(h) is comprehensive: "No findings of fact or decision of the [Secretary] shall be reviewed . . . except as herein provided." 42 U.S.C. § 405(h). *Weinberger v. Salfi*, 422 U.S. 749, 757-59 (1975) held that the sentence "prevent[s] review of decisions of the Secretary save as provided in the [Social Security] Act" and that "[e]ven if the denial is nonfinal, it is still a 'decision of the Secretary' which, by virtue of the second sentence of [section] 405(h), may not be reviewed" except as provided in the Act.

decided by the Secretary and subject to judicial review, if at all, solely based on the record compiled before the Secretary; and (2) that a claim for payment under the Medicare Act cannot be false or fraudulent unless it is made in violation of the Act or its implementing regulations.⁸⁶ Moreover,

86. In *Illinois Council on Long Term Care*, the Supreme Court explained that the circumstances in which a claim arose under the Medicare Act were extremely broad:

Those cases [i.e., *Salfi* and *Ringer*] themselves foreclose distinctions based upon the “potential future” versus the “actual present” nature of the claim, the “general legal” versus the “fact-specific” nature of the challenge, the “collateral” versus “non-collateral” nature of the issues, or the “declaratory” versus “injunctive” nature of the relief sought. Nor can we accept a distinction that limits the scope of § 405(h) to claims for monetary benefits. Claims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h). Section 1395ii’s blanket incorporation of that provision into the Medicare Act as a whole certainly contains no such distinction.

529 U.S. at 13-14.

Tested by this standard, FCA causes of action that require judicial determination of the defendant’s compliance with Medicare regulations as the predicate for establishing that a claim is false or fraudulent appear to arise under the Act. The substantive basis of the government’s claim is the allegation that the claims at issue sought payment in violation of the Medicare Act and its regulations. *Id.* The government’s injury, i.e., the basis for standing, is that the Medicare program was duped into paying ineligible claims. The relief sought is measured by the amount of Medicare benefits alleged to have been wrongly paid and the number of claims submitted to obtain such payments. At bottom, such a dispute is about entitlement to payment of Medicare benefits. The FCA in such case would seem best understood as playing a role similar to the role served by 42 U.S.C. § 1983 (2000) (creating a civil action for deprivation of rights): it creates a cause of action, but the substantive basis for the claim and for the standing to assert it must be found elsewhere. *See, e.g., Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 617-19 (1979) (stating that “one cannot go into court and claim a ‘violation of § 1983’—for § 1983 by itself does not protect anyone against anything”).

Undoubtedly the government, or a *qui tam* plaintiff, would argue that such a case arises under the FCA, not the Medicare Act. *See, e.g., Body*, 156 F.3d at 1102, 1105-10; *Tenet Healthcare Corp.*, 343 F. Supp. 2d at 928 (“[B]ecause the government’s action is predicated on the submission of inaccurate . . . claims, the common law, not the Medicare Act, provides both standing and the substantive basis for the claim.”); *Rogers*, 2001 WL 818160, at *24 (“[T]he federal government’s standing to bring this action and the substantive basis for its claims are the FCA and common law, not the Medicare Act.”). The Supreme Court, it appears, might disagree.

In *Heckler v. Ringer*, the plaintiff asked the court to determine whether a particular service was reimbursable but predicated his action on the Administrative Procedure Act and the Constitution. The court held:

Ringer’s claim may well “aris[e] under” the APA [Administrative Procedure Act] in the same sense that Salfi’s claim arose under the Constitution, but we held in *Salfi* that the

such an argument rests on a proposition—that the federal government may have better access to the courts than citizens—that, at least facially, seems antithetical to foundational constitutional principles.

The congressional policy embodied in Section 405(h) is grounded on, among other things, the desire to ensure that the Secretary's discretion and expertise can be applied to the technical and complex questions that arise under the Medicare Act.⁸⁷ Thus, even if Section 405(h) does not, by its

constitutional claim was nonetheless barred by § 405(h). It would be anomalous indeed for this Court to breathe life into the dissent's already discredited statutory argument in order to give greater solicitude to an APA claim than the Court thought the statute allowed it to give to the *constitutional* claim in *Salfi*.

466 U.S. 602, 622 (1984); *see also Ill. Council on Long Term Care*, 529 U.S. at 51-52 (Thomas, J., dissenting) (An action predicated on the Constitution and the APA arises under the Medicare Act even where payment of benefits is not sought. There is no reason to suppose that an FCA claim should fare differently.).

Ringer makes clear that claims requiring interpretation and application of the provisions of the Medicare Act arise under the Act without regard to whether the Medicare claim is inextricably intertwined with the federal RICO statute, with the APA, with the Federal Tort Claims Act, with the common law, whether the plaintiff seeks only a temporary injunction to preserve the status quo, or whether the claim is asserted as a defense to a government recoupment action. *Am. Acad. of Dermatology v. Dept of Health & Human Servs.*, 118 F.3d 1495, 1498 (11th Cir. 1997) (section 405(g) is exclusive means of challenging blanket preclusion of payment); *St. Vincent's Med. Ctr. v. United States*, 32 F.3d 548, 550 (Fed. Cir. 1994) (Medicare Act unequivocally provides that no action not specifically authorized by the Act shall be brought in any forum, Tucker Act jurisdiction precluded); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 721 (6th Cir. 1991) (Damages claims arise under Medicare Act; no federal question or Federal Tort Claims Act jurisdiction); *Bodimetric Health Servs., Inc. v. Aetna Life & Casualty*, 706 F. Supp. 619, 626 (N.D. Ill. 1989), *aff'd*, 903 F.2d 480 (7th Cir. 1990) (no jurisdiction over RICO and state law tort claims); *V.N.A. of Greater Tift County, Inc. v. Heckler*, 711 F.2d 1020, 1024-25 (11th Cir. 1983) (no jurisdiction to issue status quo injunction pending completion of administrative process); *United States v. Sanet*, 666 F.2d 1370, 1375 (11th Cir. 1982) (no jurisdiction under 28 U.S.C. § 1345 (2000) to determine entitlement to Medicare payment); *United States v. Royal Geropsychiatric Servs., Inc.*, 8 F. Supp. 2d 690 (N.D. Ohio 1998) (same). *But see United States v. Carpentieri*, 23 F. Supp. 2d 433, 437-38 (S.D.N.Y. 1998) (need for agency determination does not preclude FCA case); *U.S. ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, 945 F. Supp. 1485 (W.D. Okla. 1996).

If the claim for payment at issue in the FCA action was made under the Medicare Act and if the claim can only be false or fraudulent under the Medicare Act, it would seem to arise under the Medicare Act. There would be no false claim without the Medicare Act.

87. The Supreme Court has explained: "Insofar as § 405(h) . . . demands the 'channeling' of virtually all legal attacks through the agency, it assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts . . ." *Ill. Council on Long Term Care*, 529 U.S. at 13; *see also Ringer*, 466 U.S. at 617; *V.N.A. of Greater Tift County, Inc.*, 711 F.2d at 1035 ("The situation of disputed application of a regulation to complex and lengthy facts is particularly suited to initial agency interpretation of its own regulations.").

terms, preclude jurisdiction in an FCA case, the oft recognized, and strongly stated, congressional policy ought to be entitled to considerable weight.⁸⁸ The judicial determination of compliance with regulatory standards that is necessary to determine if a claim is false or fraudulent under the FCA has no less potential to interfere with the Secretary's discretion than a judicial determination of entitlement to Medicare payment in the first instance.⁸⁹

88. Sections 405(g) and (h) are found in Title II of the Social Security Act and are applicable to a number of Social Security Act programs. Sections 405(g) and (h) are incorporated by reference into the Medicare Act. See 42 U.S.C. §§ 1395ii, 1395w-22(5) (2000). In addition, the Medicare Act itself repeatedly stresses that determination of the applicability of the Act's provisions is for the Secretary alone. See, e.g., 42 U.S.C. § 1395kk(a) ("Except as otherwise provided in this subchapter [xviii], . . . the insurance programs established by this subchapter shall be administered by the Secretary."); 42 U.S.C. § 1395ff(a)(1) ("The initial determination of whether an individual is entitled to benefits under [the Medicare Act], [and] [t]he initial determination of the amount of benefits" shall be made by the Secretary in accordance with regulations he prescribes.). Cf. *New York v. Sec'y of Health and Human Servs.*, 903 F.2d 122, 125 (2d Cir. 1990) ("The Medicare statute unambiguously vests final authority in the Secretary, and no one else, to determine . . . whether reimbursement should be made.").

89. Insofar as the author is aware, there are few cases addressing whether an FCA case, based on the Medicare Act, is subject to Section 405's jurisdictional limitations. *Body*, 156 F.3d at 1101, was the first case to do so. See also *Ringer*, 466 U.S. at 602; *Saffi*, 422 U.S. at 749.

In *Body*, a qui tam relator claimed that Blue Cross paid Medicare reimbursement to Alabama hospitals for unallowable costs. The district court, relying on *Bodimetric Health Servs., Inc.*, 903 F.2d at 480, dismissed the complaint holding that Section 405(h) precluded jurisdiction. U.S. ex rel. *Body v. Blue Cross and Blue Shield of Ala., Inc.*, No. CV93-P-1508-S, 1995 U.S. Dist. LEXIS 22432, at *5-9 (N.D. Ala. April 28, 1995).

The Eleventh Circuit affirmed the dismissal on other grounds, but found that Section 405 did not preclude federal question jurisdiction. Acknowledging that the Supreme Court has read Section 405 very broadly, the *Body* Court, nonetheless, held that "[a]ctions such as *Body's*, which do not seek payment from the government and could not be brought under Section 405, are therefore not barred by subsection 405(h)." *Body*, 156 F.3d at 1104. The *Body* court summarized:

We rely today on . . . the distinction between a case brought by a beneficiary, who ultimately wants funds from the government and may challenge adverse decisions through the administrative process, and a case brought by a *qui tam* relator under the [FCA], who seeks to recover money erroneously paid by the government, a claim not cognizable in the administrative scheme.

Id. at 1109. The decision in *Body* predates the Supreme Court's decision in *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1. *Illinois Council on Long Term Care, Inc.*, explicitly rejected the distinction relied on by the Eleventh Circuit, explaining that whether a claim "arises under" the Medicare Act is not premised on whether the plaintiff is or is not a beneficiary seeking benefits under the Act, or upon whether the plaintiff would have been entitled to an administrative hearing. Any "action" that "dispute[s] agency policy determinations, or may . . . similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions," arises under the Medicare Act and federal court jurisdiction is precluded under Section 405 unless the claim has been "channeled

2. Courts Often Have Precluded Judicial Determination of Issues Committed to Agency Discretion Even When the Seminal Statute Did Not Expressly Bar Jurisdiction

In cases not involving the FCA, the Supreme Court has held that the existence of detailed and comprehensive regulatory and enforcement schemes indicates congressional intent to preclude enforcement of the statute by anyone other than the agency to whom Congress has delegated enforcement discretion.⁹⁰ More specifically, where a statute commits to an administrative agency the power to make a finding that is the necessary predicate for judicial action, the Court long has held that the judiciary lacks jurisdiction to act.⁹¹

In *Montana-Dakota Utilities Co. v. Northwestern Public Service Co.*, for example, plaintiff claimed common law fraud and alleged a federal statutory right to a reasonable utility rate and a common law right not to have the rate influenced by interlocking directorates.⁹² The Supreme Court held that the only rate plaintiff was entitled to was one determined by the Federal Power Commission:

A court may think a different level more reasonable. But the prescription of the statute is a standard for the Commission to apply and, independently of Commission action, creates no right which courts may enforce.

through the agency.” 529 U.S. at 4, 14. A related issue appears to have been raised, but not decided, in *Ohio Hosp. Ass'n v. Shalala*, 201 F.3d 418 (6th Cir. 1999). *But see Tenet Healthcare Corp.*, 343 F. Supp. 2d at 931 (acknowledging that whether a claim is false depends on court interpretation and application of Medicare regulation to facts, but saying “nothing in *Illinois Council* contradicts the *Body* court’s conclusion that subsection 405(h) . . . is . . . inapplicable to claims brought on behalf of the government to recover overpayments”) (internal quotation omitted).

90. *See, e.g.*, *Blessing v. Freestone*, 520 U.S. 329, 341 (1997) (“[D]ismissal is proper if Congress . . . impliedly [foreclosed a remedy] by creating a comprehensive enforcement scheme that is incompatible with individual enforcement. . . .”); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 579 (1979) (“[I]f Congress intends those customers to have such a federal right of action, it is well aware of how it may effectuate that intent.”); *Nat’l R.R. Passenger Corp. v. Nat’l Ass’n. of R.R. Passengers*, 414 U.S. 453, 458 (1974) (“A frequently stated principle of statutory construction is that when legislation expressly provides a particular remedy or remedies, courts should not expand the coverage of the statute to subsume other remedies.”).

91. *See, e.g.*, *Montana-Dakota Util. Co. v. Nw. Pub. Serv. Co.*, 341 U.S. 246, 251-53 (1951), discussed *infra* in text accompanying notes 97-100. *Cf. Tenet Healthcare Corp.*, 343 F. Supp. 2d at 930-31; *Rogers*, 2001 WL 818160, at *20 (When CMS, on referral from the court, refuses to make a regulatory compliance determination on a regulatory compliance question that determines whether a claim is “false” under the FCA, “[c]ourts can and should proceed to exercise . . . jurisdiction to adjudicate the issue.”).

92. *See generally Montana-Dakota Util. Co.*, 341 U.S. 246.

Petitioner cannot separate what Congress has joined together. It cannot litigate in a judicial forum its general right to a reasonable rate, ignoring the qualification that it shall be made specific only by exercise of the Commission's judgment, in which there is some considerable element of discretion.⁹³

Noting that Congress had given the Commission discretion to approve otherwise illegal interlocking directorates, the Court dismissed a common law fraud claim based on an interlocking directorate:

The effect of the approval is to exempt the relationship from the ban of the Act and remove from it any presumption of fraud that might be thought to arise from its mere existence. *It would be a strange contradiction between judicial and administrative policies if a relationship which the Commission has declared will not adversely affect public or private interests were regarded by courts as enough to create a presumption of fraud.* Perhaps, in the absence of the Commission's approval, such relationship would be sufficient to raise the presumption under state law, but it cannot do so where the federal supervising authority has expressly approved the arrangement.⁹⁴

Allegations that a claim is false or fraudulent under the FCA because a government contractor failed to comply with regulatory standards would seem analogous. In such a case, as in *Montana-Dakota*, a court may think that the contractor violated the regulations and, therefore, was not entitled to payment "[b]ut the prescription of the statute is a standard for the [Secretary] to apply."⁹⁵ Similarly, a plaintiff "cannot litigate in a judicial forum its general right" to pay only for reasonable services, "ignoring the qualification that it shall be made specific only by exercise of the [Secretary's] judgment, in which there is some considerable element of discretion."⁹⁶

93. *Id.* at 251.

94. *Id.* at 252-53 (emphasis added); *see also* *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994) (no jurisdiction under Federal Mine Safety and Health Act because designation of miners' representatives committed to Mine Safety and Health Administration); *Ark. La. Gas Co. v. Hall*, 453 U.S. 571 (1981) (filed rate doctrine bars jurisdiction over claims under Natural Gas Act); *Myers v. Bethlehem Shipbuilding Corp. v. MacKenzie*, 303 U.S. 41 (1938) (district courts have no jurisdiction over claim arising under National Labor Relations Act because National Labor Relations Board and Circuit Court of Appeals have exclusive initial jurisdiction over unfair labor practices); *McHugh v. Rubin*, 220 F.3d 53, 61 (2d Cir. 2000) (citing *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000)) (no jurisdiction under 28 U.S.C. § 1361 (2000) or 18 U.S.C. § 925(c) (2000) where ATF had not rendered administrative "denial" of application); *H.J. Inc. v. Nw. Bell Tel. Co.*, 954 F.2d 485 (8th Cir. 1992) (filed rate doctrine barred RICO action); *U.S. ex rel. Windsor v. DynCorp, Inc.*, 895 F. Supp. 844 (E.D. Va. 1995) (Davis-Bacon Act precluded jurisdiction over FCA case).

95. *Montana-Dakota Util. Co.*, 341 U.S. at 251.

96. *Id.*

Further, many statutes, including several provisions of the Medicare Act, give the agency power to waive a contractor's liability or continue payment in certain circumstances, despite apparent noncompliance with regulatory standards.⁹⁷ Again paralleling *Montana-Dakota*, "the effect of the [agency's] approval" of payment, notwithstanding the supplies being deemed unnecessary, would be to "remove from [the claim] any presumption of fraud."⁹⁸

Yet, the strange contradiction between judicial and administrative policies denounced by *Montana-Dakota* arises in many cases. Indeed, FCA and qui tam cases like *Hendow* often are brought in circumstances in which an agency has elected to impose no remedy or an alternate remedy, rather than seek recovery of payments made for services rendered when a contractor allegedly was in violation of regulatory standards.⁹⁹

The need to avoid the strange contradiction has led courts, in a variety of contexts, to refuse to allow FCA actions to proceed where resolution of whether the claim was false or fraudulent would require the court to decide a matter committed to the discretion of an administrative agency. In *United States ex rel. Windsor v. DynCorp, Inc.*, for example, the gravamen of the plaintiff's FCA claim was that the defendant submitted false claims because it misclassified workers and the wages paid to them in violation of the Davis-Bacon Act.¹⁰⁰ In dismissing plaintiff's claim, the court stated that it was

97. See, e.g., *United States v. Southland Mgmt. Corp.*, 288 F.3d 665 (5th Cir. 2002), *rev'd*, 326 F.3d 669 (5th Cir. 2003) (en banc) (HUD continued payment despite noncompliance); *U.S. ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002) ("HHS may also exercise discretion not to impose sanctions in a particular case."); Brief for the United States as Amicus Curiae in Support of Appellant at 9 n.3, *U.S. ex rel. Main v. Oakland City Univ.*, 426 F.3d 914 (7th Cir. 2005) (No. 05-2016), 2005 WL 3950531 (citing DOE Memorandum, *supra* note 14 (saying that the DOE reversed its policy of treating violation as "monetary loss to the Department;" instead, it treats such violations as compliance matters)).

98. *Montana-Dakota Util. Co.*, 341 U.S. at 252.

99. See cases cited *infra* note 133. In fact, in at least one instance, the government has brought an FCA case claiming that a Medicare provider billed for medical supplies that could never be eligible for Medicare reimbursement despite the rulings of numerous Medicare Administrative Law Judges in essentially identical circumstances determining that the supplies were reasonable and necessary and, therefore, ordering Medicare to pay for them. See *United States v. Gericare Med. Supply Inc.*, No. CIV.A.99-0366-CB-L, 2000 WL 33156443, at *1 (S.D. Ala. Dec. 11, 2000) (The author was counsel to defendants in the case and he has copies of the pleadings on file.). The case was settled based on a cash payment by the defendants in roughly the amount that Medicare had paid them for the supplies that had been used to deliver patient care. The case is typical of FCA actions in which the magnitude of potential damages and penalties under the FCA makes even a minimal risk of such an award an unacceptable risk.

100. 895 F. Supp. 844, 849 (E.D. Va. 1995).

impossible to determine whether DynCorp submitted a false claim to the government without first determining whether DynCorp actually misclassified an employee in a given instance. And, the responsibility for resolving such disputes rests not with the courts, but with the Department of Labor

. . . .

. . . To permit Windsor's claim to go to a jury would result in bypassing the carefully crafted administrative scheme for resolving Davis-Bacon Act classification disputes. Contrary to this scheme, a jury, not the agency, would listen to testimony of employees regarding the work they performed on various dates and then determine the appropriate classification for any given task by reference to the Department of Labor's complex classification standards.¹⁰¹

This principle would seem especially compelling when a court is required to apply Medicare regulations to determine the falsity of a claim under the FCA inasmuch as courts frequently have held that the discretionary compliance determinations required by the Act are "peculiarly within the Secretary's competence."¹⁰²

Further, judicial restraint would seem appropriate when courts are asked to interpret and apply administrative regulations in an FCA action because the processes and rules used by administrative agencies to make discretionary decisions are unlike those used by courts. In the context of the Social Security Act, such differences led the Supreme Court to comment that "[t]he differences between courts and agencies are nowhere more pronounced than in Social Security proceedings."¹⁰³ There is, however, a discomfiting split in the courts with respect to judicial authority to interpret and apply Medicare law to the facts of an FCA or common law fraud case, despite the fact that all courts recognize that the court's interpretation of Medicare law necessarily determines whether a claim is false or fraudulent.¹⁰⁴

101. *Id.* at 851-52; *see also* U.S. *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999) (FCA cannot be used "to preempt the [agency's] discretionary decision not to pursue regulatory penalties."); *United States v. Dan Caputo Co.*, 152 F.3d 1060 (9th Cir. 1998) (permitting jury in FCA case to decide key issue circumvents administrative scheme); U.S. *ex rel.* Local Union No. 217 v. G.E. Chen Constr., Inc., 954 F. Supp. 195 (N.D. Cal. 1997) (FCA case dismissed because predicate determination committed to DOL).

102. *See, e.g.*, *Heckler v. Ringer*, 466 U.S. 602, 618 (1984); *New York v. Sec'y of Health and Human Servs.*, 903 F.2d 122, 125 (2d Cir. 1990) ("The Medicare statute unambiguously vests final authority in the Secretary, and no one else, to determine" application of Medicare regulations.).

103. *Sims v. Apfel*, 530 U.S. 103, 110 (2000).

104. *Compare* U.S. *ex rel.* Sweeney v. Manorcare Health Servs., Inc., No. C03-5320RJB, 2005 WL 4030950 (W.D. Wash. March 4, 2005); *United States v. Univ. of Mass. Mem'l Med. Ctr.*, 296 F. Supp. 2d 20 (D. Mass. 2003); *and* U.S. *ex rel.* Swan v. Covenant Care,

Differences between judicial and administrative processes have caused courts in non-FCA contexts to routinely decline to substitute judicial for administrative processes. In *V.N.A. of Greater Tiff County, Inc. v. Heckler*,¹⁰⁵ for example, the plaintiff, claiming that recoupment of alleged Medicare overpayments by the Secretary would result in bankruptcy, sought an injunction precluding the Secretary from recouping money until after a final decision was rendered in his administrative appeal.¹⁰⁶ The Eleventh Circuit emphasized that “[w]here both parties engage in extensive discovery” and the court thereafter determines compliance with Medicare regulations in a fact-finding hearing, the “court does *exactly* what the [agency]” alone is authorized to do.¹⁰⁷ According to the Eleventh Circuit, “[s]uch plenary consideration violates not only the procedural structure of the Medicare Act, but it is in effect a *de novo* decision on the merits in direct contravention of the limited review mandated by statute.”¹⁰⁸ Moreover, the Eleventh Circuit explained, “[t]he situation of disputed application of a regulation to complex and lengthy facts is particularly suited to initial agency interpretation of its own regulations.”¹⁰⁹

3. The Tension Between the FCA and Modern Administrative Regulatory Programs: Who Should Decide?

If the FCA creates an exception to statutory and general jurisdictional limitations and allows courts to determine compliance with agency regulations in order to decide if a claim is false or fraudulent, such exception ought to be announced and its relationship to complex administrative regulatory and enforcement programs rationally explained in light of the FCA’s history, not presumed *sub silentio*, as has generally been the case to date. In addition, if special rules are to be applied to FCA actions involving the Medicare Act, as some courts have suggested, the rationale for such differential treatment also should be explained.¹¹⁰

Inc., 279 F. Supp. 2d 1212 (E.D. Cal. 2002), with *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1 (1st Cir. 2005); *U.S. ex rel. Body v. Blue Cross and Blue Shield of Ala., Inc.*, 156 F.3d 1098 (11th Cir. 1998); *United States v. Tenet Healthcare Corp.*, 343 F. Supp. 2d 922 (C.D. Cal. 2004); and *United States v. Rogers*, No. 1:97CV461, 2001 WL 818160 (E.D. Tenn. June 28, 2001) (CMS refrains from administrative determination and requests court to interpret Medicare rules in the first instance).

105. 711 F.2d 1020 (11th Cir. 1983).

106. *Id.* at 1022.

107. *Id.* at 1032.

108. *Id.*

109. *Id.* at 1035.

110. See *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1177 (9th Cir. 2006), *cert. denied*, 127 S. Ct. 2099 (2007) (distinguishing *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) as “specifically confined” to Medicare claims); *U.S. ex rel. Woodruff v.*

(a) *United States ex rel. Hendow v. University of Phoenix* or “Who Cares What the DOE Thinks?”

The *Hendow* case illustrates the need to reconcile the FCA and modern administrative regulatory programs. The plaintiffs, private individuals, brought a qui tam action under the FCA alleging that the UOP, a proprietary university that contracts with the DOE, falsely claimed compliance with program requirements in order to obtain a supplier contract with the DOE.¹¹¹ However, rather than treat the violation as fraud, the DOE, consistent with its published policy,¹¹² made a discretionary decision to continue making payments to UOP.¹¹³ Also consistent with its published policy, the DOE elected to treat the university’s alleged violation of the ban on incentive compensation as a regulatory enforcement matter.¹¹⁴ UOP was required to pay a fine, but the settlement “did not require UOP to repay any of the financial aid received by its students, change any of its practices for compensating admissions counselors, or discipline any of its employees.”¹¹⁵

The Ninth Circuit held that plaintiffs had stated an FCA claim.¹¹⁶ Summarily dismissing the DOE’s enforcement authority and its power to withhold funds and impose sanctions as “largely academic,” the court held that federal payments and eligibility to participate as a provider were inextricably intertwined.¹¹⁷ Consequently, the court concluded that compliance with the statutory and regulatory provisions at issue was a precondition to federal payment.¹¹⁸

Rejecting UOP’s argument that the requirement was “merely a condition of *participation*, not a condition of *payment*” as resting on a distinction without a difference, the Ninth Circuit effectively overrode, but did not overrule, its earlier decision in *United States ex rel. Hopper v. Anton*.¹¹⁹

Haw. Pac. Health, No. 05-00521 JMS/LEK, 2007 WL 1500275, at *5-8 (D. Haw. May 21, 2007) (distinguishing *Hendow* as applying to the DOE program, not to Medicare).

111. *Hendow*, 461 F.3d at 1169.

112. *Id.* at 1168-69.

113. *Id.* at 1169-70.

114. *Id.* at 1170.

115. Petition for Writ of Certiorari at 6, *Hendow*, 127 S. Ct. 2099 (2007) (No. 06-1006), 2007 WL 160712.

116. *Hendow*, 461 F.3d at 1177.

117. *Id.* at 1175.

118. *Id.* at 1175-76.

119. *Id.* at 1176. In U.S. *ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996), the plaintiff alleged that violations of the Individuals with Disabilities Act supported an FCA action. The Ninth Circuit held that the availability of “administrative and other remedies for regulatory violations” demonstrated that compliance with the regulations “was not a *sine qua non* of receipt of state funding.” *Id.* at 1267. Therefore, an FCA action would not lie.

Further, after attempting to distinguish the leading Second Circuit case from which the “participation versus payment” distinction originated, *United States ex rel. Mikes v. Strauss*,¹²⁰ the court dismissed the Second Circuit’s holding as confined to the Medicare context.¹²¹

The court’s treatment of its *Anton* ruling, which it characterized as “[t]he leading case on false certification in the Ninth Circuit,”¹²² its dismissal of *Mikes* and its mechanistic application of the FCA to claims made under a complex and detailed statute, reflect the deep-seated tension inherent in applying the terms “false or fraudulent” to types of payment claims never contemplated by the FCA’s authors. Even more pertinent, the court never considered whether the menu of administrative remedies for noncompliance that Congress made available to the DOE (other than recoupment of past payments) indicated that compliance was not a precondition to payment. Similarly, nowhere in *Hendow* does the court acknowledge that the DOE was aware of the noncompliance and, nevertheless, continued paying UOP. Likewise, the court never mentions that the DOE issued a written policy providing that, because the violation caused the government no monetary loss, the violation should be treated, not as fraud, but as a matter for administrative penalties.¹²³ To put the matter bluntly, although the court characterized the requirement that UOP allegedly violated as “a ‘prerequisite’ to funding,”¹²⁴ the DOE, the agency that Congress authorized to run the program, had determined, as a matter of policy and, specifically, in the case of UOP, that the requirement was not a material precondition or a “*sine qua non* of receipt of [government] funding” and that the agency had gotten what it paid for, suffering no monetary loss.¹²⁵

Although the *Hendow* court refused to accord the DOE’s enforcement authority any weight, other courts, including the Ninth Circuit in *Anton*, have found that the availability of a menu of administrative sanctions demonstrates that regulatory compliance is not a precondition to payment and, therefore, that noncompliance does not render a claim false or fraudulent.¹²⁶ Other courts addressing a point ignored by the *Hendow* court

120. 274 F.3d 687 (2d Cir. 2001).

121. *Hendow*, 461 F.3d at 1177.

122. *Id.* at 1171.

123. See DOE Memorandum, *supra* note 14.

124. *Id.* at 1176.

125. *Id.* at 1172 (quoting *Anton*, 91 F.3d at 1267).

126. See, e.g., U.S. *ex rel.* Willard v. Humana Health Plan of Tex. Inc., 336 F.3d 375, 382-83 (5th Cir. 2003) (Compliance with regulations clearly not condition of payment because statute authorizes government only to apply remedies prospectively); U.S. *ex rel.* Cooper v. Gentiva Health Servs., Inc., No. 01-508, 2003 WL 22495607, at *7-9 (W.D. Pa. Nov. 4, 2003) (same); U.S. *ex rel.* Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8, 19 (D.D.C. 2003) (Remedies under the FCA only apply “if compliance with the statutes or

also have refused to allow an FCA action based on regulatory noncompliance because imposition of the only remedies provided by the FCA—multiple damages and large per claim penalties—would impermissibly supplant the remedial discretion that Congress conferred on the agency.¹²⁷ Thus, courts have refused to allow FCA cases based on regulatory noncompliance because doing so would effectively “preempt” the remedial decision made by the enforcement agency,¹²⁸ and “would allow courts to take away all money a hospital received from Medicare even though the agencies charged with the enforcement of Medicare statutes and regulations would not have done so.”¹²⁹

The need to reconcile the use of the FCA to the comprehensive regulatory and enforcement programs run by the modern administrative state also is illustrated by comparing *Hendow’s* reading of *Anton* with other courts’ analyses of the *Anton* ruling. Many courts have dismissed FCA claims, citing *Anton* for the proposition that an FCA action based on regulatory violations impermissibly interferes with an agency’s remedial discretion.¹³⁰ Yet, to a significant extent, the *Hendow* court also predicates its ruling, permitting an FCA action based on regulatory noncompliance to proceed, on *Anton*.¹³¹

(b) The FCA and the Medicare Program: A Match *Not* Made in Heaven

Nowhere has the tension between the FCA and the modern administrative state been more prevalent—and more in need of resolution—than in the context of government-funded healthcare benefit programs, such

regulations was a prerequisite to gaining a benefit, and the defendant affirmatively certified such compliance.” (internal citations omitted).

127. See, e.g., U.S. *ex rel.* Conner v. Salina Reg’l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1088 (D. Kan. 2006) (finding that Congress did not intend “for the FCA to apply to the types of claims” at issue in the case); U.S. *ex rel.* Sweeney v. Manorcare Health Servs., Inc., No. C03-5320RJB, 2005 WL 4030950, at *6-7 (W.D. Wash. March 4, 2005) (allowing qui tam plaintiffs to proceed on FCA claims where HHS has chosen to waive remedies allows “plaintiffs to supplant the regulatory discretion granted to HHS”); U.S. *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1222-23 (E.D. Cal. 2002).

128. U.S. *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999).

129. *Conner*, 459 F. Supp. 2d at 1088.

130. See cases discussed *supra* note 127.

131. 461 F.3d at 1171-73. Moreover, unlike *Hendow*, most of the cases relying on *Anton* to dismiss FCA claims based on regulatory noncompliance involved alleged violations that the agency had not yet addressed. *Hendow* is not unique; it is merely the latest example of the disconnect between the FCA and the administrative state. Cf. U.S. *ex rel.* Woodruff v. Haw. Pac. Health, No. 05-00521 JMS/LEK, 2007 WL 1500275, at *6-8 (D. Haw. May 21, 2007) (discussing *Hendow* and denying defendants’ motion to dismiss an FCA claim that they had submitted facially false claims to Medicaid).

as the Medicare and Medicaid programs.¹³² The importance of directly addressing and resolving the tension is exacerbated because the federal government is the largest single purchaser of healthcare in the United States.¹³³ In 2006, the Medicare and Medicaid programs accounted for approximately 21% of all federal spending.¹³⁴

Medicare and Medicaid benefits generally are provided through private contractors (known as providers) who are paid pursuant to the Medicare and Medicaid statutes and accompanying regulations.¹³⁵ These statutes and regulations have been described by the Supreme Court as “Byzantine” texts that are “among the most intricate ever drafted by Congress.”¹³⁶ Healthcare providers daily navigate a “morass of bureaucratic complexity,” submitting thousands of claims a day to the Medicare and Medicaid programs.¹³⁷ If providers cross one of the lines in these programs’ “impenetrable texts,”¹³⁸ they expose themselves to potential liability under the FCA for treble damages and penalties of \$5,500-\$11,000 for every false or fraudulent claim knowingly presented to the government.¹³⁹

(i) The Long Term Care Survey and Enforcement Process and the Judicial Process: The Differences Could Not Be More Profound

The tension between the nursing home regulatory system established by Congress and enforced by the Secretary of Health and Human Services, on the one hand, and the use of the FCA to recover treble damages and

132. This is evident from, among other things, the number of healthcare based FCA actions. In 2006, of all FCA actions filed, 28% involved matters in which HHS was the primary agency. More FCA cases involve HHS than the Department of Defense. THE FALSE CLAIMS ACT LEGAL CENTER, U.S. DEPARTMENT OF JUSTICE: FRAUD STATISTICS - OVERVIEW (Oct. 1, 1986 – Sept. 30, 2006), available at www.taf.org/stats-fy2006.pdf (last visited Jan. 31, 2008).

133. See *Waste, Fraud, Abuse, and Mismanagement: Hearing Before the Task Force on Health of the H. Budget Comm.*, 106th Cong. 178 (2000) (Statement of Office of Inspector Gen., U.S. Dep’t of Health & Human Servs.), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:64510.pdf (describing the Health Care Financing Administration (now CMS) as the largest health care purchaser in the world) (last visited Jan. 31, 2008).

134. CONG. BUDGET OFFICE, THE BUDGET AND ECONOMIC OUTLOOK: FISCAL YEARS 2008 TO 2017, at 54 (Jan. 2007) (also noting that federal Medicare and Medicaid spending totaled \$554 billion in 2006).

135. See, e.g., 42 U.S.C. § 1395g, (2000).

136. *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981); see also *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (describing Medicare as a “massive, complex health and safety program . . . embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations”).

137. See *Herweg v. Ray*, 455 U.S. 265, 279 (1982) (Burger, C.J., dissenting).

138. *Rehab. Ass’n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994).

139. 31 U.S.C. § 3729(a)(1) (2000); 28 C.F.R. § 85.3(9) (2007).

penalties for claims that are allegedly false or fraudulent because a nursing home provider has violated one or more eligibility standards arises from: (1) the differing processes used by the Secretary and the courts to determine the existence of a regulatory violation; and (2) the extent of the discretion committed by law to the Secretary to craft a response to any regulatory violation and the range of possible responses, including continued payment for services notwithstanding the existence of a regulatory violation.

For example, the Medicare and Medicaid Acts require administrative determinations of nursing facility compliance to be made in a manner specified by the Acts that is entirely unlike—indeed, the antithesis of—the Federal Rules of Civil Procedure and Rules of Evidence that a court would use to determine whether a payment claim is false or fraudulent under the FCA.¹⁴⁰ Determinations of compliance must be made by an on-site inspection using forms, procedures, and protocols that bear no relation to the judicial fact-finding process.¹⁴¹ The survey forms, procedures, guidelines, and methodologies must have been “develop[ed], test[ed], or validate[d]” by the Secretary.¹⁴² According to the statute, the compliance determination must be made by a “multidisciplinary team of professionals,” including at least one registered nurse.¹⁴³

In further contrast to the judicial process, surveyors must use “a case-mix stratified sample of residents” to evaluate “the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and physical environment.”¹⁴⁴ Surveyors are to “directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents.”¹⁴⁵ Failure to utilize the prescribed protocol renders the results of the inspection invalid.¹⁴⁶

If the team of inspectors, called surveyors, determines that the nursing home is in *substantial* (i.e., not perfect) compliance with the regulations

140. See generally *Beverly Health & Rehab. Servs., Inc. v. Thompson*, 223 F. Supp. 2d 73 (D.D.C. 2002) (discussing the process the agency took to determine whether a nursing facility was in compliance with the statute and deciding that the process complied with statutory requirements).

141. See 42 U.S.C. § 1395i-3(g) (2000).

142. 42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C); see also 42 C.F.R. §§ 488.100-488.115, 488.300-488.335 (2007).

143. 42 U.S.C. §§ 1395i-3(g)(2)(E)(i), 1396r(g)(2)(E)(i) (2000); see also 42 C.F.R. § 488.314(a) (2007).

144. 42 U.S.C. §§ 1395i-3(g)(2)(A)(ii)(I), 1396r(g)(2)(A)(ii)(I) (2000).

145. 42 C.F.R. § 488.26(c)(2) (2007).

146. See *id.* § 442.30(a)(5)(ii)-(v) (stating that Medicare and Medicaid provider agreements are not valid if federal survey forms and procedures are not used by inspectors).

governing participation in the Medicare and Medicaid programs, payments will continue.¹⁴⁷ Even if the nursing home is not in substantial compliance at the time of the survey, in most cases, the nursing home will be given an opportunity to correct any problems and federal payment may continue for months while it does so.¹⁴⁸

In addition, if a nursing facility is noncompliant, the Secretary has discretion to impose a variety of remedies.¹⁴⁹ Some of the remedies that may be imposed include termination of a provider's prospective ability to participate in the Medicare and Medicaid programs, denial of payments to the provider, placement of a temporary manager or state monitor in the facility, and civil money penalties up to \$10,000 per incident or for each day that the violation existed.¹⁵⁰

In order to select an appropriate sanction, deficiencies are classified by seriousness.¹⁵¹ Seriousness is assessed by evaluating the severity of the deficiency (i.e., the degree of actual and potential harm) in conjunction with the scope of the deficiency (i.e., the degree to which it is pervasive or isolated).¹⁵² The selection of an appropriate administrative remedy involves considerable discretion and the Secretary must assess the "most effective remedy" to ensure "the protection of the well[-]being of the resident population,"¹⁵³ as well as the facility's "prior history of noncompliance."¹⁵⁴ In contrast, the FCA imposes multiple damages and per claim penalties whenever a claim is false or fraudulent without regard to the scope or severity of the underlying regulatory violation or the impact on those served by the regulatory program.¹⁵⁵

147. *See generally id.* §§ 488.26(b) ("The decision as to whether there is compliance . . . depends upon the manner and degree to which the provider . . . satisfies the various standards within each condition."), 488.301 (defining "[s]ubstantial compliance" as compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.").

148. *See, e.g.,* Beverly Health & Rehab. Servs., Inc. v. Thompson, 223 F. Supp. 2d 73, 110 (D.D.C. 2002) ("[I]t is unusual, if not unique" to terminate facility participation in the absence of immediate jeopardy to patients.).

149. *See* 42 U.S.C. § 1395i-3(h) (2000).

150. *See id.* §§ 1395i-3(h)(2), 1396r(h)(2).

151. *See* 42 C.F.R. § 488.404(b) (2007).

152. *Id.* §§ 488.404(b), 488.410(a); *see also id.* §§ 488.404, 488.406 (listing available remedies).

153. Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. 56,116, 56,123 (Nov. 10, 1994).

154. 42 C.F.R. § 488.404(c)(2).

155. *Hendow*, 461 F.3d 1166, 1177 (9th Cir. 2006), *cert. denied*, 127 S. Ct. 2099 (2007), is again illustrative. The policy that the DOE relied on to continue payments to UOP despite the violations was based on consideration of the impact of the violation on the student beneficiaries of the program and on assessment of the magnitude of harm that the violation

Congress viewed determination of nursing providers' regulatory compliance through use of the survey protocol and inspection methodology specified in the Acts and the remedial discretion conferred on the Secretary as critical to consistent and effective regulation of the quality of nursing facility care.¹⁵⁶ Indeed, one of the principal purposes of the comprehensive Nursing Home Reform Act passed by Congress in 1987 was to confer discretion on the Secretary to continue Medicare and Medicaid payments even where nursing facilities had regulatory violations.¹⁵⁷

(ii) Part D and the FCA: Furthering the Disconnect: Administrative Enforcement of the Medicare Prescription Drug Benefit and the FCA

The tension between the differing FCA and administrative enforcement approaches exists with many Medicare Act programs. Indeed, the disconnect between the FCA and the modern administrative state likely will be acute when FCA claims begin to implicate the new Part D prescription drug benefit.¹⁵⁸

caused the U.S. See *supra* notes 112-15 and accompanying text. In contrast, the Ninth Circuit's ruling permits imposition of damages and penalties without any consideration of the impact such remedy will have on program beneficiaries or otherwise.

156. See, e.g., 42 U.S.C. §§ 1395i-3(g)(3)(C), 1396r(g)(3)(C) (2000).

157. See 42 U.S.C. §§ 1395i-3(h)(2)(C), 1396r(h)(3)(C); COMM'N ON NURSING HOME REGULATION, INST. OF MED., *supra* note 32, at 38-39.

158. The tension between administrative enforcement and the FCA enforcement of regulatory standards will increase as Part D matures. In the past, for instance, prescription drug plans were often the victims of fraud, but now, because of their Part D responsibilities, they are just as likely to be viewed as potential perpetrators. In addition, the volume of Medicare claims made under Part D is likely to increase, resulting in more opportunities for deliberate or inadvertent violation of program requirements. Similarly, the Part D reporting requirements have grown longer and more detailed every year. CMS's *Medicare Part D Reporting Requirements: Contract Year 2008* is thirty-three pages long and CMS has cautioned that "[a]dditional reporting requirements are identified in separate guidance documents throughout the year." CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PART D REPORTING REQUIREMENTS: CONTRACT YEAR 2008, at 3 (Feb. 9, 2007), available at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_NextYear.pdf (last visited Nov. 17, 2007). Moreover, Part D imposes complex accounting requirements, including a requirement that prescription rebates and discounts be allocated by drug and by beneficiary. Further, many Part D performance standards were issued as "sub-regulatory guidance," i.e., without resort to standard Administrative Procedure Act (APA) rulemaking procedures. Even if noncompliance with a regulation adopted through the APA's rulemaking process makes a claim for payment false, it is legitimate to ask whether noncompliance with sub-regulatory guidance also can make a claim false.

Part D also expands the potential for an FCA action by making the Part D prescription plan responsible for the actions of all entities in its network. For example, the plan is responsible for the accuracy of all data it submits to CMS whether it generates the data itself, obtains it from third parties who perform plan administration or other functions or whether such data is submitted directly to CMS by third parties on behalf of the plan. Part D likewise

Administrative authority to enforce Part D's regulatory requirements is shared by CMS and the HHS Office of Inspector General (OIG).¹⁵⁹ The OIG and CMS have independent, but overlapping, authority to impose sanctions for violation of Part D requirements.¹⁶⁰ OIG may impose sanctions in addition to, or instead of, CMS.¹⁶¹

In provisions likely to mirror future FCA claims, Part D provides that sanctions may be imposed when, among other things, a participating prescription drug plan:

- “fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) . . . , and that failure adversely affects (or is substantially likely to adversely affect) the enrollee”;¹⁶²
- imposes premiums on enrollees “in excess of the monthly basic and supplemental beneficiary premiums permitted” by the law and regulations;¹⁶³
- “acts to expel or refuses to reenroll a beneficiary in violation of the [regulations]”;¹⁶⁴ or
- “misrepresents or falsifies information” that it provides to CMS or “[t]o an individual or to any other entity under the Part D drug benefit program.”¹⁶⁵

The potential administrative sanctions for such violations include:

- civil money penalties (CMPs) ranging from \$10,000 to \$100,000,
- suspension of enrollment of Medicare beneficiaries,
- suspension of Medicare payments,
- suspension of marketing activities,

expands the pool of potential relators. Qui tam actions today are commonly brought by ex-employees who, during their employment, had access to the necessary data. Under Part D, however, employees of plan administrators, retailers, manufacturers, and pharmacies all will have access to data necessary to support claims for Part D payment. See generally James G. Sheehan & Jesse A. Goldner, *Beyond the Anti-Kickback Statute: New Entities, New Theories in Healthcare Fraud Prosecutions*, 40 J. HEALTH L. 167 (2007); Nicole Huberfeld, *Pharma on the Hot Seat*, 40 J. HEALTH L. 241 (2007).

159. 42 C.F.R. § 423.756(a)(1)(ii) (2007).

160. *Id.* § 423.756(f)(1-2).

161. *Id.* § 423.756(f)(2).

162. *Id.* § 423.752(a)(1).

163. *Id.* § 423.752(a)(2).

164. 42 C.F.R. § 423.752(a)(3) (2007).

165. *Id.* § 423.752(a)(5).

- refusal to renew big plans' contracts, and
- termination of a plan's contract.¹⁶⁶

Administrative sanctions may be imposed based on harm incurred by a single beneficiary.¹⁶⁷ Some CMPs can be applied to each violation or for each week that the violation continues.¹⁶⁸ In contrast to the FCA, CMS's regulations establish a maximum amount of civil penalties that may be imposed.¹⁶⁹

As is the case with most administrative programs, decisions to impose sanctions are discretionary. To preserve the broadest possible remedial discretion, CMS has expressly refused to specify a formula or define the circumstances when sanctions will, or will not, be imposed.¹⁷⁰ CMS, however, has stated that generally, and solely as a matter of policy, it will limit civil enforcement to "[l]arge, repeat and/or egregious . . . violations" of Part D requirements.¹⁷¹ Further, CMS, in contrast to its enforcement policy with most other Medicare providers, has disavowed the intent to publicly disclose compliance actions directed at Part D plans.¹⁷²

The enforcement policy choices already made by CMS in the Part D program and the range of enforcement options available, like those in the long term care survey and enforcement system, highlight the conflict between administrative oversight and enforcement and judicial enforcement of Part D standards through the FCA. CMS's enforcement policy choices, whether one agrees with them or not, reflect, among other things, that Part D created a massive Medicare benefit de novo and virtually overnight. Further, the policy choices appear to reflect a recognition that, unless a sufficient number of prescription drug plans are induced to participate, the Part D benefit will be unavailable.

Despite Congress' decision to confer on CMS the responsibility, authority, and discretion to make the policy choices necessary to implement the Part D program and to oversee the quality of long term care, CMS's remedial decisions are easily trumped. CMS's decisions can even be trumped by a private individual who, for his or her own personal or pecuniary motives, decides to file an FCA qui tam action.

For example, a deliberate policy choice by CMS to take limited enforcement action, so as not to threaten the fiscal viability of a prescription

166. *Id.* §§ 423.750(a), 423.752(a), 423.758.

167. *Id.* § 423.758(a).

168. *Id.* § 423.758(b).

169. 42 C.F.R. § 423.758(b) (2007).

170. 70 Fed. Reg. 4194, 4366 (Jan. 28, 2005).

171. See CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T. OF HEALTH & HUMAN SERVS., *supra* note 30, at 3.

172. 70 Fed. Reg. at 4367.

drug plan that the agency believes is necessary to supply potentially thousands of beneficiaries, will mean very little and, perhaps, nothing, if a qui tam relator pursues a claim alleging that the same regulatory violations make the thousands of payment claims such plans typically submit false or fraudulent under the FCA. Allowing FCA actions based on regulatory violations, despite comprehensive administrative enforcement programs, essentially eliminates an agency's remedial discretion and replaces Congress's menu of remedies with mandatory damages and penalties.¹⁷³ Furthermore, the cost of defending an FCA action, and the potential magnitude of the treble damages and per claim penalties provided by the Act, often make such cases "bet the company cases" that must, in the exercise of reasonable business judgment, be settled, whether or not the defendant has viable defenses.

The ability of a private individual acting on his or her own initiative to institute a qui tam action when the United States would not file a damages claim, or to prosecute a qui tam when the United States declines to participate, definitely manifests the clash between the modern administrative state and the Civil War era FCA.¹⁷⁴ Indeed, a successful FCA action based on regulatory noncompliance often will result in a court—sometimes at the behest of a private relator—taking away all government payments received by a defendant, "even though the agencies charged with the enforcement of Medicare statutes and regulations would not," or could not, "have done so."¹⁷⁵

D. Lower Courts Have Struggled to Apply the FCA to Contractors Subject to Complex Regulatory, Enforcement, and Remedial Programs

Generally, the threshold question in FCA cases is whether the defendant actually presented a false or fraudulent claim within the meaning of the FCA.¹⁷⁶ The Ninth Circuit's schizophrenia, exemplified when *Hendow* and *Anton* are compared, mirrors a similar split in the decisions of other courts.

173. See, e.g., U.S. *ex rel.* Sweeney v. Manorcare Health Servs. Inc., No. C03-5320RJB, 2005 WL 4030950, at *5-6 (W.D. Wash. March 4, 2005) (allowing "qui tam plaintiffs to supplant the regulatory discretion granted to HHS . . . essentially turn[s] a discretionary denial of payment remedy into a mandatory penalty for failure to meet Medicare requirements"); U.S. *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002) (same).

174. See, e.g., U.S. *ex rel.* Williard v. Humana Health Plan of Texas, Inc., 336 F.3d 375 (5th Cir. 2003).

175. U.S. *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1088 (D. Kan. 2006).

176. See, e.g., *Hendow*, 461 F.3d at 1171-72 (discussing the nature of false or fraudulent claims).

Courts have used various derivatives of an “express false certification” theory to conclude that a contractor’s allegedly false certification of compliance with a federal statute or regulation renders subsequent payment claims false or fraudulent.¹⁷⁷ In recognizing this theory, at least one court has looked to the “causal chain” leading to payment, as opposed to the proximity between the time of the alleged false certification and the claim for payment.¹⁷⁸ Others have stated that the false certification must tie directly to the government’s decision to pay a claim.¹⁷⁹

Holding that only a subset of admittedly false claims should be subject to the FCA, other courts ask the additional question of whether the certification was in fact “material” to the government’s decision to pay the claim.¹⁸⁰ However, even those courts that recognize a materiality requirement disagree as to what standard to apply.¹⁸¹

Some courts have gone further by imposing FCA liability when an express certification is absent, ruling that the mere act of seeking payment *implicitly* certifies that the contractor has performed in conformance with all statutes and regulations.¹⁸² In contrast, other courts have expressed doubt about the validity of the implied false certification theory.¹⁸³ In other cases,

177. See, e.g., U.S. *ex rel.* Quinn v. Omnicare Inc., 382 F.3d 432, 441 (3rd Cir. 2004) (noting that although the Third Circuit had not yet adopted the “certification theory” of FCA liability, other circuits had).

178. See U.S. *ex rel.* Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005).

179. See, e.g., U.S. *ex rel.* Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 605 (7th Cir. 2005) (“False claim allegations must relate to actual money that was or might have been doled out by the government based upon actual and particularly-identified false representations.”); see also *Willard*, 336 F.3d at 382-83; *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999); U.S. *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902-03 (5th Cir. 1997).

180. See, e.g., U.S. *ex rel.* A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 445 (6th Cir. 2005) (comparing the Fourth Circuit’s “natural tendency” test to the Eighth Circuit’s “outcome materiality” test); U.S. *ex rel.* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001) (noting that the “materiality requirement holds that only a subset of admittedly false claims is subject to [FCA] liability”); *Harrison*, 176 F.3d at 788 (recognizing a “materiality” factor in the test for FCA liability).

181. See, e.g., *A+ Homecare, Inc.*, 400 F.3d at 445 (discussing a circuit split between “outcome materiality” and “natural tendency” tests for determining materiality).

182. See, e.g., *Shaw v. AAA Eng’g & Drafting, Inc.*, 213 F.3d 519, 531-32 (10th Cir. 2000) (“Permitting FCA liability based on a false certification of compliance . . . whether the certification is express or implied is consistent with the legislative history of the . . . FCA.”); see also *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 433-34 (1994), *aff’d*, 57 F.3d 1084 (Fed. Cir. 1995) (unpublished table decision).

183. See *Harrison*, 176 F.3d at 787 n.8.

courts have held that no certification of compliance is required to support an FCA action.¹⁸⁴

Judicial discomfort and confusion about applying the FCA to heavily regulated entities are also reflected in other aspects of the implied false certification cases. For example, some courts, although acknowledging the validity of the implied certification theory, have attempted to confine the theory's reach by placing strict limits on its use.¹⁸⁵ Examining these cases suggests that courts may be unwilling to allow an FCA case based on the implied certification theory to proceed unless there is evidence (or an allegation) of pervasive, repeated failures to comply with program requirements, suggesting a deliberate, willful, and even intentional noncompliance.¹⁸⁶

Lower courts' difficulties in applying the FCA to heavily regulated industries is exemplified by a series of Fifth Circuit decisions involving rent subsidies provided by the Department of Housing and Urban Development (HUD).¹⁸⁷ In *Southland I*, the owners of an apartment building certified, in their monthly requests for rent subsidies, that their building was maintained in a decent, safe, and sanitary condition, as HUD regulation and the owners' agreement with the agency both required.¹⁸⁸ Despite the fact that HUD had continued to make rent subsidy payments with full knowledge of the building's defects, the government initiated an FCA suit against the

184. See, e.g., U.S. *ex rel.* Lee v. Smithkline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001) ("Neither false certification nor a showing of government reliance on false certification for payment need be proven" if the complaint alleges services were worthless.).

185. See, e.g., *Mikes*, 274 F.3d at 700 (limiting use of implied false certification theory to cases where the "underlying statute or regulation upon which the plaintiff relies expressly states" that the contractor must comply in order to get paid); U.S. *ex rel.* Phillips v. Permian Residential Care Ctr., 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005) (same); U.S. *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1089 (D. Kan. 2006); U.S. *ex rel.* Cooper v. Gentiva Health Servs., Inc., No. 01-508, 2003 WL 22495607, at *8 (W.D. Pa. Nov. 4, 2003).

186. Compare U.S. *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1169-70 (9th Cir. 2006) (allegations that defendant bragged about violation and actively deceived agency by maintaining two sets of books), with U.S. *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266-67 (9th Cir. 1996) (refusing to allow implied certification case based on routine regulatory violations). See also U.S. *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) (same); U.S. *ex rel.* Sweeney v. Manorcare Health Servs. Inc., No. C03-5320RJB, 2005 WL 4030950, at *5-6 (W.D. Wash. March 4, 2005) (same); cf. United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051 (W.D. Mo. 2001) (alleging extreme understaffing, generalized neglect).

187. See United States v. Southland Mgmt. Corp. (*Southland I*), 288 F.3d 665 (5th Cir. 2002) *rev'd*, United States v. Southland Mgmt. Corp. (*Southland II*), 326 F.3d 669 (5th Cir. 2003) (en banc).

188. See *Southland I*, 288 F.3d at 671.

building's owners after they failed to rectify concerns raised by HUD regarding the building's deteriorating condition.¹⁸⁹

In *Southland I*, a divided Fifth Circuit panel initially held that the FCA provided a viable cause of action.¹⁹⁰ The panel decision held that "when the government conditions payment of a claim upon a claimant's certification of compliance with a statutory or regulatory condition, a claimant submits a false claim *as a matter of law* when he or she falsely certifies compliance with that condition."¹⁹¹ After rehearing en banc, however, a ten-judge majority—that included two judges from the panel who had initially permitted the FCA cause of action—voted, instead, that no FCA cause of action arose because no false claims had been submitted within the meaning of the FCA.¹⁹²

No false claims were submitted, the court reasoned, because the rent subsidy contract itself specified remedies for dealing with noncompliance and provided that, during such time, rent subsidy payments would continue.¹⁹³ Moreover, the court noted that continued payments arguably were necessary to fund the improvements required by HUD.¹⁹⁴

The express and implied false certification theories have been at least equally problematic in cases involving the federal healthcare benefit programs. For example, in *Mikes v. Straus*, a former employee of a physician practice filed suit alleging that her former employer sought and received Medicare reimbursement for tests that were improperly performed, thereby making the test results unreliable and the claims for reimbursement false or fraudulent.¹⁹⁵ Because neither Congress nor the Supreme Court has defined "false or fraudulent," the Second Circuit resorted to *Webster's Dictionary* for guidance in an attempt to understand what exactly Congress sought to prohibit by the FCA¹⁹⁶ and concluded that the statute was aimed at claims that attempted to extract money that the government otherwise

189. *See id.* at 673.

190. *Id.* at 669.

191. *Id.* at 678.

192. *Southland II*, 326 F.3d at 675.

193. *See id.* at 676.

194. *Id.*; *see also* U.S. *ex rel.* Willard v. Humana Health Plan of Tex., Inc., 336 F.3d 375, 382-83 (5th Cir. 2003) (recognizing that the "Government is merely authorized" to impose penalties, "rather than withhold payment for those already enrolled" in the plan); U.S. *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1018-20 (7th Cir. 1999) (government was fully aware of violations but continued payments); U.S. *ex rel.* Cooper v. Gentiva Health Servs., Inc., No. 01-508, 2003 WL 22495607, at *8 (W.D. Pa. Nov. 4, 2003) (compliance with conditions of participation not a precondition to payments).

195. 274 F.3d 687, 693 (2d Cir. 2001).

196. *Id.* at 696.

would not have paid.¹⁹⁷ The *Mikes* court cautioned that the FCA “does not encompass those instances of regulatory noncompliance that are irrelevant to the government’s disbursement decisions.”¹⁹⁸ According to the Second Circuit, “the [FCA] was not designed for use as a blunt instrument to enforce compliance with all . . . regulations—but rather only those regulations that are a precondition to payment.”¹⁹⁹

The Ninth Circuit, in *United States ex rel. Hopper v. Anton*, similarly noted that “[i]t is not the case that any breach of contract, or violation of regulations or law, or receipt of money from the government where one is not entitled to receive the money, automatically gives rise to a claim under the FCA.”²⁰⁰ The *Anton* court held that in order for a regulatory violation to be actionable under the FCA, compliance with the regulation at issue had to be a *sine qua non* of payment, a point given short shrift in *Hendow*.²⁰¹ According to the *Anton* court, the presence of administrative remedies to address regulatory issues, demonstrated that compliance was not a precondition for payment.²⁰²

In *Hendow*, by contrast, the Ninth Circuit paid obeisance to, but ultimately disregarded, the important distinction between those requirements that actually affect the government’s decision to pay and those that do not.²⁰³ According to the court, “if [it] held that conditions of participation were not conditions of payment, there would be no conditions of payment at all—and thus, an educational institution could flout the law at will.”²⁰⁴ Such is clearly not the case. Rather than allowing UOP to “flout the law at will,” the DOE conducted an investigation and exercised its discretion to continue making payments to UOP and treat the school’s alleged violation of the regulations as a regulatory enforcement matter.²⁰⁵ DOE, based on its assessment of the best interests of program beneficiaries and the absence of actual harm to the government, merely took a different path than that provided by the FCA.²⁰⁶ The court, however, never even mentions the

197. *Id.* at 697.

198. *Id.*

199. *Id.* at 699.

200. 91 F.3d 1261, 1265 (9th Cir. 1996).

201. *Id.* at 1267.

202. *Id.*

203. *See* 461 F.3d 1166, 1176 (9th Cir. 2006).

204. *Id.*

205. *Id.*

206. *See generally id.* at 1176-77 (discussing the DOE interest in the institutions’ ongoing conduct).

DOE's actions. In this respect, *Hendow* is at odds with many, and perhaps most courts.²⁰⁷

E. Can the FCA and the Modern Administrative State Be Reconciled?

1. The Questions That Must Be Answered

As reflected in the *Hendow-Anton* split, the inconsistencies in the case law give rise to at least four questions that must be answered to reconcile the FCA with the modern administrative state:

- First, assuming for the sake of argument that a claim for payment can be false or fraudulent based on a regulatory violation, is it in a court's province to determine whether the predicate regulatory violation exists when Congress has committed such decisions to agency discretion?

207. See U.S. *ex rel.* Willard v. Humana Health Plan of Tex., Inc., 336 F.3d 375, 382-83 (5th Cir. 2003) (noting that compliance with regulations is not a condition of payment because, if defendant violated regulations, "the Government is merely authorized to suspend future enrollment, suspend *future* payments, or impose monetary penalties, rather than withhold payment for those already enrolled."); *Anton*, 91 F.3d at 1267 ("[R]egulatory compliance was not a *sine qua non* of receipt of state funding. There are administrative and other remedies for regulatory violations."); U.S. *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1087 (D. Kan. 2006) ("Denial of government payment is not the exclusive remedy . . . in the event of a regulatory violation"; CMS has "discretionary authority whether to impose sanctions in a particular case," therefore payment not conditioned on compliance with regulations); U.S. *ex rel.* Sweeney v. Manorcare Health Servs., Inc., No. C03-5320RJB, 2005 WL 4030950, at *6 (W.D. Wash. Mar. 4, 2005) (availability of regulatory and other remedies other than denial of payment shows that payment not conditioned on regulatory compliance; allowing case to proceed would permit *qui tam* relator to supplant agency discretion); U.S. *ex rel.* Cooper v. Gentiva Health Servs., Inc., No. 01-508, 2003 WL 22495607, at *8-9 (W.D. Pa. Nov. 4, 2003) (Regulations providing for prospective revocation of billing privileges rather than retrospective denial of payment shows payment not conditioned on regulatory compliance); U.S. *ex rel.* Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8, 19 (D.D.C. 2003) (Loss of accreditation triggers inspection, not loss of entitlement to payment showing that accreditation is not a precondition to payment); U.S. *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002) (Variety of sanctions, other than denial of payment and discretion to choose whether to impose any sanction for regulatory violation shows regulatory compliance is not condition of payment; allowing FCA action "where HHS may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment . . . would improperly permit *qui tam* plaintiffs to supplant the regulatory discretion granted to HHS under the Social Security Act."); see, e.g., *United States v. Dan Caputo Co.*, 152 F.3d 1060, 1062 (9th Cir. 1998) (citing U.S. *ex rel.* Windsor v. DynCorp., Inc., 895 F. Supp. 844, 851-52 (E.D. Va. 1995)) (permitting jury in FCA case to decide key issue would circumvent administrative scheme); U.S. *ex rel.* Local Union No. 217 v. G.E. Chen Constr., Inc., 954 F. Supp. 195, 197 (N.D. Cal. 1997) (same); cf. *V.N.A. of Greater Tift County, Inc. v. Heckler*, 711 F.2d 1020, 1027 (11th Cir. 1983) (discussing the administrative procedures yet to be taken in the case).

- Second, because administrative agencies use their own unique and generally informal procedures (or the procedures and protocols mandated by Congress) to determine the existence of regulatory violations, is it appropriate for courts to determine the predicate regulatory violation using the Federal Rules of Civil Procedure and the Federal Rules of Evidence?
- Third, because statutes creating public benefit programs rely on administrative agencies' expertise to select a discretionary response to a regulatory violation and often permit continued payment for services despite alleged or actual violations, is it appropriate for a court to use the FCA to recoup as damages payments that the enforcement agency has not found inappropriate?
- Finally, if it is appropriate for courts to allow FCA actions brought directly by the government in the circumstances described above, is it nonetheless inappropriate to permit such actions to be brought by private relators, who are complete strangers to the discretion that Congress conferred on an administrative agency to weigh the nature of any violation, consider the competing interests, and decide what, if any, enforcement action is appropriate?

2. Easy Answers Are Not Always Accurate Answers: Misplaced Reliance on a 1986 Senate Report

Rather than applying traditional principles of statutory construction and determining the meaning given to "false or fraudulent" by the 1863 Congress that wrote and adopted the terms, most courts that have recognized the false certification theory rest their decisions on a 1986 Senate committee report. These courts say the report evidences that the words "false or fraudulent" should be broadly construed to include claims based on statutory and regulatory violations.²⁰⁸ For example, the Ninth Circuit in *Hendow* explained that "in amending the [FCA] in 1986, Congress emphasized that the scope of false or fraudulent claims should be broadly construed."²⁰⁹

208. See U.S. *ex rel.* *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (citing S. REP. NO. 99-345, at 9 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5274, for the proposition that "a false claim" includes one for goods or services "provided in violation of . . . regulation"); *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir. 2000) (same); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 (4th Cir. 1999) (same).

209. *Hendow*, 461 F.3d at 1170-71. "[E]ach and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false

Courts relying on the 1986 Senate report overlook a critical fact pointed out in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*.²¹⁰ In *Stevens*, the Supreme Court found the same 1986 Senate report to be of *no* value in discerning the meaning of terms that were not added to the FCA in 1986 or otherwise amended by the 1986 Congress.²¹¹

Stevens addressed whether the FCA's use of the word "person" included a state.²¹² Like the terms "false or fraudulent," the term "person" was adopted in the original 1863 Act and remains unamended in the current FCA.²¹³ Ruling that a state was not a person, the Court flatly rejected language in Senate Report 99-345 to the contrary.²¹⁴

The portion of Senate Report 99-345 at issue in *Stevens* purported to describe the law as it existed at the time Congress enacted the 1986 amendments.²¹⁵ However, according to the Court, the passage did nothing more than "set[] forth a Senate Committee's (erroneous) understanding of the meaning of the statutory term enacted some 123 years earlier."²¹⁶ Similarly, that 1986 Senate report's sweeping pronouncements on the meaning of "false or fraudulent"—words that originated in the 1863 Act—should be of little or no value.

IV. CONCLUSION

The Supreme Court has not yet determined how the FCA should be applied in the context of heavily regulated government contractors who are confronted with thousands of pages of statutes and agency regulations, manuals, and other informal guidance. For example, the Court has not determined how falsity should be defined in the regulatory context, nor has it addressed the effect private initiation of FCA actions has on programs whose administration is committed to agency discretion by Congress.²¹⁷

The lack of guidance can be especially problematic for Medicare and Medicaid providers. The statutory and regulatory framework that healthcare providers, such as nursing homes and Part D plans, operate within

statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim." *Id.* (quoting S. REP. NO. 99-345, at 9).

210. 529 U.S. 765 (2000).

211. *Id.* at 783 n.12.

212. *See id.* at 780-81.

213. *See id.* at 783 n.12.

214. *Id.*

215. *Stevens*, 529 U.S. at 783 n.12.

216. *Id.*

217. *See, e.g., U.S. ex rel. Windsor v. DynCorp., Inc.*, 895 F. Supp. 844, 851-52 (E.D. Va. 1995) (finding it impossible to determine whether defendant submitted false claims because to do so would bypass the "carefully crafted administrative scheme" established by Congress).

demonstrates that periodic non-compliance is anticipated and built into the administration of the Medicare and Medicaid programs. To illustrate, at the time the *Hendow* opinion was issued, nursing homes in the nine states comprising the Ninth Circuit averaged nine regulatory deficiencies on their annual surveys.²¹⁸ Yet, these nursing homes rarely are denied Medicare or Medicaid payment for the services provided to beneficiaries of those programs.²¹⁹

Payment for services when a healthcare provider violates one or more of the hundreds of Medicare and Medicaid requirements is rarely refused because, just like imposition of multiple damages and penalties in an FCA action, such action diverts resources from patient services, limits the resources available to improve care, and may well delay or preclude improvement.²²⁰ Such a result is at odds with Congress's purpose in adopting a range of intermediate sanctions. Congress's goal, and the fundamental purpose of the alternative remedies used in the course of administering the Medicare and Medicaid programs, is to create incentives for providers to quickly come back into substantial compliance with program requirements and avoid terminating payment for services and forcing nursing home residents to be transferred to other facilities. Allowing the FCA to be used to redress violations of Medicare and Medicaid participation requirements circumvents congressional policy. As the District Court for the Eastern District of California explained in *United States ex rel. Swan v. Covenant Care, Inc.*:

To allow FCA suits to proceed where government payment of Medicare claims is not conditioned on perfect regulatory compliance—and where HHS may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment—would improperly permit *qui tam* plaintiffs to supplant the regulatory discretion granted to HHS under [federal law], essentially turning a discretionary denial of payment remedy into a mandatory penalty for failure to meet Medicare requirements.²²¹

The number of FCA lawsuits has grown dramatically over the past two decades.²²² The healthcare industry has faced the brunt of this upsurge and

218. This average can be obtained by looking at the data for each of the nine states that comprise the Ninth Circuit available at Ctrs. for Medicare & Medicaid Servs., Nursing Home Compare, www.medicare.gov/NHCompare (last visited Jan 31, 2008).

219. *Cf. Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 22 (2000) (terminations from the Medicare and Medicaid programs are rare.).

220. *Cf. United States v. Southland Mgmt. Corp. (Southland II)*, 326 F.3d 669, 680 (5th Cir. 2003) (en banc) (discussing similar problems with imposing penalties for violations of HUD program).

221. 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002).

222. See Letter from Laurie E. Ekstrand, Dir., Homeland Security & Justice, U.S. Gov't Accountability Office, to Rep. Sensenbrenner, Rep. Cannon, & Sen. Grassley, Subject:

implementation of the Part D prescription drug program is likely to precipitate even more FCA actions directed at healthcare providers.²²³

While the United States government pursues about one-third of those lawsuits, relators prosecute many of the remaining actions alone, motivated in part by the statute's contingent bounty provision and not constrained by concerns about the impact their suits will have on the larger healthcare delivery system.²²⁴ Relators effectively usurp agency authority and discretion and may exalt punishment and pecuniary gain over all other considerations. Moreover, the overwhelming majority of the healthcare qui tam cases that the United States does not prosecute produce no recovery for the United States (or the relator) and a substantial number of those cases are dismissed, but only after burdensome and expensive pre-trial litigation.²²⁵

The fact that FCA enforcement policy is shaped in large part by self-deputized relators who sue on behalf of the government amplifies the need for definitive guidance reconciling the FCA and administrative regulatory and enforcement programs. Such persons wield extraordinary power and make important decisions in qui tam litigation that affect the public interest. Yet, relators have no obligation to serve any interest but their own.

The financial consequences of running afoul of the FCA can be extraordinary. The statute not only provides for treble damages, it also authorizes penalties of up to \$11,000 per claim.²²⁶ Lack of clarity regarding what constitutes a false or fraudulent claim within the meaning of the FCA often places extreme pressure on companies to settle otherwise unmeritorious suits to avoid risking financial ruin caused by an adverse ruling under the FCA. Because so much of healthcare delivered in the United States is paid for by the federal government, this situation is not good for the providers or for the public.

Information on False Claims Act Litigation 25 (Jan. 31, 2006), available at www.gao.gov/new.items/d06320r.pdf (last visited Oct. 31, 2007) (stating that 8,869 new FCA cases were filed between 1987 and 2005).

223. See *id.* (noting that 45.98% of qui tam cases involved alleged healthcare fraud).

224. Cf. *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("*Qui tam* relators are . . . less likely than is the Government to forgo an action arguably based on a mere technical noncompliance with reporting requirements that involved no harm to the public fisc.>").

225. See, e.g., *U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556-61 (8th Cir. 2006), *cert. denied*, 127 S. Ct. 189 (2006); *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1309-12 (11th Cir. 2002).

226. 31 U.S.C. § 3729(a) (2000); 28 C.F.R. § 85.3(9) (2007).