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THE MORAL HAZARD PROBLEM WITH PRIVATIZATION OF PUBLIC ENFORCEMENT: THE CASE OF PHARMACEUTICAL FRAUD

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This Article takes a law and economics approach to exploring some of the costs that arise when governments rely on private enforcement to accomplish the goals of public law. The analysis focuses on qui tam enforcement under the Civil False Claims Act, because a remarkable body of empirical data demonstrates the expansive role private qui tam relators are playing in enforcing Medicare and Medicaid fraud and abuse laws. The Article further focuses on the application of these laws to the pharmaceutical industry. This focus is enlightening because the Government, as well as private enforcers have recently targeted this industry so that emerging legal trends in private enforcement are readily evident. The economic concept of moral hazard—a well-recognized theory that a person takes more risks and exercises less care when insured than she would if uninsured—is applied to reconceptualize the costs and benefits of private enforcement. These costs are most dramatic when, as in the case of pharmaceutical fraud, the government overwhelmingly cedes to private enforcers its responsibility to protect the social good. This phenomenon is called the "privatization" of public enforcement. The analysis demonstrates a fundamental divergence between private and public incentives in False Claims Act prosecutions. The availability of private enforcers creates significant opportunities for public prosecutors to overenforce. Moreover, the reduction in short-term risk causes Government prosecutors to reduce the care that typically controls their exercise of prosecutorial discretion. The explanatory power of the moral hazard analysis is borne out by a review of case law that demonstrates private enforcement patterns that significantly depart from the public goals of federal anti-fraud law. The Article concludes by proposing legislative language that would reform the qui tam statute, and bring public and private enforcement goals into alignment.

INTRODUCTION

Private enforcement of public law is a central feature of the modern regulatory state in areas as wide-ranging as civil rights,

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environmental protection, antitrust, securities law enforcement, and civil prosecution to protect the United States against Medicare and Medicaid fraud. Much has been written about whether and when it is appropriate to authorize private actions to pursue public objectives in these various contexts. Scholarly attention in this area has focused primarily on the misalignment between incentives that drive so-called "private attorneys general" and the public good. Some have highlighted the risks of overenforcement by private attorneys in civil rights cases.[1] Others have raised concerns of prosecutorial error in environmental protection suits.[2] Still others have warned of misdirected resources in antitrust[3] and securities litigation.[4] At the same time, some scholars have argued for judicial control to limit the perverse incentives that drive private enforcers.[5] Others advocate executive branch control to prevent private enforcers from overreaching.[6] Yet, despite the well-deserved, scholarly attention on both sides of this debate, the literature has missed a different and vitally important set of incentive effects: the effects that the availability of private enforcement have on the *Government's* incentives.

This Article fills that gap. Here I demonstrate that the concept of moral hazard—the well-recognized theory that a person takes more risks and exercises less care when insured than she would if uninsured—provides substantial explanatory power to reconceptualize the costs and benefits of private enforcement. The availability of private enforcers creates significant opportunities for public prosecutors to overenforce. Moreover, the reduction in short term risk causes public prosecutors to reduce the care that typically controls their exercise of prosecutorial discretion. Focus-

1. Myriam E. Gilles, *Reinventing Structural Reform Litigation: Deputizing Private Citizens in the Enforcement of Civil Rights*, 100 COLUM. L. REV. 1384, 1452 (2000).

2. *See id.* at 1452; *see also* Barton H. Thompson, Jr., *The Continuing Innovation of Citizen Enforcement*, 2000 U. ILL. L. REV. 185, 204–06 (2000) (claiming evidence of underenforcement by private agencies, where the private enforcers fail to bring suits that would benefit the common good).

3. Joseph F. Brodley, *Antitrust Standing in Private Merger Cases: Reconciling Private Incentives and Public Enforcement Goals*, 94 MICH. L. REV. 1, 2 (1995).

4. Joseph A. Grundfest, *Disimplying Private Rights of Action Under the Federal Securities Laws: The Commission's Authority*, 107 HARV. L. REV. 961, 970 (1994). Grundfest also observed that the converse is true; private plaintiffs may fail to bring cases under the federal securities law that the government would pursue if it had the resources. *Id.* at 970.

5. Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1205 (1982).

6. Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 106 (2005); *see also* Robert F. Blomquist, *Rethinking the Citizen as Prosecutor Model of Environmental Enforcement Under the Clean Water Act: Some Overlooked Problems of Outcome-Independent Values*, 22 GA. L. REV. 337, 338 (1988).

ing on the moral hazard analogy offers a new set of tools with which to approach the current debates about private enforcement of public laws. Furthermore, focusing on the application of these tools to the Civil False Claims Act provides fertile ground to examine the "real life" consequences of moral hazard in private-public prosecution. The Civil False Claims Act (FCA)[7] is the Government's "weapon of choice" for combating fraud.[8] The *qui tam*[9] provision of that statute allows the Government to enlist the *assistance* of private parties in the Government's prosecution of fraud.[10] The statute, for

7. 31 U.S.C. § 3729 (2000). The FCA provides in pertinent part, as follows:

> (a) LIABILITY FOR CERTAIN ACTS.—Any person who—
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) 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;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; . . .
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . .

Id. at § 3729(a)(1)–(3), (7); *see also* Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321 (1996); Civil Monetary Penalties Inflation Adjustment, 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999) (to be codified at 28 C.F.R. pt. 71).

8. Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest?*, 87 GEO. L.J. 499, 502 (1998). *See generally* Dan L. Hargrove, *Soldiers of Qui Tam Fortune: Do Military Soldiers Have Standing to File Qui Tam Actions Under the False Claims Act?*, 34 PUB. CONT. L.J. 45, 47 (2004) (explaining the FCA is the U.S. Government's most potent weapon against contractor fraud).

9. *Qui tam* plaintiffs are called "relators" and may bring a civil action for violation of the FCA and, according to 31 U.S.C. § 3730(b), may recover up to twenty-five percent of the government's total judgment or settlement proceeds awarded in an FCA action pursuant to 31 U.S.C. § 3730. The phrase "qui tam" is a truncation for the Latin phrase given to the private causes of action a plaintiff may bring on behalf of the government. The entire Latin phrase is "qui tam pro domino rege quam se ipso in hac parte sequitur," which means "who as well for the king as for himself sues in this matter." BLACK'S LAW DICTIONARY 1282 (8th ed. 2004).

10. 31 U.S.C. § 3730 defines the *qui tam* action as follows:

> A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

31 U.S.C. § 3730 (b)(1).

sound legal and policy reasons, was drafted to place the Government squarely in control of all FCA prosecutions, including those involving *qui tam* relators. However, the data presented here shows that the Government is losing control of these actions at an alarming rate.

Since 1986, over 4,700 *qui tam* cases have been filed and a total of $15 billion has been collected in settlements and judgments against defendants under the FCA.[11] Total *qui tam* recoveries have soared from a mere $390,000 in the year 1988, to $1.1 billion in 2005.[12] Most notably, the percentage of privately initiated FCA actions reflects that an overwhelming majority of the cases brought under the statute in pursuit of public anti-fraud goals are now being brought by private, not public enforcers. In 1987, over ninety percent of FCA actions were filed by the Government alone, but by 2005, nearly eighty percent of all new FCA actions were filed by private *qui tam* litigants. This dramatic privatization of FCA claims has hindered the orderly development of well-reasoned substantive law and has clearly distorted the market incentives and relationships between industry actors.

Nowhere is this trend more pervasive than in the FCA cases against the pharmaceutical industry. Nearly all of the largest settlements and judgments announced against pharmaceutical defendants during the last three years have involved a *qui tam* relator. In fact, the impact of private litigants' leadership in these cases has been significant, and contrary to the original intent of the Act. Therefore, FCA prosecution of pharmaceutical fraud provides an ideal case to study what occurs when the Government overwhelmingly cedes its responsibility to protect the social good to private enforcers.

In light of the increase in privatization of prosecutions of claims against the Government, this Article examines the fundamental divergence between private and public incentives in FCA prosecutions. Understanding the effects that private enforcement has on Government incentives in the FCA context suggests a new approach to aligning public and private incentives elsewhere. I propose a solution focused on reinvigorating the traditional role that public agencies play in overseeing private attorneys general. Reforming the FCA to solve the moral hazard problem is imperative, and can shed important light on how to conceptualize private enforcement across the entire spectrum of public regulation.

11. JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS H-1 (3d ed. 2006).
12. *See id.*

Part I of the Article compares the statutory role of the *qui tam* relator to empirical evidence of the actual function of private plaintiffs in fraud prosecution. It then presents data describing the enormity of the current trend—away from the oversight and control the statute originally intended the Government to exercise, towards independence on the part of private enforcers—that I call "privatization." In Part II, I use the concept of moral hazard to explain the results of this trend. The Government's abdication of authority under the FCA results in over-prosecution and a harmful reduction in the Government's exercise of caution in the selection and pursuit of these cases. Part III tests the moral hazard explanation by offering several examples of recent, enormously lucrative and highly publicized FCA prosecutions against pharmaceutical defendants. It confirms that the moral hazard explanation is informative in this context. These cases show that privatization is costly. Due to the moral hazard problem that arises from privatization, FCA claims increasingly attract plaintiffs with questionable motives who advance and inadvertently make bad law, which supplants the reasoned regulatory regime that should govern Government contractors' conduct.[13]

The explanatory power of the moral hazard concept is demonstrated by several examples of FCA actions against pharmaceutical companies that have resulted in billions of dollars in settlements and judgments without any clear finding of fault or liability. In Part IV, I propose a revision for the *qui tam* statute, and provide suggested legislative language to accomplish this much needed reform.

I. DISTORTING THE RELATIONSHIP BETWEEN THE GOVERNMENT AND THE *QUI TAM* RELATOR

The plain language of the FCA reveals the originally-intended balance between the Government and private relators' roles in prosecuting fraud under the FCA. Congress intended the

13. For example, in 2004, the largest and most lucrative of all FCA health fraud cases was a *qui tam* filing in which the Government learned the proof was insufficient to criminally convict the defendants only *after* spending hundreds of millions of public dollars to pay *qui tam* relators and litigation costs, only *after* the pharmaceutical firms paid hundreds of millions of dollars in civil and criminal fines, and only *after* individual physician defendants capitulated and pled guilty to criminal charges, leaving the private *qui tam* relator to repeat the same charges anew, against another defendant. *See* Neil Weinberg, *The Dark Side of Whistleblowing*, FORBES, Mar. 2005, at 90.

Government to control FCA litigation by *qui tam* relators.[14] Congress crafted the FCA statute to grant permission to private parties to litigate on behalf of the Government, but the statute requires such parties to be meticulously accountable and subordinate to the Government in such cases. This section reviews the statutory language of the FCA that preserves the Government's authority over FCA prosecutions, and then reviews data that reveals that the Government's statutory authority has been usurped.

Although the FCA was originally enacted in 1863 to encourage private individuals to join in the fight against fraud on the Government during the Civil War, the statute laid virtually dormant until 1986.[15] In that year, Congress amended the FCA's whistleblower or *qui tam* provision to substantially increase the rewards available to private persons who bring actions on behalf of the Government.[16] This amendment brought the partnership between public and private enforcement of the FCA to life.

The originally contemplated structure of the law placed the U.S. Government squarely in control of all anti-fraud litigation. Recent experience, however, indicates that Congress' intent has not been borne out in practice, to the detriment of both the Government and the *qui tam* relator. According to the plain language of the statute, the *qui tam* relator is intended to assist in the prosecution of the action subject to the Government's leadership. The *qui tam* provision creates a private cause of action that allows the relator to engage in litigation both for himself and on behalf of the U.S. Government.[17] The statute requires that actions filed by a *qui tam* relator remain under seal while the Government is allowed a period of time to investigate the claim and decide whether or not to intervene and prosecute the claim directly.[18] After sixty days, the

14. *See, e.g.*, Myriam E. Gilles, *Representational Standing:* U.S. ex rel. Stevens *and the Future of Public Law Litigation*, 89 CAL. L. REV. 315 (2001); *see also* John H. Beisner, Matthew Shors & Jessica Davidson Miller, *Class Action "Cops": Public Servants or Private Entrepreneurs?*, 57 STAN. L. REV. 1441 (2005).

15. *See* False Claims Amendment Act of 1986, Pub. L. No. 99-562, §§ 3–4, 100 Stat. 3153, 3154–58 (1986) (codified as amended at 31 U.S.C. § 3730); James B. Helmer, Jr. & Robert Clark Neff, Jr., *War Stories: A History of the Qui Tam Provisions of the False Claims Act, the 1986 Amendments to the False Claims Act, and Their Application in the* United States ex rel. Gravitt v. General Electric Co. *Litigation*, 18 OHIO N.U. L. REV. 35, 46 (1991); James Roy Moncus III, *The Marriage of the False Claims Act and the Freedom of Information Act: Parasitic Potential or Positive Synergy?*, 55 VAND. L. REV. 1549, 1553–55 (2002).

16. *See* 31 U.S.C. § 3730(d)(1)–(2) (2000) (a *qui tam* plaintiff may receive between 15 and 30 percent of trebled damages proved and of fines between $5,500 and $11,000 per fraudulent claim, plus expenses including attorneys fees); Pamela H. Bucy, *Private Justice and the Constitution*, 69 TENN. L. REV. 939, 943 n.21 (2002).

17. 31 U.S.C. § 3730(a) provides in salient part that any person may bring an action under the False Claims Act on behalf of himself, as well as on behalf of the Government.

18. 31 U.S.C. § 3730(b)(2).

Complaint may be unsealed, and the *qui tam* relator may proceed with prosecuting the claim.[19] If the Government chooses to intervene, the Government takes over the prosecution of the case. If, however, the Government declines to intervene, the Government may actively monitor the case, which includes the right to review all pleadings[20] and to later join the case for "good cause shown."[21] In fact, the statute gives the Government a number of additional options so that it can control a case, even if it decides neither to intervene nor declines to intervene until the case is about to conclude.[22] The Government may request an indefinite number of continuances while it considers and reviews the case at issue.[23] When the Government does intervene, its primacy is unquestionable.[24] The *qui tam* relator must give its full cooperation, or the

19. *Id.*

20. *Id.* § 3730(b)(3).

> If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

31 U.S.C. § 3730(c)(3).

21. *Id.*

22.

> Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—
>
> (A) proceed with the action, in which case the action shall be conducted by the Government; or
>
> (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

Id. § 3730(b)(4)(A)–(B).

23. *Id.* § 3730(b)(3) ("The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2).").

24. "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." *Id.* § 3730(b)(5).

> If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

Government may choose to limit the private party's role in litigation.[25]

Additionally, the Government has several other entitlements throughout the course of litigation. The Government must receive a full disclosure of "substantially all" the *qui tam* relator's material evidence.[26] During the virtually unlimited period of time when it may review the contents of the relator's claims, the private plaintiff must give the Government its full cooperation in the investigation. The Government may cause the *qui tam* relator's claim to be stayed.[27] The Government may preempt the relator's claim by pur-

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Id. § 3730(c)(1).

25.

> Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—
>
> (i) limiting the number of witnesses the person may call;
> (ii) limiting the length of the testimony of such witnesses;
> (iii) limiting the person's cross-examination of witnesses; or
> (iv) otherwise limiting the participation by the person in the litigation.

Id. § 3730(c)(2)(C).

> Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

Id. § 3730(c)(2)(D).

26.

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

Id. § 3730(b)(2).

27.

> Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with

suing the matter through alternative means.[28] The Government may settle the matter over the *qui tam* relator's objection.[29] The Government may also simply dismiss the claim.[30] Ultimately, the Government may even move to reduce the relator's statutory share, or completely cut the relator out of his share of proceeds at the end of a case that the Government and relator have litigated together for years.[31]

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reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

Id. § 3730(c)(4).

28.

Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

Id. § 3730(c)(5).

29.

The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

Id. § 3730(c)(2)(B).

30.

The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

Id. § 3730(c)(2)(A).

31. *See, e.g.*, United States *ex rel.* Merena v. SmithKline Beecham Corp., 114 F. Supp. 2d 352, 371 (E.D. Pa. 2000), *remanded from* 205 F.3d 97 (3d Cir. 2000), *rev'g* 52 F. Supp. 2d 420 (E.D. Pa. 1988) (After working extensively with plaintiff, the Department of Justice tried unsuccessfully, through protracted litigation under the FCA, to limit the relator's share of settlement proceeds negotiated with SmithKline). The fact that the Government can and sometimes does seek to prevent any recovery by the relator raises the possibility of the Government simply riding the coattails of litigation largely prosecuted by the relator, winning in court, and then attempting to bar the relator from enjoying any of the fruits of the litigation. Such a situation would produce a serious disincentive for the Government to participate in, much less lead, a *qui tam* case.

In exchange for the information and assistance the *qui tam* relator provides, the statute gives the plaintiff a right to share in the proceeds from any settlements or judgments paid by the defendant, whether or not the Government intervenes.[32] However, the Government's decision to intervene is a vitally important one to the relator, not only because it determines the percentage share of recovery that a *qui tam* relator may be awarded, but also because the evidence shows that when the Government intervenes and takes over the lead role of prosecuting FCA cases, the chances of success and monetary value of that claim increase substantially.[33]

The relators' share of rewards in FCA cases is greatly enhanced by the Government's presence.[34] Not only are the amounts of relators' recoveries and rewards greater when the Government intervenes, but the chances of winning those rewards are improved greatly by the Government's participation.[35] As of September 30, 2005, the Government had intervened in 940 FCA cases.[36] The Government had declined to intervene in 3,288 cases, and 901 FCA matters were open and under investigation at that time.[37] When the Government intervenes, the disposition of the case is far more likely to end in judgment or settlement, resulting in financial recovery for both the Government and the *qui tam* relator.

Eighty-three percent of the cases in which the Government has intervened have resulted in settlement or judgment, while only six percent of the cases in which the Government has declined to intervene have had the same result. Conversely, the percentage of cases dismissed where the *qui tam* relator proceeds alone—eighty percent—is huge when compared to the mere four percent of cases dismissed when the Government is present.[38] Certainly, the

32. In a successful false claims action, the *qui tam* relator is statutorily entitled to receive between twenty-five and thirty-five percent of the proceeds of any recovery or settlement paid in a case in which the Government does not intervene. *See* 31 U.S.C. § 3730(d)(2). In a case in which the Government does intervene, the relator is entitled to receive between fifteen and twenty-five percent of the recovery of settlement or judgment paid based upon "the extent to which the person substantially contributed to the prosecution of the action." *Id.* § 3730(d)(1).

33. Since 1986, a total of $9.239 billion has been recovered in cases where the Government has intervened, while during the same period, $400 million has been recovered in cases pursued by relators alone. *See* BOESE, *supra* note 11, at H-2.

34. Since 1986, relators' rewards in cases where the Government has intervened have totaled $1.5 billion, while relators have recovered only $99.3 million in cases where the Government did not participate. *Id.*

35. Since 1986, a total of 5,129 FCA cases have been filed. *Id.*

36. *See id.* at H-6.

37. *Id.*

38. *See* ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE § 4.01[3], at 4–53 (Release 19, Law Journal Press 2006).

benefits the relator receives from the Government's intervention are clear.[39]

On the other hand, the Government receives benefits from *qui tam* relators' participation in FCA cases as well. The Government's investigation and prosecution is made more effective by the inside information the *qui tam* relator provides. This information enhances the Government's chances of success and the size of recoveries from defendants.[40] Certainly, the Government is able to pursue a larger number of cases in the presence of *qui tam* relators than it would without such private enforcement assistance.

Although the Government has committed significant resources to FCA enforcement, these resources are stretched. There are a number of state and federal enforcement agencies simultaneously investigating and prosecuting pharmaceutical fraud. In some instances, these agencies are engaged in a coordinated effort, sharing investigatory information, and centrally managing a prosecutorial effort. However, in many instances there is no coordination, and investigations as well as prosecutorial efforts overlap.[41] Despite the number of agencies, and professionals within

39. Alternatively, one might surmise that the *qui tam* relators perform a sorting function for the government, reducing the total universe of potential FCA cases, to the most colorable or valuable claims. That private attorney generals might filter the meritless cases is not supported by the examples of cases dismissed and criminal claims tried after civil settlements have been reached. *See infra* Part III. While the higher quality claims may be the ones that are settling, the cases going to trial are examples of claims that could and perhaps should have been foreclosed even before they were disposed of by expensive litigation. *Id.*

40. *See* Pamela H. Bucy, *Games and Stories: Game Theory and the Civil False Claims Act*, 31 FLA. ST. U. L. REV. 603, 616 (2004).

41. Annually, the Office of Inspector General of the Department of Health and Human Services (OIG) issues a "Work Plan" to announce the areas of its investigative focus. For example, the Work plan for the fiscal year 2003 indicated that the OIG would be focusing on illegal marketing and distribution of prescription drugs and other fraudulent schemes as an area of its investigative focus. Office of Inspector Gen., U.S. Dep't of Health & Human SERVS., WORKPLAN FISCAL YEAR 2003 (2003), *available at* http://oig.hhs.gov/reading/workplan/2003/Work%20Plan%202003.pdf. Both the Civil and Criminal Divisions of the Department of Justice participate in the evaluation and investigation of *qui tam* actions filed under the False Claims Act. Each United States Attorney's Office also has a health care fraud coordinator and prosecutes local cases. Several programs to coordinate these efforts operate under the auspices of the DOJ. For example, under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 § 201, 110 Stat. 1936, 1992–96 (codified at 42 U.S.C. §§ 1320a-7c) (HIPAA), the National Health Care Fraud and Abuse Control Program is run by the Attorney General, and the Secretary of the Department of Health and Human Services (DHHS). Similarly, the National Health Care Fraud Task Force, chaired by the Deputy Attorney General, coordinates prosecutions run by the DOJ, DHHS/OIG, The Centers for Medicare and Medicaid Services (CMS), and state and local prosecutors. The Department of Health and Human Services Office of Inspector General conducts fraud audits and investigations and then refers cases to the Department of Justice for administrative, civil, and criminal prosecution. In addition to the Department of Justice, several other investigatory and prosecutorial federal departments, including the Defense Criminal

those agencies addressing the health care fraud problem, the Government continues to be shorthanded in its effort to find and prosecute pharmaceutical and other health care fraud. When large corporations engage in fraud, it is often only revealed in ways that are difficult to uncover and complex to unravel.[42] For these reasons, the *qui tam* relator is often essential to uncovering and understanding the fraudulent schemes, and is essential to the prosecutorial effort.

When the Government and *qui tam* relators work together, both benefit. However, Congress sought to balance the Government's primacy under the statute by including protections for relators within the terms of the FCA. The statute creates a cause of action for a plaintiff who suffers retaliation from his or her employer, and provides for the recovery of damages plus twice the amount of back pay, compensatory and special damages, and attorneys' fees.[43] The 1986 Amendments to the FCA provided powerful protection for the *qui tam* relator, whenever she has a good-faith reasonable belief when reporting that his employer has defrauded the Government.[44] The statute also contains protections against abuses by relators such as the original source jurisdictional bar.[45]

Reviewing the FCA's procedural and substantive terms, it is clear that Congress lodged leadership on anti-fraud claims with the Government, notwithstanding the symbiotic relationship between the Government and the *qui tam* relator.

Recent cases indicate a departure from the balanced system the FCA was intended to implement. Prior to 1986, an average of six claims per year[46] were filed under the old statute.[47] There have been 4,704 *qui tam* cases filed since that year.[48] *Qui tam* recoveries

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Investigative Service, the Federal Bureau of Investigation, the Postal Inspection Service, and the Drug Enforcement Agency, are involved in prosecutorial activities ranging from record reviews to criminal indictments involving pharmaceutical fraud. *See* Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL'Y 55, 59–60 (2004).

42. *See* Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV. 1, 3–5 (2002).

43. 31 U.S.C. § 3730(h).

44. *Id.*

45. *Id.* § 3730(d)(1) (providing that if the false claims suit brought by the *qui tam* relator is based on allegations that have already been publicly disclosed, however, the *qui tam* relator is the "original source" of that publicly disclosed information, and the relator is barred from recovery). *See also* United States *ex rel.* Merena v. SmithKline Beecham Corp., 205 F.3d 97, 106 (3d Cir. 2000) (finding a *qui tam* relator may not receive proceeds from a settlement claim publicly disclosed, for which the relator was not the original source).

46. *See* Bucy *supra* note 42, at 156.

47. During the 1986 revision of the False Claims Act, the statute was regarded as underutilized, and therefore, the Legislature's objective was to increase the number of cases being filed. *See* S. REP. No. 99-345, at 1–2 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5266–67.

48. *See* BOESE, *supra* note 11, at H-1.

have increased by over one hundred thirty percent during the past ten year period, providing a significant incentive to motivate private parties to prosecute fraud against the Government.[49] The data also make it easy to see why relators are eager for Government intervention. The Government's participation markedly increases the absolute dollar amount of recoveries available to *qui tam* plaintiffs.[50] Recent reports of several high profile FCA cases, each of which cost taxpayers hundreds of millions of dollars to prosecute but which ultimately had questionable basis in fact,[51] belie the seductive influence of the large financial incentives imbedded in the FCA statutory structure. Often, the DOJ announces settlements from health care providers that pay *qui tam* awards to individual plaintiffs in excess of $15 million.[52] Awards to plaintiffs of between $1 million and $10 million are announced regularly.[53] Over the eighteen years since Congress amended the FCA statute, relators have collected the majority of their earnings under the statute within the last five years. Since 1986, private False Claims Act plaintiffs have been awarded $1.42 billion in total judgments and seventy percent of that total—$995.0 million—has been paid out to relators since the year 2000.[54] The data below in Table 1 illustrates significant

49. *See infra* Table 1.

50. *See* MICHAEL G. SCHEININGER & GREGORY T. JAEGER, ABA CTR. FOR CONTINUING LEGAL EDUC. NAT'L INST. NOV. 19–20, 1998, THE PRE-INTERVENTION PRESENTATION TO THE GOVERNMENT: AN IMPORTANT STEP IN SUCCESSFUL QUI TAM DEFENSE M-2 (1998).

51. *See* Weinberg, *supra* note 13, at 90.

52. *See* FABRIKANT ET AL., *supra* note 38, § 4.01[3][f]; *see also* John F. Murphy, What Are the Rewards, Examples of Recoveries by Whistleblowers, http://www.whistleblowerlawyer.com/reward.htm (last visited Nov. 30, 2006) (on file with the University of Michigan Journal of Law Reform) (indicating a recovery for $22.5 million to the relator in a case against United Technologies, Inc. which involved a helicopter contract and $18.45 million paid to the relator who filed against Lucas Industries, Inc. to allege falsification of gear box records on Navy fighter jets and Army rocket launchers).

53. FABRIKANT ET AL., *supra* note 38, § 4.01[3][f]. When Congress amended the False Claims Act in 1986 to treble the damages available to *qui tam* relators, Congress clearly intended to provide a strong financial incentive for private parties to report and prosecute fraud. S. REP. NO. 99-345, at 10–12 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5275–77. In fact, the size of *qui tam* relator recoveries in health care fraud cases alone has been increasing substantially since 1986. These rewards, paid to individuals as well as to corporate *qui tam* relators, in recent years, have often exceeded $20 million. LAURIE E. EKSTRAND, U.S. GOV'T ACCOUNTABILITY OFFICE, INFORMATION ON FALSE CLAIMS ACT LITIGATION: BRIEFING FOR CONGRESSIONAL REQUESTORS DEC. 15, 2005 1–2 (Jan. 31, 2006), *available at* http://www.gao.gov/new.items/d06320r.pdf. In 1998, two *qui tam* relators earned $52 million for their role in prosecuting SmithKline Beecham Corporation in an FCA action alleging fraud and improper billing practices by SmithKline. United States *ex rel.* Merena v. SmithKline Beecham Corp., 52 F. Supp. 2d 420 (E.D. Pa. 1998). *But see* United States *ex rel.* Merena v. SmithKline Beecham Corp., 114 F. Supp. 2d 352 (E.D. Pa. 2000) (revising relators' awards based on original source and "first to file" jurisdictional bars).

54. *Id.*

trends in *qui tam* litigation over the past seven years. Table 1 below shows that the Government has proportionately increased its returns on funds expended for enforcement. This suggests the Government is getting more than it is spending on anti-fraud prosecution under the FCA. This is an advantageous outcome for the Government.

TABLE 1[55]
QUANTIFYING THE RECENT ROLE OF THE *Qui Tam* RELATOR
(1998–PRESENT)

	1998	1999	2000	2001	2002	2003[56]	2004	2005	Increase[57]
Total Recovered Amount	613.6	713.4	1,572.37	1,795.3	1,210.2	2,219.2	681.2	1,418.5	131%
Recovery Amount Returned to Government for Future Prosecution	119.6	137.5	158.2	181.9	209.0	240.6	240.6	240.6	50.3%
Number of New FCA Matters	589	623	463	398	383	427	528	494	(16.1%)
Number of New *Qui Tam*	470	482	367	310	320	334	415	394	(16.2%)
Percent *Qui Tam*	79.8	77.4	79.3	77.9	83.6	78.2	78.6	79.8	—
Number of New Health Cases	323	340	260	215	212	243	304	306	(17.0)%
Percent *Qui Tam*	88.9	91.4	85.8	83.7	92.9	89.3	90.8	88.2	—
Number of New Defense Case	107	143	87	85	88	89	115	110	2.8%
Percent *Qui Tam*	72.9	76.9	88.5	87.1	81.8	87.6	86.1%	88.2%	—

The data in Table 1 tells at least two important stories. First, it illustrates the profitable enterprise that FCA litigation is for both private *qui tam* relators and for the Government. Second, these statistics illustrate the sizeable share of FCA prosecutions led by

55. *See* Fried, Frank, Harris, Shriver & Jacobson LLP, *Qui Tam* FCA Statistics, Sept. 30, 2003, http://www.ffhsj.com/quitam/fcastats.htm (last visited Nov. 30, 2006) (on file with the University of Michigan Journal of Law Reform).

56. Data from 2004 and 2005 present some notable aberrations. In 2004, although a total of 528 new matters were filed, and nearly eighty percent of those were *qui tam* actions, total fraud recoveries declined to $681.2 million. This represents a 69.3% drop in recoveries, despite a twenty-one percent increase in the number of *qui tam* actions filed over the previous year. In 2005, however, overall recoveries rose again to $1.4 billion. There was a 16.1% increase in the number of new matters filed overall. While we cannot tell from this data what might account for the decline in 2004 recoveries, two observations are relevant. First, the 2005 data suggests the upward trend in privatization has resumed. Second, the privatization trend is most pronounced in health care cases where nearly ninety percent of FCA litigation is initiated by a *qui tam* plaintiff. *See* BOESE, *supra* note 11, at H-2.

57. Aside from the aberration in 2004, on average, FCA recoveries have increased 119.24% each year during the period from 1998 to 2005. *See id.*

private plaintiffs in every major category of fraud cases prosecuted under the statute.

Table 1 also shows that in FCA prosecutions generally, the annual share of FCA matters filed by *qui tam* plaintiffs has remained relatively constant over the period from 1998 to 2005. The data further confirm that the Government is not merely recovering misspent funds lost to fraud, but actually making a profit on its anti-fraud enforcement activities. During this time, the Government certified an increasing amount of recovered settlements, judgments, and fines to return to its coffers for future enforcement. However, the increase in the amounts recovered during this time grew faster than enforcement expenditures.[58]

The most striking information conveyed by this data, however, is the extent to which private *qui tam* enforcement has become the leading method of prosecuting fraud under the FCA.[59] However, even Table 1 does not tell the whole story. Looking only at recent history, it appears from Table 1 that the level of *qui tam* activity under the statute has remained relatively stable.

Table 2 summarizes the substantial growth in private prosecutions under the FCA since the statute's last amendment in 1986 and demonstrates the tremendous impact private parties have had on FCA enforcement.

58. *See* JACK A. MEYER, FIGHTING MEDICARE FRAUD: MORE BANG FOR THE FEDERAL BUCK: PREPARED FOR TAXPAYERS AGAINST FRAUD EDUCATION FUND (May 21, 2004) (on file with the University of Michigan Journal of Law Reform) [hereinafter MEYER REPORT], *available at* http://www.taf.org/meyerreport.htm; *see also* Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims*, 76 IND. L.J. 525, 582–83 (2001) (discussing the impact of the Government's share of enforcement proceeds exercised by independent prosecutorial discretion).

59. In 1999, 481 new FCA claims were filed. The next year that number dropped precipitously to only 366 cases. In 2001, 300 cases were filed under the FCA; 320 were filed in 2002; and 326 were filed in 2003. This means there has been an 8.6% increase in the number of cases filed over the past three years. This is despite a 42.6% increase in the total spending outlays for Federal Civil False Claims Act enforcement in the health care fraud area alone. *See* CIVIL DIV., U.S. DEP'T OF JUSTICE, FRAUD STATISTICS—OVERVIEW (Oct. 1, 1986–Sept. 30, 2005) (on file with the University of Michigan Journal of Law Reform), *available at* http://www.ffhsj.com/quitam/pdf/stats_overview.pdf (noting the total federal costs of health care fraud enforcement); *see also* Whistleblowersonline.com, Qui Tam False Claims Act-Statistics, http://www.whistleblowersonline.com/demographics.htm (last visited Nov. 30, 2006) (on file with the University of Michigan Journal of Law Reform) (noting the total number of *qui tam* cases filed).

TABLE 2
QUANTIFYING THE HISTORICAL ROLE OF THE *QUI TAM* RELATOR (1987–PRESENT)

	1987	2005	Increase
Number of New FCA Matters	393	494	25.7%
Percent *Qui Tam*	8.1%	79.7%	—
Number of New Health Care	18	306	1600%
Percent *Qui Tam*	22.2%	88.2%	—
Number of New Defense	263	110	(58.2%)
Percent *Qui Tam*	6.8%	88.1%	—

Table 2 provides concrete evidence of the privatization of False Claims Act prosecution. Taken together, the data in Tables 1 and 2 show: an increase in the absolute number of new FCA claims filed over the past ten years; a dramatic increase in the percentage share of those claims being brought by private plaintiffs; and an astounding increase in the number of those FCA cases that are brought against defendants in the health care sector. From 1987 to 2005, the percentage of new FCA claims filed by private *qui tam* parties increased nearly ten-fold from 8% in 1987 to 79.7% in 2005. The upsurge in the number of health care fraud cases is overwhelmingly driven by private enforcement. In 1987, eighteen new cases were filed by the Department of Health and Human Services and four of those, or 22%, were filed by *qui tam* parties. By contrast, in 2005, 306 new health care fraud matters were filed and 270 of those, or 88%, were filed by private litigants.

The empirical fact is that the vast majority of anti-fraud enforcement is conducted by private, rather than Government, enforcers. While the balance of power appears to have shifted away from the Government and towards private enforcement, in order to determine whether this data represents a true departure from the original design of the statute the salient question is whether these *qui tam*-directed cases are different in any meaningful way from cases the Government controls. The trend is a significant one only if the Government's declining role and the increased presence of private enforcement results in some substantive departure from the statute's intent. The important question is whether privatization changes either the Government's procedural decisions or the substantive law decided in FCA cases. The next section introduces the moral hazard theory to explain the ways in which privatization has a profound impact on the Government's enforcement decisions.

II. THE MORAL HAZARD PROBLEM OF THE *QUI TAM* RELATOR

Without question, the *qui tam* statute provides a key dimension to the anti-fraud effort. The law grants relators a lucrative share in settlement and judgment proceeds as an incentive to encourage private attorneys general to undertake the discovery of fraud. The private enforcers can minimize the costs of proving fraud by providing valuable "inside information."[60] On the other hand, there are also costs associated with the *relator's* participation. Privatization means the *qui tam* relator is not being effectively subordinated to the Government's direction or supervision. This has impact on the quality of cases pursued, the number of cases pursued, and the strength of legal theories advanced when cases are pursued. Due to the sizable potential of financial gain, some *qui tam* relators will pursue cases with poor factual support or pursue flimsy legal theories that establish bad precedent and waste public resources. In contrast to the Government, the *qui tam* relator does not have the ethical obligation to protect the interests of the public at large. Moreover, the private relator has neither an ethical nor financial interest compelling it to consider the impact of frivolously imposing defense costs on target companies. The Government, on the other hand, is expected to exercise prosecutorial discretion that takes into account what social goods might be sacrificed by initiating a lawsuit. However, when relators initiate FCA claims, the Government's initial prosecutorial choice—whether or not to sue—has been usurped by a private party. Where a relator has initiated the FCA claim, the investment choices the Government now faces are very different.

Compare the Government's investment choices with and without relators when deciding whether to initiate an FCA suit: When the Government initiates an FCA claim independently, it does not know in advance what the outcome of that lawsuit will be. Because its enforcement budget is limited, the Government chooses which cases are meritorious and most likely to lead to a return on its investment of scarce public resources. A key part of the Government's calculus includes its obligation to choose litigation opportunities and strategies that will further legislatively-established objectives for the public good. With these goals in mind, the Government will effectively triage the cases it pursues based on the size of the case, the seriousness of the fraud alleged,

60. Pamela Bucy, *Information as a Commodity in the Regulatory World*, 39 HOUS. L. REV. 905, 908 (2002).

the potential proceeds that may come from the case, the time it will take to litigate the case, the quality of information available about the case, and several other considerations.[61] If the costs of pursuing any particular case outweigh the potential benefits, the Government will decline to pursue that case and Government resources will be available for use in other cases.

The Government's calculus changes in the presence of a *qui tam* relator. When the Government decides whether to intervene in a case brought by a *qui tam* relator, the Government spends virtually no public resources to initiate a *relator*–directed lawsuit. Moreover, the Government incurs only minimal monitoring costs to sit back and allow the private party to file an FCA case and to pay the up front litigation costs for pursuing that claim. The potential return on this small investment ranges from zero to seventy percent of trebled damages. Therefore, the incentive for the Government to allow these cases to go forward is very high. It is of no moment that the *relator*-directed cases may be ones which the Government would not bring directly given its limited resources. Moreover, whereas the Government gets the benefit of employing its resources elsewhere if it declines to pursue a case directly, the Government frees negligible resources by opposing the progress of a *qui tam* initiated case. In fact, at first blush, the most expensive alternative available to the Government is to prematurely intervene in a case that will then become the Government's responsibility to prosecute. The structural incentives for the Government all point in one direction: stand back and allow *qui-tam* suits to go forward. This problematic incentive structure is explained by the concept of moral hazard.

A. Applying the Theory of Moral Hazard to Private Qui Tam *Enforcement*

Moral hazard, simply defined, is opportunistic behavior on the part of an insured party. The term moral hazard describes a problem that increases the size of losses an insured suffers when the insured party exchanges its cost-minimizing behavior, for cost-generating conduct, based on the presence of an insurance contract.[62] Moral hazard results when an insured party is less averse to risk due to the knowledge that any losses from risky behavior will

61. Ben Depoorter & Jef De Mot, *2006 Whistle Blowing: An Economic Analysis of the False Claims Act*, 14 SUP. CT. ECON. REV. 135, 148–51 (Francesco Parisi et al. eds., 2006).

62. *See* ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 50 (3d ed. 2000).

be borne by the insurer.[63] As a result of the decrease in risk-averse behavior, moral hazard increases costs.[64]

A well-known example of moral hazard involves insured medical patients' overconsumption of health care services: An insured patient may visit the doctor more often than an uninsured one, simply because the immediate personal cost to do so is less to the insured than to the uninsured patient who must pay "out of pocket" for each visit. The end result, however, is that the patient's changed behavior is based on the presence of insurance that was intended to reduce overall costs, but which ironically will increase the medical costs borne, not only by the insured patient, but by all participants in the health care system. Insurance makes the patient more prone to act as a hypochondriac, visiting the doctor more often than he would absent insurance, and thus increasing utilization and overall costs to care for that patient. The example of an insured patient describes how moral hazard results in overconsumption of resources.

Another paradigmatic moral hazard problem involves insured property owners who exercise suboptimal care over their property. When a car owner is insured against losses due to theft, she may not bother to lock her car doors, purchase an alarm, or choose well-lit locations when parking in a high crime area. The same car owner, if uninsured, will exercise more care to prevent automobile theft, in order to avoid the personal cost of replacing her car if it is damaged or stolen.[65] In this case, the car owner's expectation that insurance coverage will pay for any losses due to theft decreases the care the insured automobile owner takes to prevent costly crimes, even though the insurance contract was intended to reduce costs. The example of the careless automobile owner provides an illustration of how moral hazard causes a suboptimal exercise of caution.[66] The thesis of this section of the Article is that moral hazard can also describe the ways in which the Government changes

63. Rickerford v. Westchester Fire Ins. Co., 186 So. 109 (La. Ct. App. 1939), *reinstated on reh'g by*, 187 So. 676 (La. Ct. App. 1939); *see* LEE R. RUSS & THOMAS F. SEGALLA, COUCH ON INSURANCE § 81:98 (3d ed. 2005) ("The term 'moral hazard' means a *substantial* hazard, one that would influence the conduct of a reasonable person, as distinguished from a mere psychological or ethical risk. . . . [S]uch as to sustain a holding that the insured would suffer *less* by a destruction of the property than would ordinarily be the case in the absence of its breach." (emphasis added)).

64. *See* COOTER & ULEN, *supra* note 62, at 50 ("Moral hazard arises when the behavior of the insuree [sic] changes after the purchase of insurance so that the probability of loss or the size of the loss increases.").

65. *See* SHERMAN FOLLAND, ALLEN GOODMAN & MIRON STANOM, THE ECONOMICS OF HEALTH AND HEALTH CARE 153 n.3 (4th ed. 2004).

66. *Id.*

its behavior when private enforcers—specifically, *qui tam* relators—are present. The moral hazard impact of private enforcers causes both the overconsumption of enforcement resources, and a suboptimal exercise of prosecutorial discretion or care on the part of the Government.[67] Here is how the analogy works:

When a *qui tam* relator prosecutes the Government's false claims case, the Government acts as an insured party. The presence of the private plaintiff in *relator*-directed FCA cases insures the Government from the costs associated with initiating litigation, pursuing discovery, generating and responding to pre-trial motions, and directly bearing the risk of failure if the claim proves frivolous or specious. Instead of incurring these costs, the Government may rely upon the relator, who is motivated to search out and investigate potentially lucrative allegations of fraud by the generous rewards available under the FCA,[68] to absorb these costs by prosecuting on the Government's behalf. In a real sense then, the Government spreads its prosecutorial risk to private *qui tam* plaintiffs. However, to the extent that the private plaintiff does not discriminate between worthy and frivolous claims the way the Government would, for reasons discussed below, moral hazard will increase the number and decrease the quality of anti-fraud cases prosecuted.

Moral hazard causes the Government to make different prosecutorial decisions because of the presence of the *qui tam* relator, than it would otherwise make in the absence of the insurance provided by the private plaintiff. Because of the presence of *qui tam* relators, the Government prosecutes or allows the relator to prosecute excessive numbers of FCA cases that the Government alone would not bring. When forced to allocate scarce enforcement resources, the Government will carefully choose the strongest cases to pursue; these are cases with credible witnesses, firm evidence, and colorable theories of recovery. However, because the Government's investment in spurious *qui tam* suits is minimal,[69] and the potential payoff is sizeable,[70] the Government will behave opportunistically

67. *See* Tom Baker, *On the Genealogy of Moral Hazard*, 75 TEX. L. REV. 237, 274 (1996) (providing an excellent discussion of several additional "multiple" problems of moral hazard).

68. *See* 31 U.S.C. § 3729(a) (2000). A *qui tam* plaintiff may receive between fifteen and thirty percent of trebled damages proved and of fines between $5,500 and $11,000 per fraudulent claim, plus expenses including attorneys fees.

69. The Government does bear some minimal monitoring costs. Some argument can also be made that the more the Government entertains frivolous suits, the more it signals a willingness to participate in specious litigation, thus inviting an increase in the number of cases that it has to monitor but would not pursue.

70. The Government may intervene the more likely settlement appears.

and allow the relator to prosecute excessive numbers of FCA cases, regardless of their merit.

Moreover, the Government, as a result of moral hazard, exercises suboptimal caution in selecting legal theories, which arguments to make, and which strategies to employ. There is no immediate payoff for monitoring the quality of *qui tam* cases that proceed independently. The Government imagines it has nothing to loose even if these cases fail because all immediate costs of failed cases under the FCA are borne by the private plaintiff. Thus, in the face of weak monitoring incentives, the Government will allow cases based on weak facts or even unfounded or experimental theories of recovery to proceed. Nothing is immediately lost to the Government for this carelessness.[71] Most cases settle before the weakness of the relator's theory can be tested, or cases are dismissed with minimal monitoring costs imposed on the Government. The cases that are tried may not be tried in time to establish the strength of allegations beneath the FCA claim. Often they are novel and no precedent serves to guide the Government's discretion. In either event, the Government may rely on the *qui tam* relator to incur the vast majority of litigation costs for frivolous as well as worthy claims and so the Government makes little attempt to distinguish the two.

Once a *qui tam* plaintiff files an action under the FCA, the Government is protected against two eventualities. First, it is protected against the cost that the charged fraud will go undetected. Second, the Government is protected against the costs of prosecuting the alleged fraud even if the allegations are frivolous. The Government then has assurance that whether it intervenes or not, the relator's self-interest will cause the case to be prosecuted, at minimum, with the zeal that is warranted by the relator's expectation of earning a thirty percent share of the proceeds from the case. This, it turns out, is enough zeal to allow the Government to rely perhaps too easily on the relator's decisions and prosecutorial strategies. Instead of investing the resources to come up with its own theories, or, at least to test those proposed by the relator, the Government can pursue multiple untested cases with minimal effort. The Government is not required to test the credibility of the witnesses (including the relator) when it declines to intervene. Absent intervention, the Government may not confirm the soundness of documentary evidence or the support for allegations. This

71. Arguably, the Government's calculus is incomplete because it does not take into account the social costs of allowing to proceed litigation that is likely to be unproductive.

suboptimal exercise of care allows the Government to take on (or allow) prosecution of cases that well may be weakly supported, poorly reasoned and therefore of limited value as either a legal precedent or as a signal to future actors who wish to avoid engaging in fraudulent conduct. When such cases proceed, the public good is not served. In this way the moral hazard incentives have the same impact here as in any other case of an insured party. Moral hazard results in the Government relying on its insurance, in the form of a *qui tam* relator, to allow it to exercise too little care while taking on too many cases.

Before going further, a note about one simplifying assumption is in order. Here, the moral hazard model presents only two possible choices for the Government. Either the Government can prosecute an FCA case on its own, or it can risk the moral hazard of allowing a *qui tam* plaintiff to prosecute independently on its behalf. In fact, many more choices exist for the Government between these two extremes. Just as an insured may reduce the impact of moral hazard by choosing to incrementally increase the level of care exercised,[72] the Government could choose to monitor more closely, intervene earlier, or even to conduct a comprehensive evaluation of each case and dismiss the frivolous ones at the earliest possible opportunity. However, the model here offers only a binary choice for two reasons. First, this simplification more closely reflects the statutory reality. Under the FCA, there is little reason for the Government to choose any of the moral hazard mitigating behavior listed above. Secondly, the binary simplification appears to more closely reflect the empirical reality. Recall the startling trend toward privatization and the increased numbers of privately filed FCA suits. The sheer volume of these cases suggests the Government is choosing between two extremes.

Having laid out the basic structure of the moral hazard analogy, the theory offers some useful principles about how to address the problems caused by moral hazard. Economists describe moral hazard as the "rational response to economic incentives brought about by the elasticity of demand to the price of care."[73] Assume FCA cases represent investment opportunities for the Government.[74]

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72. For example, in the face of a $1000 deductible, the insured automobile owner will exercise more care and mitigate the effects of moral hazard more effectively than the owner might in the face of a $200 deductible. The owner need not be relieved of one hundred percent of the costs to be subject to moral hazard.

73. *See* FOLLAND, GOODMAN & STANOM, *supra* note 65, at 153.

74. This analogy makes sense because the Government does not begin a lawsuit knowing what its return will be. Like an investor, the Government chooses to expend funds on a somewhat uncertain enterprise.

When the Government determines how many cases it will prosecute, it is making an investment decision about unknown future events. Thus, the Government's demand for FCA cases is a function of the price (or the litigation costs) associated with each prosecutorial decision, and the expected benefits the Government will receive from the case. As the cost of prosecuting a given case increases, the Government's demand for that case will generally decrease. This describes a normal, downward-sloping demand curve for cases. However, for some FCA cases, where the expected benefit is greater, the Government's demand curve is steeper. Some cases will be so potentially lucrative or otherwise attractive to the Government that the Government will prosecute (or invest in) those cases at all costs. For example, the Government may focus attention on prosecuting a particularly egregious fraudulent scheme that has impact on a vulnerable group.[75] Call these the "high stakes cases." In these instances, the Government's demand for such cases is inelastic and the danger of moral hazard is minimal. In all other cases—say the "regular cases"—the Government's demand for FCA cases is more elastic and the danger of moral hazard is present.

The solution economists propose to mitigate the danger of moral hazard is to insure only those goods for which the insured's demand is inelastic. In the FCA context, applying this solution would require the Government to declare that its interest in certain FCA cases is inelastic, before the Government may rely wholly on the *qui tam* relator to prosecute the case. If the law required the Government to first establish its own assessment and basis for prosecuting each case before allowing *qui tam* relators to control its litigation, then the risks and resulting costs of moral hazard might be controlled.

B. Understanding the Costs of Moral Hazard

Moral hazard costs include the loss associated with imprudently wasting scarce Government enforcement resources, the risk of compromising socially important goals, the imposition of unnecessary litigation costs on parties to excessive litigation, the risk of establishing unclear or affirmatively bad legal precedent, and the risk of sending mixed deterrence signals to other providers and

75. *See, e.g.*, United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149 (W.D. Mo. 2000).

manufacturers who may be targeted as FCA defendants in the future. To understand how excessive costs are generated by moral hazard, consider Kenneth Arrow's observation that moral hazard occurs when an insured party who benefits from insurance has control over the events that give rise to insured losses.[76]

Again, the analogous party to an insured in the FCA context is the Government. The events that give rise to losses are the statutory precautions that the Government could, but fails to, exercise under the current law. The FCA currently permits the Government to choose not to monitor closely or select carefully where frivolous lawsuits are concerned. This is the same as the property owner who retains control but does not exercise care with his property, failing to take steps to prevent fires (install smoke detectors) or theft (park where well lit). The *laissez faire* choices of both the Government and the insured property owner give rise to preventable losses due to fire, theft and frivolous FCA claims, respectively. The more insurance protection is available, the greater the insured's reliance on coverage will be. Sherry Glied describes this phenomenon as "dynamic moral hazard" because as insurance increases, the insured party engages in increasingly more costly behavior, on the assumption that insurance will pay for the increased costs.[77] We have seen that as FCA prosecution becomes increasingly privatized, the Government appears to permit more and more costly claims to proceed.[78]

A final method for understanding the costs imposed by moral hazard in FCA litigation is to compare the distinctive cost curves faced by the Government and *qui tam* relators.[79] When the Government sues a defendant pharmaceutical company under the FCA, whether directly, or by a *qui tam* plaintiff, the Government stands to benefit from the prosecution. The Government expects certain public policy benefits such as curbing illegal conduct, deterring future wrong-doing, and recovering misspent public dollars. Indeed, health care-related civil fraud recoveries in 2005

76. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 942, 961 (1963), *reprinted in* 26 J. HEALTH POL. POL'Y & L. 851, 871 (2001).

77. *See* Sherry A. Glied, *Health Insurance and Market Failure Since Arrow*, 26 J. HEALTH POL. POL'Y & L. 957, 964 (explaining that ever more costly medical technology develops in response to the availability of insurance to pay for the new products, regardless of the new products' cost or marginal utility).

78. *See supra* Tables 1 & 2.

79. Here it is important to specify who precisely is the object of the term, "the Government." The active participant in FCA litigation enforcement is "the Government" referred to here. This branch of the government is distinguishable from entities such as the CMS who may be beneficiaries of the enforcement effort. Throughout this discussion, "the Government" is the actor who prosecutes fraud, either at the federal or state level, with or without the *qui tam* relator.

alone totaled over $1.1 billion.[80] Additionally, the Government will obtain some financial benefit from prosecuting fraud. Over the past five years, the Government has recovered $5.7 billion in settlements and judgments from health care corporations under the FCA.[81] The vast majority of these recoveries (eighty-three percent)[82] are returned to the Medicare Trust Fund to administer that program in future years. The remaining, smaller percentage is awarded to the Government's enforcement agencies for future prosecutions of health care fraud. Therefore, when the Government assesses the benefits of prosecuting false claims, it primarily considers benefits that accrue to the public good. These include the satisfaction of stopping fraud, deterring fraud, returning funds to the taxpayers, and the political advantages the Government obtains by increasing its fraud enforcement success. An individual Government prosecutor may receive a raise, promotion, accolade, or other benefit from having successfully participated in obtaining an FCA recovery, but for the most part the FCA recovery does not directly turn into purchasing power for the Government's individual prosecutor. Although the Government must also consider its tangible cash benefits that flow directly from its certified share of financial recoveries, the Government's interests in serving the public good are relatively large when compared to the smaller, direct financial benefits received by *qui tam* relators who are successful plaintiffs in FCA cases. The reverse is true for the *qui tam* relator.

A *qui tam* relator who obtains a $1 million share of any recovery obtained or earned from a target corporation will receive the direct and individual financial benefit of each dollar of the recovery amount. The relator may save this money, spend it, or otherwise purchase gratification with her award. A smaller percentage of the *qui tam* relator's benefits are intangible and directed toward public welfare. The plaintiff derives some satisfaction from stopping and deterring fraud, and from being helpful to the Government. However, the largest benefit to a *qui tam* plaintiff is from the financial share he receives when funds are recovered. For this reason, the immediate and direct financial benefit received by individual *qui tam* relators when they make a prosecutorial decision largely overwhelms the indirect benefit the relator derives from serving the

80. *See* BOESE, *supra* note 11, at H-3.

81. *See* MEYER REPORT, *supra* note 58.

82. *See id.* This number was calculated by aggregating the four-year total returns to the Medicare Trust Fund of $3.346 billion and the four-year aggregate of total returns in health care recoveries from 1999 to 2002 of $4 billion, and then dividing the first number by the second.

public good. On the other hand, the immediate and direct financial gain to the Government prosecutor is minor, when compared to the larger benefit of serving the public good. Thus, when the Government independently selects cases to prosecute, it is motivated only in small part by the potential for direct financial gains, and motivated more directly by its proportionately larger duty to serve the public good. Private plaintiffs do not select the same type or number of FCA cases to pursue as the Government would; the public mission is unlikely to be at the core of the *qui tam* plaintiff's motivation to prosecute. To the extent, then, that privatization results in the Government following the private plaintiffs' prosecutorial choices instead of its own, the Government is likely to harm the public good.

Now with the moral hazard theoretical model in place, the next step is to examine a set of real life public-private prosecutions in order to determine whether the theory of moral hazard is borne out by the facts. The next section focuses on one category of FCA cases in particular—pharmaceutical fraud—to seek evidence of the moral hazard effect of privatization. Pharmaceutical fraud is a target for Government prosecution so there are a number of cases to examine and the FCA data about them is readily available. The examples from private-public enforcement in this area are most likely examples that can be duplicated across many other industries and many other examples of public enforcement through private attorneys general.

III. THE "REAL LIFE" IMPACT OF MORAL HAZARD IN GOVERNMENT ENFORCEMENT IN PHARMACEUTICAL FRAUD CASES

The Department of Justice is committed to enforcing the FCA in order to reduce the substantial number of Medicare and Medicaid dollars the American people pay annually to finance fraudulent health care schemes.[83] This is a worthy goal.[84] It is also clear that the pharmaceutical industry is the most recent and intense focus of the

83. *See* Press Release, U.S. Dep't of Justice, Justice Dept. Civil Fraud Recoveries Total $2.1 Billion for FY 2003: False Claims Act Recoveries Exceed $12 Billion Since 1986 (Nov. 10, 2003), http://www.usdoj.gov/opa/pr/2003/November/03_civ_613.htm (last visited Oct. 1, 2006) (on file with the University of Michigan Journal of Law Reform) [hereinafter Press Release, DOJ, Nov. 10, 2003].

84. Estimates are that ten percent of the nation's health care expenditures are paid to reimburse fraud. Joan Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL'Y 55, 55 (2003).

Government's anti-fraud campaign.[85] One can easily see why. The pharmaceutical industry accounts for approximately ten percent of all health care expenditures in the United States.[86] The industry's net sales and operating revenues for the year 2003 averaged $58.927 billion.[87] Moreover, the pharmaceutical industry is about to be injected with an unprecedented flow of additional revenues to be paid by the federal Government. The largest reform in Medicare and Medicaid since 1965 became law on December 8, 2003. On that date, President Bush signed the Medicare Prescription Drug Improvement and Modernization Act of 2003,[88] a law that will expand the Medicare program's reimbursement for prescription drug purchases by at least $534 billion[89] over the next ten years. By some estimates, the cost of this program could be as much as $1.2 trillion.[90] This new law represents the largest expansion in Medicare's history and importantly increases mandatory

85. *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS. & THE DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FY 2003 (Dec. 2004), http://www.usdoj.gov/dag/pubdoc/hcfacreport2003.htm (on file with the University of Michigan Journal of Law Reform) [hereinafter HEALTH CARE FRAUD ANNUAL REPORT 2003] ("The HHS/OIG recommended that CMS work with states to pursue more efficient means of purchasing pharmaceuticals and initiate a review of the Medicaid rebate program . . . ."); U.S. DEP'T OF HEALTH & HUMAN SERVS., & THE DEP'T OF JUSTICE, HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FY 2002 (Sept. 2003), http://www.usdoj.gov/dag/pubdoc/hcfacreport2002.htm (on file with the University of Michigan Journal of Law Reform) ("HHS/OIG estimated that the Medicaid program could have saved as much as $1.6 billion in 1999 for the top 200 brand and generic drugs if reimbursements had been made suing [sic] the lower [prices]."); U.S. DEP'T OF HEALTH & HUMAN SERVS., & THE DEP'T OF JUSTICE, HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FY 2001 (Apr. 2002), http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm (on file with the University of Michigan Journal of Law Reform) ("In Medicare, HHS/OIG studies spanning the last 4 years have revealed that Medicare and its beneficiaries pay considerably more than do other Federal health care programs for prescription drugs. . . . The HHS/OIG recommended that CMS continue to seek administrative and legislative remedies to reduce excessive drug reimbursement . . . .").

86. Annual U.S. health expenditures are estimated to reach $1.9 trillion in 2005. *See* TOMMY G. THOMPSON, U.S. DEP'T OF HEALTH & HUMAN SERVS. ET AL., HEALTH, UNITED STATES, 2004: WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS 4 (2004).

87. U.S. CENSUS BUREAU, U.S. DEP'T OF COMMERCE, 3 QUARTERLY FINANCIAL REPORT FOR MANUFACTURING, MINING, AND TRADE CORPORATIONS: 2003 100 (2003).

88. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071 (2003). Ironically, this statute also contains provisions making FCA prosecution of pharmaceutical companies easier for plaintiffs. Id. at Title III, §§ 301–03.

89. *See* OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, DEP'T OF HEALTH & HUMAN SERVS. at "Medicare Advantage Enrollment" (2005), http://www.whitehouse.gov/omb/budget/fy2005/hhs.html (on file with the University of Michigan Journal of Law Reform).

90. *See* Ceci Connolly & Mike Allen, *Medicare Drug Benefit may Cost $1.2 Trillion*, WASH. POST, Feb. 9, 2005, at A1.

Government payments for prescription drugs exponentially between now and 2015.[91]

The result of a large and largely unregulated industry,[92] poised to receive enormous infusions of the federal money, earmarked by a massive reform statute for mandatory payment to Medicare vendors, who must pay treble damages if their billings are found to be fraudulent, and where up to one third of those trebled damages might be paid to private parties who file claims that allege improper billing for prescription drugs is not surprisingly a boon for potential private plaintiffs. Some have called it "the perfect storm."[93]

The Government has collected $1.6 billion from pharmaceutical firms in settlements and judgments over the last three years.[94] Another $600 million in criminal penalties has been collected from defendant drug companies during the same period.[95] The overwhelming majority of these reported cases have involved a *qui tam* relator; few were initiated by the Government alone.[96] It is clear that the Government could not prosecute these large, lucrative FCA cases against pharmaceutical companies without the help of *qui tam* relators. The cases allege complex schemes of pricing, marketing, and payment schemes for which insider information is crucial.[97] However, where the FCA statute contemplates a prosecutorial effort led and directed by the Government,[98] instead, private plaintiffs appear to be directing the Government's exercises of

91. In the year 2000, Americans spent $132 billion on prescription drugs. *See* Andrew Harris, *Recent Congressional Responses to Demands for Affordable Pharmaceuticals*, 16 LOY. CONSUMER L. REV. 219, 223 (2004).

92. *See* Daniel Higgins & Sandra Golze, *OIG to Pharmaceutical Companies: Nearly all Marketing Incentives Suspect; Between the Lines, a Caution to Doctors, Hospitals and GPOs*, 11 HEALTH L. REP. 41, at 1485 (2002) (citing the HHS Inspector General Janet Rehnquist's "Compliance Program Guidance for Pharmaceutical Manufacturers," Draft, 67 Fed. Reg. 62057 (2002), which referred to "ill-fitting regulations" that make the pharmaceutical industry a difficult one for the government to provide prospective guidance).

93. Terry Carter, *Drug Wars: Coalition Tactics Make Price Fight Look Like Battle over Tobacco*, 88 A.B.A. J. 41, 41 (2002) ("Like so many weather fronts and patterns coming together in one place at the same time, this 'perfect storm' over prescription drug prices is made up of public opinion, consumer groups, regulators, criminal investigators, politicians and plaintiffs lawyers.").

94. *See* BOESE, *supra* note 11.

95. *Id.*

96. *Id.*

97. *Id.*

98. *See, e.g.*, 31 U.S.C. § 3730 (b)(1) (2000) (defining the central role of the Government in a *qui tam* action from its inception to its conclusion: "A person may bring a civil action for a violation of section 3729 for the person *and for the United States Government.* The action *shall be brought in the name of the Government.* The action may be dismissed *only if the court and the Attorney General give written consent* to the dismissal and their reasons for consenting." (emphasis added)).

prosecutorial discretion, for example, choosing what actions to initiate and determining what theories of recovery to advance against target defendants. The Government's recently failed case against TAP Pharmaceutical executives is an example of how the Government is ceding, if not losing control of FCA prosecution.

A. The Tap Pharmaceutical Prosecution

Tap Pharmaceuticals (TAP) is a joint venture between Abbott Laboratories and Takeda Chemical Industries of Japan.[99] TAP manufactures the prostate cancer drug Leuprorelin Acetate under the name Lupron in the United States and under the name Prostap in the United Kingdom.[100] Lupron is used by physicians and, therefore, reimbursed under Medicare, Part B.[101]

Two *qui tam* relators initiated FCA suits against TAP, sometime around 1996. Former Vice President for Sales at TAP Douglas Durand and urologist Dr. Joseph Gerstein, alleged in independent actions that the company engaged in three basic fraudulent pricing and marketing schemes to sell Lupron. First, the relators charged that TAP fraudulently set and controlled Medicare reimbursement rates for Lupron by inflating the Average Wholesale Price (AWP) it reported for the prescription drug. The AWP is a series of rates generated by the pharmaceutical industry, and published by independent publishing companies that compile data annually to report the average prices of pharmaceutical products. Although these numbers are self-reported by the industry, the AWP provides the base number upon which the Federal Government calculates its percentage share of the reimbursement amount that providers will receive under Medicare, Part B for the drugs that they prescribe.[102] Durand alleged that TAP committed fraud under

99. Mary Ann Liebert, *On The Move*, 24 BIOTECHNOLOGY L. REP. 59, 59 (2005); Press Release, U.S. Dep't of Justice, Justice Department Recovers Over $1 Billion in FY 2002 (Dec. 16, 2002), http://www.usdoj.gov/opa/pr/2002/December/02_civ_720.htm (on file with the University of Michigan Journal of Law Reform).

100. David L. Douglass & Olabisi A. Onisile, *Pharmaceutical Marketing Practices: Providers Beware*, 16 HEALTH L. 6, 31 (2004); *see* David Spurgeon, *Companies May Face Tighter Regulation over Promoting Drugs*, 329 BRIT. MED. J. 998 (Oct. 30, 2004).

101. Medicare, Part B, reimburses providers for the cost of certain prescription drugs that are administered by physicians directly to patients. The Government will reimburse providers up to eighty percent of the allowable cost of these prescription drugs. Beneficiaries must pay the remaining twenty percent of the cost of these drugs. Both percentage shares are based upon the self-reported AWP that industry pharmaceutical companies provide annually. *See* 42 U.S.C.A. § 13956 (West Supp. 2006).

102. *Id.*

the FCA by violating the Prescription Drug Marketing Act (PDMA)[103] when the pharmaceutical manufacturer marketed the spread between the discounted price physicians paid for Lupron and the inflated AWP it reported for purposes of Medicare reimbursement. This alleged scheme allowed physicians to pay a lower price for prescription drugs, but then receive a higher Medicare reimbursement for the cost of those drugs based on the inflated AWP.[104]

Durand and Gerstein also alleged that TAP violated the federal anti-kickback laws[105] by giving gifts and grants to induce physicians to switch from competitors' drugs to Lupron.[106] Finally, the relators alleged that TAP committed fraud when it provided free samples of Lupron to physicians, knowing that those physicians would bill Medicare and Medicaid to collect reimbursements for these free drugs.[107] Durand and Gernstein alleged TAP's fraudulent conduct extended over several years.[108] If proved, their allegations would have exposed the manufacturer to trebled damages for each physician's claim for reimbursement for Lupron, throughout the multi-year period. In 2003 alone, TAP's U.S. Lupron sales totaled $788 million and its overseas sales totaled $183 million.[109] Thus, TAP's exposure in this claim was enormous.

In October 2001, TAP pled guilty to conspiracy to violation of the Prescription Drug Manufacturing Act and agreed to pay $875 million, the largest health fraud settlement in U.S. history, to resolve criminal and civil fraud allegations against it.[110] TAP paid

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103. *See* Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (amending sections 331, 333, 353 and 381 of the Food Drug and Cosmetic Act, 21 U.S.C. § 301, to "place restrictions on the distribution of drug samples, to ban certain resales of drugs by hospitals and other health care entities, and for other purposes").

104. Marc J. Scheineson & Shannon T. Kinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 FOOD & DRUG L.J. 1, 8 (2005).

105. 42 U.S.C. § 1320a-7b(b) (2000). The anti-kickback statute is a criminal statute that prohibits transactions that intentionally induce patient referrals in exchange for remuneration.

106. For example, the *qui tam* complaints alleged that TAP offered Dr. Joseph Gerstein $65,000 to reverse his decision to switch from TAP's product Lupron to Zoladex, manufactured by AstraZeneca, an apparently lower-cost competitor to the TAP product. *See* Press Release, U.S. Dep't of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges (Oct. 3, 2001), http://www.usdoj.gov/opa/pr/2001/October/513civ.htm (on file with the University of Michigan Journal of Law Reform) [hereinafter Press Release, DOJ, Oct. 3, 2001].

107. *See* Douglass & Onisile, *supra* note 100, at 32.

108. *See* Press Release, DOJ, Oct. 3, 2001, *supra* note 106.

109. *See* Product Portfolio: Lupron Depot/Lucrin, ESPICOM Pharmaceutical & Medical Company Profiles (Apr. 2004) ((on file with the University of Michigan Journal of Law Reform), *available at* Westlaw, PHARMEDPROF Database.

110. *Huge Settlement Announced in TAP Pharmaceutical Case*, HEALTH CARE FRAUD & ABUSE NEWSL. (L.J. Newsl., New York, N.Y.), Oct. 2001, at 1.

criminal fines of $290 million, $559.5 million to settle FCA claims, and $22.5 million to settle state law claims.[111] TAP also agreed to enter into a corporate integrity agreement, requiring the company to report its AWPs to Medicare and Medicaid under supervision.[112] The *qui tam* relators in this case, Durand and Dr. Gerstein received $77.9 million and $17 million, respectively, as their share of the settlement proceeds, plus attorneys' fees and costs.[113] At settlement, none of the three underlying allegations against TAP had been proved. However, a criminal trial on the merits of the underlying fraud claims followed.

On the same day that FCA settlement with TAP was announced, the Government filed separate criminal charges against eleven individual TAP executives allegedly responsible for engaging in the fraudulent conduct that was the basis for the now settled FCA case.[114] The Government's star witness was the *qui tam* relator, Douglas Durand.[115] Durand and Gernstein testified during the criminal trial that lasted from April 11, 2004[116] to July 2004 when a Boston jury returned an unequivocal "not guilty" verdict in favor of the TAP executives.[117] Apparently, the private relators' testimony did not convince jurors that TAP executives had committed criminal fraud.[118] First, charges were dropped against three TAP executive defendants, either for insufficient evidence or due to "undisclosed health reasons."[119] Then the Court dismissed the anti-kickback charges entirely, also reversing one defendant's guilty plea, because the court held that as a matter of law, the defendants could not have committed the alleged anti-kickback crimes where

111. *Id.*

112. *See* Press Release, DOJ, Oct. 3, 2001, *supra* note 106.

113. *Huge Settlement Announced in TAP Pharmaceutical Case, supra* note 110.

114. *See* Weinberg, *supra* at note 13, at 90; Press Release, DOJ, Oct. 3, 2001, *supra* note 106.

115. *See* Matthew Arnold, *Federal Court Acquits TAP Employees of Kickback Charges*, MED. MARKETING & MEDIA, Aug. 2004, at 11.

116. *Defense Makes Closing Argument in Trial of Drug Company Employees*, OBESITY, FITNESS & WELLNESS WK., July 31, 2004, at 708.

117. *See* Matthew Arnold, *supra* note 115; *see also* JAMES D. WAREHAM & CANDICE S. SHEPHERD, GEORGETOWN UNIV. LAW CTR. CONTINUING LEGAL EDUC., MANAGING WHISTLEBLOWER CLAIMS UNDER THE FALSE CLAIMS ACT, (Mar. 10–11, 2005), 2005 WL 1611863; Alice Dembner, *TAP Officials on Trial Today In Fraud Case*, BOSTON GLOBE, Apr. 20, 2004, at A1; Alice Dembner, *TAP Trial Jurors say Proof was Lacking: Enough Doubt Seen for Acquittals*, BOSTON GLOBE, July 27, 2004, at B1 [hereinafter Dembner, *TAP Trial Jurors say Proof was Lacking*].

118. Dembner, *TAP Trial Jurors say Proof was Lacking: Enough Doubt Seen for Acquittals, supra* note 117.

119. *Defense Makes Closing Argument in Trial of Drug Company Employees, supra* note 116, at 708.

HMOs were concerned.[120] Next, if reports about the case that appeared in the popular business press are credited, the private *qui tam* relators' underlying factual story fell apart. The evidence showed that payments alleged to physicians were never made, and overcharges allegedly sent to Medicare did not actually take place.[121] In the end, jurors simply did not believe the evidence was sufficient to support a criminal conviction. The foreman said, "there was enough doubt that you couldn't send somebody to jail."[122]

The jury verdict for the defense in the TAP litigation provides one illustration of private litigants directing public prosecution in a way that serves their personal interests but harms the public good. While we know the substantial extent to which the private parties' financial interests were served by this litigation, we are left somewhat baffled by the Government's passivity as this saga unfolded. One might legitimately question the extent to which the Government paid attention to the social goals of the underlying statutes which include restricting prescription drug re-sales prohibited by the PDMA and containing overutilization of health care resources via enforcement of the Medicare Anti-Kickback statute. One wonders why the Government did not foresee the weakness of the relators' claims in advance of the criminal trial, the plea bargains, and the lucrative settlement agreement. Did the Government rely so completely on the financially self-interested *qui tam* relators that it risked building its case upon fabricated testimony? We cannot really know what the Government prosecutors were thinking at the time, but we do know enough to examine *why* the Government behaved as it did.

We do know the charges that provided the basis for the largest health care fraud settlement in U.S. history were not proven beyond a reasonable doubt. Notwithstanding the obvious difference between the standards of proof required in criminal and civil cases, the jury's decision in the criminal case does cast a shadow on the strength of the civil *qui tam* case. Yet the private relators convinced the Government to bring an action that resulted in enormous settlement concessions from defendants for whom litigation becomes financially unfeasible. We know that the relators' allegations proved potent enough to deprive the defendants not only of money, but three physician defendants pled guilty to criminal charges to settle the allegations of wrong-doing against them. And

120. *See* Weinberg, *supra* note 13, at 90.

121. *Id.*

122. *See* Dembner, *TAP Trial Jurors say Proof was Lacking*, *supra* note 117.

yet the story Mr. Durand told the jury was not potent to convince them to convict. Therefore, it does not seem likely that the Government chose to not intervene in this claim solely on the strength of the relator's underlying case, because the relator's claims were strong enough to stand on their own without Government intervention.

In *qui tam*-directed litigation, the strength of the underlying claims may not drive the settlement negotiations. Instead, the Government's responsibility to examine *relators'* assertions and control the prosecution of public cases appears to have been influenced by the magnitude of possible recoveries—for both the private and public enforcers—and the willingness of the *qui tam* relator to pursue these recoveries with or without the Government's intervention. The irony is that this incentive structure is not costless. For example, TAP found out too late that Durand's story could not convince a jury; the defendants had already written the check and "done the time." Also, despite the size of the Government's financial investment in this prosecution, the outcome does little to advance the cost-containment goals Congress had in enacting the relevant public laws. Durand, on the other hand, after six-plus years meeting and working with federal investigators and attorneys, collected his $77.9 million and moved to Florida to retire with his family.[123] But not before he filed another *qui tam* action against a second pharmaceutical company, AstraZeneca Pharmaceuticals, L.P., alleging almost identical charges and claims.[124] While we do not know whether Mr. Durand's allegations against AstraZeneca will prove any more convincing at trial, we do know that Mr. Durand was paid another $47.5 million for his work on the AstraZeneca case.[125]

TAP is not the first or only case that the Government has settled first and then tried in related proceedings only to find that the FCA allegations proved insufficient to support a criminal conviction. Caremark, a pharmacy benefits management firm,[126]

123. *See Huge Settlement Announced in TAP Pharmaceutical Case, supra* note 110.

124. *See infra* Part III.B (discussing the AstraZeneca facts).

125. Jonathan K. Henderson & Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 ANNALS HEALTH L. 107, 121 (2006); Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees to Pay $355 Million to Settle Charges (June 20, 2003), http://www.usdoj.gov/opa/pr/2003/June/03_civ_371.htm (on file with the University of Michigan Journal of Law Reform) [hereinafter Press Release, DOJ, June 20, 2003]; *see also AstraZeneca Pays $355 Million to Settle False-Claims Case*, 5 ANDREWS GUN INDUS. LITIG. REP. No. 8, at 28 (Dec. 26, 2003).

126. See *infra* Part III.D (discussing PBM's and their market role).

paid $161 million before its employees were exonerated of wrongdoing.[127] Blue Cross Blue Shield of Illinois also paid $144 million before learning in a related trial that the basis of the FCA suit it settled would not withstand scrutiny.[128] In each of these cases, defendants admitted criminal liability for conduct that ultimately proved not to be criminal at all. In each instance, the Government paid the cost of prosecuting the *relator*-directed case.[129] In each case, no reported legal determination serves to clarify the parameters of permissible conduct for future market participants. This approach to enforcement raises important questions about the social impact of incurring substantial enforcement costs in cases of uncertain substantive strength. Ideally, the Government is accountable for weighing the social costs and benefits of each case. However, the privatization trend calls this into question. The TAP litigation is not an isolated example of a case in which the Government's oversight may have been compromised by privatization. The next section surveys several recent pharmaceutical fraud prosecutions to illustrate other costs imposed by this trend.

B. Government Inaction Invites Litigation

About the same time that he initiated the TAP litigation discussed above, Mr. Durand filed another *qui tam* action in the U.S. District Court for the District of Delaware against AstraZeneca Pharmaceuticals, LP (AstraZeneca), another pharmaceutical manufacturer and marketer.[130] This *qui tam* action alleged that from January 1991 through December 2002, AstraZeneca engaged in conduct that violated the FCA in the manufacturing and marketing of its anti-prostate cancer drug, Zoladex.[131] The Complaint alleged three types of violations.[132] First, AstraZeneca was charged with inducing physicians to purchase Zoladex by offering illegal remunerations in the form of free samples, unrestricted educational grants, travel, and entertainment gifts.[133] Durand argued these marketing favors violated the Anti-Kickback Law.[134] Second, the Complaint alleged criminal violations against AstraZeneca in

127. *See* United States v. Brown, 108 F.3d 863 (8th Cir. 1997); *see also* Jan Crawford Greenburg, *Health Penalties in Caremark Fraud Case*, CHI. TRIB., June 17, 1995, at NEWS, p. 3.

128. *See* Weinberg, *supra* note 13, at 90.

129. *See* Press Release, DOJ, Oct. 3, 2001, *supra* note 106.

130. *See* Press Release, DOJ, June 20, 2003, *supra* note 125.

131. *Id.*

132. *Id.*

133. *Id.*

134. 42 U.S.C. § 1320a-7b(b) (2000).

connection with its pricing of Zoladex and other drugs.[135] Specifically, the Complaint alleged that AstraZeneca significantly inflated the Average Wholesale Prices (AWP) upon which Medicare reimbursements are based.[136] The Complaint further alleged that AstraZeneca reported an AWP that bore no relation to the actual cost of the drug Zoladex.[137] Instead, AstraZeneca ran a program called "Return-to-Practice" inviting physicians to purchase Zoladex at a discounted rate, knowing that because the AWP was inflated, the reimbursement rate that the Government would pay for the drug was much higher than the actual cost to physicians.[138] AstraZeneca allegedly marketed the spread between the reported AWP and the discounted purchase price physicians actually paid for its drug. The third allegation against AstraZeneca was that the company gave free samples of Zoladex to physicians, knowing that the physicians would bill Medicare and Medicaid, as well as other federally-funded insurance programs and private insurers, for reimbursement for the cost of these free drugs.[139]

In December 2003, AstraZeneca settled its case despite the fact that many of the allegations Durand alleged were identical to those raised in the TAP litigation.[140] Durand's presence as the relator and the similarity of charges raises a question as to the underlying value of his claims. AstraZeneca pled guilty to conspiring to violate the Prescription Drug Manufacturing Act and agreed to pay a total of $355 million to settle the criminal, FCA, and state Medicaid charges against it.[141] AstraZeneca paid $63.9 million in criminal fines; $266.2 million to settle the FCA liability claims; and $24.9

135. Press Release, DOJ, June 20, 2003, *supra* note 125.

136. It is important to note that neither Medicare statutes nor regulations historically have defined the AWP. FABRIKANT ET AL., *supra* note 38, § 10.02[2], at 10-9. Instead, Medicare contractors performed and reported their own AWP calculations, based on pharmaceutical pricing publications and databases. *See* Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 266 (2004–05). In 1997, the Balanced Budget Amendment began to prescribe a percentage of the AWP for which the government would reimburse drug manufacturers. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, in 2006, prescription drug benefits will be added to Medicare which will pay seventy-five percent of drug costs between a patient's deductible and $2,250; beneficiaries will pay for drug costs between $2,250 and $5,100; and Medicare will pay ninety-five percent of drug costs above $5,100. Rick Mayes, *Medicare and America's Healthcare System in Transition: From the Death of Managed Care to the Medicare Modernization Act of 2003 and Beyond*, 38 J. HEALTH L. 391, 417–19 (2005). Until 2006, Medicare will base its reimbursement for outpatient drugs on the AWP. *Id.*

137. *See* Press Release, DOJ, June 20, 2003, *supra* note 125.

138. *Id.*

139. *Id.*

140. *Id.*; *see also, AstraZeneca Pays $355 Million to Settle False Claims Case, supra* note 125.

141. Press Release, DOJ, June 20, 2003, *supra* note 125.

million to settle the state law claims.[142] AstraZeneca also entered into a corporate integrity agreement designed to monitor the way it reports AWP for prescription drug reimbursements in the future.[143] Finally, in addition to the plea agreement, criminal fines, and civil fines, AstraZeneca paid $47.5 million to Mr. Durand.[144]

The fact that Douglas Durand was the plaintiff whistleblower in both the TAP case and the case against AstraZeneca should not be overlooked. The similarity between the charges brought in both instances should not be viewed as coincidence. Mr. Durand was employed at TAP for approximately seven months as a Vice President of Sales.[145] After quitting his job in 1996, Durand worked for approximately eight years on the AstraZeneca and TAP litigation and earned in excess of $125 million for his work as a whistleblower.[146] Undoubtedly, his presence in the FCA cases made it possible for the Government to obtain inside information about the pricing and marketing practices of pharmaceutical companies that they would not have otherwise had without a management-level source of information. Nevertheless, the fact that the Government had been involved in investigating pharmaceutical pricing on an industry-wide basis before Durand filed his suits and the fact that Durand was employed at TAP for less than a year before filing his suits suggest that some questions might be raised about the proportionality relationship between the contribution Durand made to prosecution and the amount of his compensation as a *qui tam* relator. Douglas Durand is not the only repeat player among recent *qui tam* relators.

Most notable among repeat *qui tam* relators is an enterprise called Ven-A-Care. A company based in the Florida Keys, Ven-A-Care has been the lead plaintiff in at least three recent FCA *qui tam* cases.[147] Ven-A-Care now operates as a professional *qui tam* relator

142. *See id.*

143. *Id.*; *see* FABRIKANT ET AL., *supra* note 38, § 10.02[1], at 10-4 (discussing how the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2065 (Dec. 8, 2003), changed the Average Wholesale Price methodology); *see also* FABRIKANT ET AL., *supra* note 38, § 10.02[2], at 10-8 to 10-9 (discussing the old reimbursement for Medicare Part B drugs and biologicals based upon AWP, and quoting the CMS proposal for replacing the old AWP calculation).

144. *See* Press Release, DOJ, June 20, 2003, *supra* note 125.

145. Weinberg, *supra* note 13, at 90.

146. *Id.*

147. Ven-A-Care's first claim was a suit against a Germany-based medical care company, Fresenius Medical Care (Fresenius). Fresenius agreed to pay the U.S. Government $486 million to settle a lawsuit in which Ven-A-Care alleged Fresenius defrauded the Medicare and Medicaid programs. Ven-A-Care received $40 million as its share of the Government's recovery. Second, Ven-A-Care filed the original *qui tam* suit against Bayer Corporation, which resulted in a $14 million settlement by the defendant pharmaceutical company in order to

with several cases pending, now under seal.[148] Ven-A-Care is unique in that the cases it pursues did not involve first-hand experience with an allegedly fraudulent Medicare pharmaceutical vendor, but rather are based on their own private investigation work leading to a *qui tam* action.[149] Prior to 1994, when Ven-A-Care filed its first *qui tam lawsuits* against Fresenius, the organization was a small pharmaceutical company located in a strip mall in Key West, Florida.[150] Annual revenues barely amounted to $1 million in sales per year and increased competition, along with declining reimbursements, threatened its future.[151] According to the Ven-A-Care principals, they got into the *qui tam* relator business on a "hunch" that one of its competitors was falsifying patient records.[152] After hiring an FBI agent, Ven-A-Care filed and settled a False Claims Act claim for $486 million.[153] The principals of Ven-A-Care, Louis Cobo and Mark Jones, no longer sell intravenous drugs for a living; they are now professional *qui tam* relators.[154]

Another *qui tam* relator of interest is George Couto. Mr. Couto was involved in developing a program for the Bayer Corporation to enable it to offer a forty percent discount on its drugs sold to one of its major clients, Kaiser-Permanente Medical Care.[155] The price break was under the "private labeling program," which Mr. Couto, in his capacity as Marketing Manager for Bayer Corporation, helped to design.[156] Under the private labeling program, Bayer discounted the sale price of its drug Cipro and other pharmaceuticals

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resolve allegations that Bayer defrauded forty-five states' Medicaid programs by falsely overstating the average wholesale prices for its drugs. Third, Ven-A-Care filed *Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Warrick Pharmaceuticals Corp.*, No. GV002327 (Tex. Dist. Ct. April 20, 2004) (settlement agreement and release) (on file with the University of Michigan Journal of Law Reform). In April 2004, the defendants agreed to settle that case, and Ven-A-Care netted $5.3 million for its work as relator in that litigation.

148. David Villano, *Spy: Fraud; Key West's Ven-A-Care Is Getting Rich Ferreting out Abuse in the Healthcare Industry*, FLA. TREND MAG., May 2002, at 76 ((on file with the University of Michigan Journal of Law Reform).

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*

153. Ven-A-Care declined Fresenius' predecessor's offer to participate in a scheme that Fresenius' predecessor promised would quickly lead to large profits. Ven-A-Care declined because they were suspicious that any company could make "quick money" given the nature of their business. This "hunch" led Ven-A-Care to investigate and then prosecute Fresenius and subsequently began its new business of investigating and filing *qui tam* claims. *Id.*

154. *Id.*

155. *See* Press Release, DOJ, Nov. 10, 2003, *supra* note 83.

156. Peter Aronson, *A Rouge to Catch a Rouge*, NAT'L L.J. (Aug. 18, 2003), *available at* http://www.law.com/jsp/nlj/PubArticlePrinterFriendlyNLJ.jsp?id=1059980477198.

to Kaiser in order to keep that company's business.[157] However, since Medicaid reimbursements[158] were based upon the "best price" that Bayer offered to its Medicaid purchasers,[159] the private labeling program allowed Bayer to sell drugs to Kaiser at a discount that was not reported to the Government for best pricing purposes.[160] Couto not only negotiated this transaction with Kaiser, but is reported to have believed that the program was "potentially illegal" at the time

157. *Id.*

158. Under Medicaid, states have substantial discretion in setting provider reimbursement rates generally. However, Federal regulations limit Medicaid reimbursement rates in order to control costs. *See* Etienne E. Pracht & William J. Moore, *Interest Groups and State Medicaid Drug Programs*, 28 J. HEALTH POL. POL'Y & L. 9, 13 (2003).

159. At the time of the case, the "best price" was defined in the Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396r-8(c)(1)(C) (2000) as follows:

> (i) In general
>
> The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—
>
> > (I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;
> >
> > (II) any prices charged under the Federal Supply Schedule of the General Services Administration;
> >
> > (III) any prices used under a State pharmaceutical assistance program; and
> >
> > (IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.
>
> (ii) Special rules
>
> > The term "best price"—
> >
> > (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
> >
> > (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and
> >
> > (III) shall not take into account prices that are merely nominal in amount.

Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396r-8(c)(1)(C) (2000).

160. When states extend outpatient prescription drug coverage to Medicaid beneficiaries, participating pharmaceutical manufacturers must sign a rebate agreement with the Government. The rebate agreement indirectly controls drug prices that the government pays. It requires drug manufacturers to offer the government either 15.1% off the "average manufacturer price" of a drug sold to a private purchaser, or the "best price" given to a non-Medicaid purchaser. 42 U.S.C. § 1396r-8 (2000).

that he negotiated the deal with Kaiser.[161] Nevertheless, Couto and his team,

> [f]aced with the potential of losing all of Kaiser's [Cipro] business . . . due to deep, deep discounting and our need to balance Kaiser's sales with impact on [Government] best pricing scenarios [sic], [we have] constructed various contracting scenarios . . . [and have] responded professionally, efficiently, and most of all, very quickly.[162]

After Couto completed the Kaiser deal in late 1999, in February 2000, he filed an FCA action against Bayer.[163] In it, he alleged that the private labeling program resulted in Bayer's filing numerous false claims for payment from the Government, and violated the False Claims Act.[164] In April 2000, the U.S. Attorney's Office in Boston announced a $257 million settlement and plea agreement with Bayer.[165] George Couto's share of that settlement was twenty-four percent, or $34 million.[166] George Couto died at the age of thirty-nine, five months before the case settled; his children are the primary beneficiaries of his work as a *qui tam* relator.[167]

Privatizing FCA prosecution invites *qui tam* players like Durand, Ven-A-Care, and Couto. These relators used their information of wrongdoing to file suit rather than to effect change within the organizations or laws at issue. Moreover, by their claims, little has been done to improve or clarify the legal regime under which future manufacturers must operate. When the Government is a prosecutor independent of *qui tam* relator influence, its self-interest is clearly subordinated to its duty to serve the public good. However, when the Government is influenced by self-interested *qui tam* relators the result of their influence may deleteriously affect the law.

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161. Aronson, *supra* note 156.

162. *Id.*

163. *Id.*

164. *Id.*

165. *Boston U.S. Attorney's Office Announces Agreement with Bayer, GlaxoSmithKline to Settle Medicaid Overcharges*, KAISER DAILY HEALTH POL'Y REP. Apr. 17, 2003, *available at* http://www.kaisernetwork.org/daily_reports/rep_ind ex.cfm?DR_ID=17232; *Bayer Agrees to Biggest Medicaid Fraud Settlement*, USA TODAY, Apr. 16, 2003, *available at* http://www.usatoday.com/money/industries/health/drugs/2003-04-16-drug-settlement_x.htm; *see also* HEALTH CARE FRAUD ANNUAL REPORT 2003, *supra* note 85, at 2.

166. *Bayer Agrees to Biggest Medicaid Fraud Settlement*, *supra* note 165.

167. *Id.*

C. The Substantive Limitations of Qui Tam*-Made Law*

Highly motivated *qui tam* plaintiffs develop and press theories of recovery that often require aggressive interpretations of existing law. In many instances, as with the TAP Pharmaceutical case, these matters are settled without any judicial or legislative opportunity to change the law in an orderly fashion that provides guidance for future transactions. In other instances, courts have sufficient precedent to realize that the relator's theory of recovery would be an imprudent advancement in the law. In still other cases, relators present issues of first impression for the courts that regulators have been addressing for years. Whether *qui tam* relators raise wholly novel issues or issues that are new to courts but not regulators, courts have found themselves making brand new law in response to *qui tam* claims.[168] A recently settled *qui tam* case that centered on a well-established practiced called "off-label marketing" illustrates the shortcomings of such *qui tam* made law.

On May 13, 2004, the Department of Justice (DOJ) entered into a Settlement Agreement and Release with Warner-Lambert Company, Inc. (Warner-Lambert); its parent company, Pfizer, Inc. (Pfizer), a pharmaceutical manufacturer; Parke-Davis, a subdivision of Warner-Lambert; and Dr. David Franklin, the *qui tam* relator who initially filed the action alleging pharmaceutical fraud.[169] Under this settlement, the defendants agreed to plead guilty to criminal charges alleging violation of the Food, Drug and Cosmetic Act (FDCA) and to pay $430 million to resolve criminal and civil charges against it.[170] In addition to the criminal fines of $240 million, Warner-Lambert paid to settle the FCA claims, Warner-Lambert also agreed to pay $83.6 million to the federal Government, and another $38 million to settle the alleged state law

168. *See* Joan H. Krause, *"Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1368 (2002) ("When health care FCA suits are settled rather than tried, these innovative theories are not subject to review by a court—raising the very real possibility that federal prosecutors are themselves 'legislating' an expansion of the law.").

169. *See* United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001); Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Ability Relating to Off-Label Promotion (May 13, 2004), http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm (on file with the University of Michigan Journal of Law Reform) [hereinafter Press Release, DOJ, May 13, 2004].

170. Letter from Michael J. Sullivan, United States Attorney for the District of Massachusetts, to Robert B. Fiske, Jr., and James P. Rouhandeh, Attorneys, Davis Polk & Wardwell (May 13, 2004) (on file with the University of Michigan Journal of Law Reform). The recent Parke-Davis settlement brings the total amount collected from pharmaceutical companies to settle civil claims in the last three years to $1.6 billion.

consumer claims.[171] Under the agreement, Warner-Lambert will pay $24.6 million to the relator, Dr. David Franklin.[172]

The Warner-Lambert Company manufactures and sells pharmaceutical products through its division and co-defendant Parke-Davis.[173] Both entities were acquired by Pfizer.[174] The Food and Drug Administration (FDA) approved the Parke-Davis drug, Neurontin, as a second-line drug to treat epilepsy.[175] However, Parke-Davis, through its parent, Warner-Lambert, aggressively marketed Neurontin as a treatment for other purposes. Neurontin was marketed as a treatment for pain, attention deficit disorder, migraine headaches, drug and alcoholic withdrawal seizures, restless leg syndrome, Amyotrophic Lateral Sclerosis, and as a first-line mono-therapy treatment for epilepsy.[176] Because these were not FDA approved uses, they are called "off-label" uses for the drug Neurontin. Physicians in most states are permitted to prescribe off-label uses for FDA-approved drugs, provided the FDA has approved of the use and the physicians believe, in their best medical judgment, that the drug would serve the best interest of their patient.[177] Nevertheless, in an Information filed in the United States District Court for the District of Massachusetts on May 13, 2004, the U.S. Attorney alleged violations of various sections of the Food Drug and Cosmetic Act.[178]

The allegations included charges that the companies marketed Neurontin for uses unapproved by the FDA, misbranded Neurontin for uses unapproved by the FDA, and deliberately decided not to seek FDA approval for the unapproved uses it encouraged in order to increase its Neurontin sales.[179] The core of the

171. Press Release, DOJ, May 13, 2004, *supra* note 169.

172. *Id.* Franklin filed his *qui tam* action on August 20, 1996. During the period from 1996 through 1999, the Government considered intervening. In 1999, the Government declined to intervene and instead filed an amicus brief and preserved its option to intervene at a later date, and the case seal was lifted. The settlement on May 13, 2004 completed an eight-year period of investigation and litigation against Parke-Davis. Parke-Davis, 147 F. Supp. 2d at 46; *see also* Bernadette Tansey, *Huge Penalty in Drug Fraud Pfizer Settles Felony Case in Neurontin Off-Label Promotion*, S.F. CHRONICLE, May 14, 2004, at C-1;

173. *Parke-Davis*, 147 F. Supp. 2d at 44; *see also* Aronson, *supra* note 156. Also, for all of the facts alleged, see the original complaint. Complaint, United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001) (No. 96-11651PBS), 1996 WL 33578368.

174. *Parke-Davis*, 147 F. Supp. 2d at 44 n.2.

175. *Id.* at 45.

176. Press Release, DOJ, May 13, 2004, *supra* note 169; *see also* Parke-Davis, 147 F. Supp. 2d at 45.

177. *Parke-Davis*, 147 F. Supp. 2d at 44.

178. Complaint, United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001) (No. 96-11651PBS), 1996 WL 33578368.

179. *Id.*

Government's allegations against Warner-Lambert consisted of the charge that the company fraudulently promoted off-label sales of Neurontin for use as a pain medication and for other unapproved applications, using well-prepared sales representatives, "medical liaisons" who falsely posed as objective medical representatives to promote off-label use of Neurontin, conference presentations, and teleconferences including fraudulent clinical updates of the drug's efficacy as a non-epilepsy use drug.[180] Further allegations included anti-kickback charges against Warner-Lambert.[181] The *qui tam* relator alleged that the defendants paid kickbacks to physicians in the form of preceptor fees, consultant fees, and travel gifts, in exchange for prescribing large quantities of Parke-Davis drugs in violation of 42 U.S.C. § 1320(a-7)(b).[182] The Complaint further alleged that Parke-Davis promoted scientifically invalid drug studies to encourage the use of Neurontin.[183] Lastly, Franklin's Complaint contained mislabeling allegations.[184] The relator alleged that Neurontin was distributed with labels and instructions that were inadequate as directions for the use for which the drug was introduced into interstate commerce in violation of the FDCA.[185]

These allegations came to light on August 20, 1996 when Dr. David Franklin filed a *qui tam* action against Warner-Lambert, under seal, in the United States District Court for the District of Massachusetts. Dr. Franklin, a Ph.D. who had been employed by Warner-Lambert as a medical liaison for five months, filed the charges that later appeared in the Government's Information against Warner-Lambert.[186]

Most of Dr. Franklin's allegations were dismissed early in the case.[187] For example, the court held that a violation of the Federal Anti-Kickback statute was not a *per se* violation of the False Claims Act.[188] Rather, the court said that in order for a kickback violation to become actionable under the FCA, the Government must have conditioned payment of the claim upon a certification, whether implied or expressed, that the claimant was in compliance with the

180. *Id.*

181. *Id.*

182. Press Release, DOJ, May 13, 2004, *supra* note 169.

183. *Id.*

184. *Id.*

185. *Id.*

186. United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44, 46 (D. Mass. 2001).

187. For example, the court dismissed Dr. Franklin's claims relating to the Veterans' Administration, holding these were not pled with sufficient specificity under FED. R. CIV. P. 9(b) to survive a motion to dismiss. *See id.* at 43–50, 55 (denying in part and granting in part defendant's Rule 9 and 12(b)(6) motions).

188. *Id.* at 54.

anti-kickback provision itself.[189] No such certification was filed by the defendant in this case.[190] Therefore, the Court held that the relator's claim could not rest on any false certification theory.[191] Significantly, the court declined to adopt Dr. Franklin's novel notion that the theory of false certification could cover claims filed not by the defendant itself, but by third parties. Declining this extension of the false claims theory promoted by the relator, the court dismissed the anti-kickback allegations under the FCA in this case.[192]

Also, the court dismissed the relator's claim that the defendants violated FDA regulations that required clinical trials to be provided free of charge.[193] The *Parke-Davis* Court identified its view of the proper limits to Medicare fraud prosecution under the FCA, saying that the plaintiff's clinical trials count was an example "of the Relator improperly seeking to use the FCA as a means to enforce various regulatory proscriptions of the FDA."[194] The court declined to allow the relator to use the FCA to prosecute various alleged regulatory violations as fraud, and cited the *Pogue* case[195] with approval for its proposition that the FCA was not "intended to operate as a stalking horse for the enforcement of every statute, rule or regulation."[196]

However, Dr. Franklin's off-label marketing claims did survive early dismissal. These were allegations that the Parke-Davis marketing scheme caused submission of numerous off-label prescriptions for Nurontin to the Medicaid program through the use of false and fraudulent statements about the safety and efficacy of the drug.[197] Remarkably, Parke-Davis' defense rested essentially on the argument that it had not submitted the false claim for reimbursement for Nurontin. Rather, Parke-Davis actually conceded that

189. *Id.* at 54–55; United States *ex rel.* Augustine v. Century Health Servs., Inc., 289 F.3d 409, 415 (6th Cir. 2002); Gublo v. Novacare, Inc., 62 F. Supp. 2d 347, 355 (D. Mass. 1999); United States *ex rel.* Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996).

190. *Parke-Davis*, 147 F. Supp. 2d at 55. *But see* United States *ex rel.* Franklin v. Parke-Davis, No. Civ.A. 96-11651PBS, 2003 WL 22048255, at *7 (D. Mass. Aug. 22, 2003) (finding arguments regarding implied certification persuasive though the court declined to reverse the claim).

191. *Parke-Davis*, 147 F. Supp. 2d at 55.

192. *Id.*

193. *Id.*

194. *Id.*

195. United States *ex rel.* Poque v. American Healthcorp, Inc., 914 F. Supp. 1057, 1513 (M.D. Tenn. 1996).

196. Parke-Davis, 147 F. Supp. 2d at 55.

197. *Id.* at 51–53, 55.

submitting claims for reimbursement for off-label prescriptions was a violation of the False Claims Act; the defendants simply alleged that the providers, not the manufacturers, would be liable under such a theory of recovery.[198] The core of the court's decision to permit the off-label use charges to proceed rested on the relator's allegation that defendants used false and fraudulent statements to induce the providers to submit false and fraudulent claims for reimbursement for Neurontin. The Court conceded that "[a] much closer question would be presented if the allegations [against Warner-Lambert] involved only the unlawful—yet truthful—promotion of off-label uses to physicians . . . ."[199] Thus, the cumbersome machinery of an FCA action was mobilized to address whether or not Warner-Lambert's advertising was truthful. Despite the defendant's admission of liability, it is important to note that this court did not conclude that off-label marketing was directly actionable under the FCA. In fact, the court observed that the FDA permits physicians to prescribe drugs for off-label usage.[200] On the other hand, the FDA does prohibit drug *manufacturers* from marketing and promoting drugs for off-label uses,[201] and the FDA prohibits the distribution of drugs where the labeling includes information about off-label uses.[202] In fact, the *Parke-Davis* Court found the terms of the FCA provided limited ability to address the complex policy issues and wide variety of state practices regarding off-label marketing.[203]

The court limited off-label claims to ones that satisfied a "double-falsehood" requirement.[204] These would apply only to the relator's claims resting on 31 U.S.C. § 3729(a)(2)—the false *statements* provision of the FCA. The court held that under this provision, both the statements by the defendants used to induce the filing of claims for reimbursement, and the claims for reimbursement themselves, had to be false in order to be actionable under the FCA.[205] However, the court did not completely foreclose

198. *Id.* at 51–53. Defendants allege that the physicians' submission of false claims were an intervening cause, breaking the chain of liability to the manufacturer for promoting off-label use. The Court rejected this claim, holding that physicians' prescriptions were foreseeable, and therefore, not an intervening force to break the causal connection between the pharmaceutical companies' conduct and liability. *Id.* at 52–53.

199. *Id.* at 52.

200. *Id.* at 44 (citing Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 350 (2001) (finding that the FDA seeks to regulate pharmaceuticals without interfering with the practice of medicine)).

201. 21 U.S.C. § 331(d) (2000).

202. *Id.*

203. *Parke-Davis*, 147 F. Supp. 2d at 52.; *see also* United States *ex rel.* Franklin v. Parke-Davis, No. Civ.A. 96-11651PBS, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003).

204. *Parke-Davis*, 147 F. Supp. 2d at 52, 55.

205. *Id.* at 51–52.

FCA actions alleging that only the claim for reimbursement was false under the false claims provision of the FCA, 31 U.S.C. § 3729(a)(1). This "much closer question" remains a possible, colorable cause of action.[206] The debate then turned to the question of whether a claim for reimbursement for an off-label use was indeed false in each of the relevant states. The court concluded that where a state's Medicaid program permitted off-label uses of drugs, a claim for such reimbursement would not be false within the meaning of the FCA.[207] The Court concluded, and in fact Parke-Davis conceded, that eight states did not provide reimbursement for off-label drug prescriptions and, therefore, in those states off-label claims for reimbursement were by definition false within the meaning of the FCA.[208]

The *Parke-Davis* case is significant for the unique approaches the *qui tam* relator took to existing law. First, the *qui tam* asserted that pharmaceutical companies may be held liable under a false certification theory for false claims that they themselves did not submit, but rather for the claims of physicians that were submitted as a result of the marketing and promotion of off-label uses for non-FDA approved drugs.[209] This third-party approach to false certification under the FCA is unique to pharmaceutical fraud cases. Secondly, the pharmaceutical manufacturers' statements used to induce or "cause" filing of false claims under the false statements provision of the FCA must be actually false in order to support FCA liability. However, claims defined as "false" are fully reimbursed by several states, and recognized by the federal courts as important to the regular practice of medicine.[210]

Although Warner-Lambert agreed to plead guilty to the counts which rested on its practice of promoting off-label usage of its products,[211] it is unlikely that this *qui tam* settlement in any way clarifies or has advances the regulatory law that controls the complex issue of off-label marketing. In some ways, the *qui tam* approach to this issue ignores existing common and statutory law on point entirely. First, it should be noted that the U.S. Supreme Court has held that off-label marketing is "necessary" to the FDA's

206. *Id.*

207. *Parke-Davis*, 2003 WL 22048255, at *2.

208. *Id.* at *3

209. *Parke-Davis*, 147 F. Supp. 2d at 53–54.

210. *Parke-Davis*, 2003 WL 22048255, at *3.

211. Warner-Lambert agreed to plead guilty to two criminal counts alleging violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1) & 355. These counts alleged crimes of distributing unapproved new drugs and misbranding drugs with labels for inadequate directions for use, in violation of the FDCA. Letter from Michael J. Sullivan, *supra* note 170.

mission.[212] Second, the Supreme Court has specifically recognized that primary jurisdiction over this issue properly rests with the administrative authority of the FDA.[213] Third, the Supreme Court has cited both the statutory complexity and the importance of competing interests it balances as two compelling reasons that should—but likely will not—dissuade *qui-tam* litigants from attempting to alter off-label marketing rules *via* the FCA. Rejecting the plaintiff's fraud claims based on off-label marketing of a medical device, the Court in *Buckman Co. v. Plaintiffs' Legal Committee* explained,

> [F]lexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives. For example, . . . "off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an *accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. . . . Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.*[214]

In fact, while manufacturers like Warner-Lambert may not lawfully promote off-label uses themselves, physicians may do so.[215] Moreover, several states require insurance companies to cover prescriptions for off-label usage of drugs.[216] Yet, the FDA has

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212. *See* Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 350 (2001) (holding plaintiffs' tort claims for injury from FDA approved orthopedic bone screws were preempted by the Food Drug and Cosmetic Act and the Medical Device Amendments (MDA) thereto).

213. *Buckman*, 531 U.S. at 348 ("The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law."); *id.* at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.").

214. *Id.* at 349–50 (emphasis added).

215. *See* Allergan, Inc. v. Alcon Laboratories, Inc., 324 F.3d 1322, 1324 n.1 (Fed. Cir. 2003).

216. For example, thirty-four states including Kansas, Maine, and Massachusetts require coverage of off-label prescriptions. KAN. STAT. ANN. § 40-2-167 (West 1999); ME. REV. STAT. ANN. tit. 24-1, § 4324-D (1997); MASS. GEN. LAWS ANN. ch. 176G, § 4G (West 1998). New Mexico and Washington have non-legislative agreements with insurance providers to cover off-label usage. And Hawaii regulators have promulgated an administrative rule with the force of law which requires insurance coverage of off-label usage. *See* Drusilla S. Raiford,

repeatedly revised its regulations concerning the practice by manufacturers, because it has long acknowledged the important role played by off-label or unapproved usages in medical practice.[217] Courts have deferred direct common-law regulation of off-label marketing, based on their appreciation of the danger presented by interfering with the delivery of health care and relationships between manufacturers, physicians and their patients.[218] There are even issues of Constitutional dimension raised by off-label marketing.[219]

None of these larger concerns is directly addressed by Dr. Franklin's litigation against Warner-Lambert. Nothing in the Warner-Lambert record suggests that Dr. Franklin's *qui tam* action addressed: any of the existing regulations on point; the FDA's years of effort to balance competing public health concerns at issue; the federalism, primary jurisdiction and preemption issues courts face when addressing the matter; or even the first amendment rights raised by this long-standing practice. By definition and design, the FCA action compels a narrow focus on the issue of fraud and, consequently, *relator*-made law fails to address important substantive and policy issues. Off-label promotion practices are one example of the shortcomings of *relator*-made law.

D. The Expensive Proliferation of Weak Claims

Three additional recent pharmaceutical cases filed under the FCA underscore one final detriment presented by the proliferation of *relator*-directed lawsuits. *Qui tam* relators have begun to allege a wide variety of regulatory violations and oversight as the basis for an FCA claim.[220] This approach to the law has the potential to

Sheila R. Shulman, & Louis Lasagna, *Determining Appropriate Reimbursement for Prescription Drugs: Off Label Uses and Investigational Therapies*, 49 FOOD & DRUG L.J. 37, 39 (1994).

217. *See* Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820-01 (Nov. 18, 1994); Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412 (Nov. 27, 1992). *But cf.* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1,000-01 (Jan. 6, 2000).

218. *See, e.g.*, Sigma-Tau Pharm., Inc. v. Schwetz, 288 F.3d 141, 147–48 (4th Cir. 2002).

219. *See* Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 28 n. 1 (D.D.C. 1995).

220. *See, e.g.*, United States v. Whiteside, 285 F.3d 1345, 1351 (11th Cir. 2002); United States *ex rel.* Hunt v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430, 436 (E.D. Pa. 2004); *In re* Genesis Health Ventures, Inc. v. Debtors, 272 B.R. 558, 563 (D. Del. 2002); *see also* United States *ex rel.* Perales v. St. Margaret's Hosp., 243 F. Supp. 2d 843, 852 (C.D. Ill. 2003) (dismissing allegations that the purchase of medical practices at prices in excess of fair market value violated Stark and Antikickback laws and were actionable under the FCA).

create poorly reasoned precedent and to expend considerable judicial resources in the process. So far, courts appear to be discerning the difference between federal level fraud, and the regulation questions *qui tam* relators are raising. Nevertheless, this method of sifting the "wheat from the chaff" is expensive and does not guarantee that a uniform or consistent body of law will result.

In the first case, Medco Health Solutions, one of the world's largest pharmaceutical benefits management company (PBM),[221] was sued in the Eastern District of Pennsylvania by three *qui tam* relators: Hunt, Gauger, and Piancentile. In this case, the Government intervened,[222] and the U.S. Attorney, as well as twenty state attorneys general, joined the case, alleging that Medco encouraged providers to prescribe its drugs by switching patients to prescriptions it claimed would save both patients and their prescribers money.[223] Instead, the switches to Medco products actually increased costs to health plans and to patients.[224] These marketing techniques were not *per se* illegal. Rather, in the case of *United States of America v. Merck-Medco Managed Care, L.L.C., et al.*, the United States and state attorneys general alleged that the switching program Medco sponsored caused providers and patients to incur increased costs, despite the representations made by Medco that these switches would save costs.[225] Thus, the falsity in this case, for FCA purposes, was provided by the defendants' misrepresentations, not by the underlying switching conduct itself. Whether a charge of federal fraud is the proper tool to address false advertising is open to question. In an industry as large as pharmaceuticals, creating legal precedent based on a few large, potentially aberrational cases may not only overstate the law, but may unnecessarily

221. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d at 436. A PBM contracts as an intermediary between health plans (purchasing prescription drugs) and pharmacies that provide those drugs to the patients enrolled in health plans. The list of drugs distributed by a PBM is called a formulary. Since they first appeared approximately thirty years ago, PBMs have sponsored sales promotion, rebate, and network programs to induce sales of their respective formulary products.

222. *See Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d at 434. Under the FCA, a person may initiate an action on behalf of himself and the United States Government under 31 U.S.C. § 3730(b)(1) (1994). Upon filing, the plaintiff must also serve a copy of the complaint and a sealed disclosure to the government. 31 U.S.C. § 3730(b)(2) (1994). Thereafter, under 31 U.S.C. 3730(b)(4) (1994), the Government has sixty days, which may be extended, during which it must notify the court whether it will intervene and proceed with the litigation, or that it declines to intervene. However, 31 U.S.C. 3730(c)(3) (1994) preserves the Government's right to intervene in that action at any time.

223. *See Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d at 447. The drug switching count is one of several allegations against the defendant PBM in this case.

224. *Id.*

225. *Id.*

interfere with the development of a healthy and cost effective market.[226]

In a second case, the Civil False Claims Act provided the basis for a Bankruptcy Court finding in the matter of *Genesis Health Ventures, et al. v. Debtors.*[227] West End Pharmacy, Inc. (West End) a pharmaceutical provider, supplied services to Cherry Hill Convalescent Center (CHCC). Vitalink Pharmacy Services, Inc., a multi-state pharmaceutical provider, acquired West End and was later acquired by NeighborCare, whose parent is Genesis. Genesis is a Chapter 11 debtor. In a separate action, CHCC filed an FCA case against Genesis. The basis of this *qui tam* relator's claim was that Genesis violated the FCA when it failed to credit the Government for the return and resale of unused drugs supplied to the CHCC nursing home. When Genesis went into Chapter 11 bankruptcy, CHCC filed a proof of claim, seeking to value its FCA action against Genesis at $324 million. According to CHCC, its allegations under the FCA claim proved that Genesis had damaged the Government by overcharging for Medicaid drugs supplied to CHCC by West End.[228]

The FCA claim at issue in *Genesis* was filed by *qui tam* relator R. Steven Scherfel. The *Genesis* Court declined to ascribe any value whatsoever to this FCA claim. It held that claims for payment are not false in the absence of clear federal statutory or regulatory requirements that West End credit the Government for unused pharmaceuticals.[229] Noting significant differences in the various states' approaches to reimbursement for unused drugs, the Court said this variety of approaches negates any "opportunity to conclude" that a failure to provide credits constitutes a false or fraudulent claim under the FCA.[230] The debtor, West End, did not act knowingly to file false claims, where there was no specificity about crediting returns under statutes, regulations or contracts.[231] Finally, the Court concluded that crediting returned drugs is not a condition of payment and, therefore, no false certification cause of

226. *See* Higgins & Golze, *supra* note 92, at 1485.

227. *In re* Genesis Health Ventures, Inc. v. Debtors, 272 B.R. 558, 571 (D. Del. 2002) (granting motions to value claimant's proof of claim based on *qui tam* action at zero).

228. West End provided pharmacy supplies to CHCC, stocking its drug carts for patient use. CHCC returned unused drugs to West End, which West End allegedly resold to other purchasers. However, CHCC alleged that West End billed Medicaid for returned drugs, without crediting the Government, for the fact that these pharmaceuticals were resold to other purchasers. *Id.* at 562–63.

229. *Id.* at 569.

230. *Id.*

231. *Id.* at 570

action existed against West End.[232] The *Genesis* Court's analysis is of particular importance, because it is a bankruptcy court; bankruptcy courts have special expertise in determining when a set of inchoate rights has value. An essential element of the FCA cause of action against West End was that it made a claim for payment against the Government's public fisc. Finding no claim, and further no falsity, the *Genesis* Court's reasoning is instructive for future analysis of what might constitute a claim for payment under the FCA. This case illustrates that in the absence of any clear federal statute or regulation requiring a condition precedent to payment, the failure to satisfy that condition cannot result in transforming a claim for payment into an actionable claim under the FCA.

On similar grounds, the Eleventh Circuit in *United States v. Whiteside*[233] reversed a conviction under the Criminal False Claims Act, based upon the Government's failure to prove that its regulatory scheme could not be reasonably interpreted as the defendant argued.[234] In that case, the defendant was indicted on conspiracy and false statement charges arising out of cost reports that classified debt as being capital-related.[235] The relator's claims in this case challenged a debatable characterization of interest expense on the defendant's cost reports.[236] The court in *Whiteside* ruled that because the Government did not discharge its burden to prove beyond a reasonable doubt that the defendant's statement was not true under a "reasonable interpretation" of the law,[237] the conviction below had to be reversed. Courts appear appropriately unwilling to classify as fraud misinterpretations of vague, ambiguous, or contradictory regulatory schemes.

Without question, the Government's resources are stretched, and its ability to investigate and prosecute fraud effectively is compromised by its limited budget and personnel.[238] However, accommodating questionable *qui tam* plaintiffs, who advance novel but untested theories of recovery concerning small and contestable regulatory points related to pricing, accounting, and the delivery of care, replaces thoughtful, flexible, and appropriate regulatory authority with a privately-driven system of penalizing a range of non-fraudulent conduct, as though it were true fraud. Neither the

232. *Id.*

233. United States v. Whiteside, 285 F.3d 1345, 1351 (11th Cir. 2002).

234. *Id.* at 1352.

235. *Id.* at 1350.

236. *Id.* at 1351.

237. *Id.* at 1352.

238. Pamela H. Bucy, *Civil Prosecution of Health Care Fraud*, 30 WAKE FOREST L. REV. 693, 756–57 (1995).

plain language of the statute nor the evidence we have of Congress' intent suggest that this is an advantageous arrangement.

The data along with summaries of the preceding pharmaceutical fraud cases confirm that the Government is allowing *qui tam* relators to influence its exercise of prosecutorial discretion. The *qui tam*-directed litigation hinders the development of good law, and costs companies, individuals, and taxpayers hundreds of millions of dollars.[239] In the case of the pharmaceutical industry, this approach to FCA enforcement leaves an already unregulated and disorderly industry in even further disarray. However, to appreciate fully the source of the Government's misdirection requires a closer look at the *qui tam* partnership between the private and the public enforcer.

The role of the *relator* in FCA litigation far exceeds the role of private attorney generals in other public-private forms of enforcement. For example, the citizen suit provisions of environmental statutes require all recoveries to be returned to the United States Treasury.[240] In marked contrast to the FCA, this allocation of funds significantly reduces the influence that private financial gain might have on private enforcement of these statutes. In many cases, a condition of settling environmental citizen suits requires defendants to donate funds to environmental advocacy groups.[241] Even this distribution of post-settlement funds does not represent the same level of financial self-interest with which *qui tam* relators must contend. In antitrust litigation, private enforcement is constrained by the standing requirement that requires the private plaintiff to have suffered an antitrust injury in order to bring a private cause of action.[242] Thus, only plaintiffs whose personal injuries are aligned with the offense to the public goal of promoting competition are eligible to recover treble damages. In contrast, courts construing the FCA have determined that a *qui tam* plaintiff need not have suffered any injury at all, either based on the reasoning that the Government is the real party in interest, or based upon the view that a *qui tam* plaintiff has a vested interest in recovery.[243] In securities class action suits, brought to enforce the laws that protect U.S. financial markets from fraud, recent legislation has reduced the

239. *See, e.g.*, James F. Barger, Jr. et al., *States, Statutes and Fraud: An Empirical Study of Emerging State False Claims Acts*, 80 TUL. L. REV. 465, 481 (2005).

240. *See, e.g.*, The Clean Water Act of 1977, 33 U.S.C. § 1251–1387 (1994).

241. *See* Thompson, *supra* note 2, at 205–09.

242. Brodley, *supra* note 3, at 16.

243. *See* Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 148–52 (2001).

independence of private attorneys and tied their interests to the individual investors in the class they represent.[244] For example, the law now requires a lead plaintiff to be named, and discovery cannot commence until after the initial pretrial motions have concluded.[245] These reforms more closely align the interests of private enforcers with the public goals of protecting the integrity of U.S. capital markets.

The pharmaceutical cases reviewed above offer numerous examples of the moral hazard problem with privatized public enforcement. Yet, these same inducement concerns, and questions about the expense and efficacy of developing law under such conditions, apply in other contexts as well—wherever the Government is overwhelmed by private prosecutors under environmental, antitrust, securities, and other public law statutes. Therefore, the next section explores ways to fix the moral hazard problem, by realigning private enforcers' interests with public priorities in the FCA context. However, the principles applied to suggest the following FCA reform, may be useful in looking at ways to improve private prosecution of public statutes generally.

IV. A PROPOSED SOLUTION: REVISING THE *QUI TAM* PROVISION OF THE CIVIL FALSE CLAIMS ACT[246]

The data empirically demonstrate the unquestionable trend toward private enforcement of the FCA generally.[247] In these examples of public-private partnerships for enforcing the law, the public enforcer is no longer leading the majority of FCA cases. The trend is away from the Government's control over these federal claims, and from the formation of the underlying law it used to control. The most important cost imposed by this trend is the potential compromise of the social objectives that public enforcement is intended to serve. Where large financial payoffs inure to the personal benefit of the private enforcer, there is a

244. *See* Joseph A. Grundfest & Michael A. Perino, *The Pentium Papers: A Case Study of Collective Institutional Investor Activism in Litigation*, 38 ARIZ. L. REV. 559, 559–62 (1996) (describing the Private Securities Litigation Reform Act of 1995).

245. Joseph A. Grundfest & Michael A. Perino, *Securities Litigation Reform: The First Year's Experience*, *in* 1015 CORPORATE LAW & PRACTICE COURSE HANDBOOK SERIES, 955, 961–62 (1997), *available at* Westlaw, 1015 PLI/Corp 955.

246. Of significant concern, but beyond the scope of this Article, are the Constitutional issues raised by *qui tam* relators prosecuting fraud under the FCA without adequate government supervision. The U.S. Constitution's Appointments and "take care" clauses may be sources of liability for inadequate supervision. *See generally* Bucy, *supra* note 16, at 955.

247. *See supra* Part.I.

greater likelihood that private economic interests will lead plaintiffs to pursue claims that diverge from the public goals of a public statute. Moreover, when a private plaintiff has the ability to proceed regardless of any meaningful quality control exercised by the public enforcement authority, the result is a proliferation of lawsuits that may prove personally lucrative, but inconsistent with the public purposes of the statutory scheme.

The pharmaceutical industry prosecutions provide numerous examples of the issues raised by the privatization trend because these lawsuits are being aggressively pursued to the fullest extent that the FCA will allow.[248] These cases provide examples of a long list of social costs imposed by overenforcement. The TAP Pharmaceutical litigation illustrates that weak cases will impose litigation and enforcement costs not internalized by the private plaintiff. Settled cases such as the Bayer Corporation private labeling case and the Parke-Davis "off-labeling" cases will do little to advance the law in a way that will predictably order future behavior. Excessive private enforcement compromises the ability of administrative agencies such as the FDA or the Department of Health and Human Services—charged with lawmaking and adjudicative authority under a public law—to exercise prosecutorial discretion and make use of complex procedural and substantive provisions to control abuses under the statutes like the Anti-Kickback statute and the FDCA. Overly lucrative financial incentives invite questionable plaintiff practices such as the plaintiffs who appear repeatedly in *qui tam* cases or plaintiffs who accept employment for short periods of time before their employer becomes a target defendant. The Parke-Davis litigation also illustrates that in cases where private enforcers advance novel interpretations of existing law, reliance on courts as the primary vehicle for screening inappropriate theories will inevitably lead to inconsistent interpretations of the law without agency oversight and control in the broad range of cases filed. The uncertainty that continues to surround the practice of off-label marketing, for example, is made no better by the piecemeal approach to litigation that private enforcement necessarily involves. The danger of establishing bad legal precedent remains as seen by the *Merck-Medco*,[249] *Genesis Health*,[250] and *Whiteside*[251] cases. The conclusion of this analysis is that Congress must now act to

248. *See* FABRIKANT *supra* note 38, § 1.05.

249. United States *ex rel.* Hunt v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430 (E.D. Pa. 2004).

250. *In re* Genesis Health Ventures, Inc. v. Debtors, 272 B.R. 558 (D. Del. 2002).

251. United States v. Whiteside, 285 F.3d 1345 (11th Cir. 2002).

reform the Civil False Claims Act, bringing it back in line with its original objectives and reasonable limitations. The FCA should be amended to reflect a lesson derived from moral hazard theory. In the insurance law context, eliminating moral hazard occurs when an insured is exposed to potential losses so that the presence of insurance is less likely to increase unnecessary utilization or reduce the exercise of reasonable caution.

Applying that principle here, the Government must be exposed to the potential losses present in cases brought by *qui tam* relators. This will create an incentive for the Government to monitor these cases more closely and to more closely align the private enforcer's interests with those of the public. Moreover, comparing the procedural approaches to other public-private enforcement regimes also suggests reform to the FCA statute that may return the Government to a position of control in public enforcement, while not compromising the benefits provided by private plaintiffs. The enforcement statutes that govern environmental citizen suits, antitrust, and securities enforcement, all include procedural mechanisms that operate to reduce the likelihood that a private plaintiff will base the decision to prosecute solely on the potential for private financial gain.[252] Whether it is the requirement to pay recovered funds into the U.S. Treasury, judicially imposed standing requirements, or class action reforms such as the requirement to name a lead plaintiff, the lesson of other public-private regimes is that private enforcers' interests must be legislatively subordinated to the public good.

All these reform objectives would be served if Congress amended the FCA statute to require the Government to evaluate the underlying merits of all cases in which it permits *qui tam* relators to prosecute in its stead. This could be done by requiring the Government to either join or move to dismiss each *qui tam* case within a certain statutory time period.[253] If the case is joined, the Government may return to a "monitor only" approach, allowing it

252. *See e.g.*, Meghrig v. KFC Western, Inc., 516 U.S. 479, 484 (1996) (explaining that the citizen suit provisions in the Resource Conservation and Recovery Act allow a private party bringing a waste clean-up suit to obtain injunctive relief but not damages for past clean-up costs); Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990) (explaining that a private plaintiff may not recover damages for showing a simple injury, but must show the exact type of injury the antitrust statute was designed to prohibit); Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 (1976) (holding that a private cause of action for damages will not arise without an allegation that the "sceinter" had the "intent to deceive, manipulate, or defraud").

253. Proposals requiring the Government to join or dismiss a *qui tam* case have recently been proposed in other contexts. *See* Aaron R. Petty, *How Qui Tam Actions Could Fight Public Corruption*, 39 U. MICH. J.L. REFORM 851 (2006) (proposing *qui tam* actions as a supplement to federal prosecution of state and local public corruption).

to multiply its enforcement efforts but only where worthwhile cases are concerned. The full range of monitoring—choosing alternative enforcement, settling, and dismissing these worthy cases—would still be available to the Government. However, as a co-litigant, such a rule would cause the Government to allow *qui tam* relators to take over its leadership position of cases for which the Government's demand is more inelastic than elastic. This would minimize the moral hazard risk that the Government will rely upon the *qui tam* relator to prosecute costly, frivolous claims. The legislative language required to accomplish this reform is simple. The *qui tam* section of the Civil False Claims Act[254] could be amended to add the italicized language and omit the bracketed language below:

(b) Actions by private persons.—

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information. *The Government may elect not to intervene but to allow the action to proceed. In this case, the Government must certify that it has evaluated the claim and, in accordance with Rule 11 of the Federal Rules of Civil Procedure, deems the case worthy to continue. The Government may elect to intervene and proceed with a certified action at any time.*

(3) The Government may, for good cause shown, move the court for extensions of the time during which

254. 31 U.S.C § 3730(b).

the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(d) Award to qui tam plaintiff.—

(1) If the Government proceeds with an action brought by a person under subsection (b), *or if the Government certifies an action to be conducted by a person under subsection (b),* such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than [25] *30* percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action . . . .

These minimal changes in the statute will address the problems highlighted in this Article and demonstrated in the "real life" examples of several recently prosecuted pharmaceutical fraud cases. Adopting the changes suggested above will insert into the FCA protections already contained or implied in the approach of other statutes that employ private attorneys general for public law enforcement. Finally, the legislative reform this Article suggests corrects the moral hazard problem contained in the current FCA statutory structure. The Government would be placed once again in a position of control with respect to all FCA prosecutions. The Government will be responsible under the revised statute to cause frivolous claims to be dismissed, to intervene in cases requiring the Government's prosecutorial leadership, or to certify cases that pro-

ceed under the direction of *qui tam* relators independently, have merit, and will serve the public good. The FCA reform proposed would reverse the unchecked trend toward private parties' dominance in public enforcement, and reverse the unacceptably large social costs privatization imposes on society, and return the Civil False Claims Act to its original design to serve the public goals and achieve benefits that private-public enforcement is intended to protect.

CONCLUSION

Overenforcement by zealous "private attorneys general" has been a concern for decades. The seminal literature on joint public-private enforcement abounds with examples. When advancing her proposal to deputize private citizens to enforce civil rights statutes in police brutality cases, Professor Myriam Gilles counseled the need to limit private enforcement actions to those actually injured because such a limitation "promotes manageability and insulates the Justice Department from a potential onslaught of meritless or vexatious petitions."[255] Professor Frank Cross, in his article that is generally critical of citizen suits brought to enforce environmental statutes, found common ground with Professor Barton Thompson when it came to the potential dangers of excesses and overdeterrence,[256] though the latter wrote to champion not only private prosecutorial efforts, but also the role of private parties as monitors and informants under the environmental regulatory scheme.[257] Even Professor Thompson admitted that where private agencies bring suits the Government would not, these actions create the potential for overenforcement, which Professor Thompson calls "added zealousness error."[258] Private enforcers play a key role in promoting the socially beneficial goals that underlie the antitrust laws.[259] And yet, after noting that private remedies such as treble and punitive damages are "exceptionally powerful,"[260] Joseph Brodley wrote that "private enforcers, driven by their own self-interest,

255. Gilles, *supra* note 1, at 1432.

256. Frank B. Cross, *Rethinking Environmental Citizen Suits*, 8 TEMP. ENVTL. L. & TECH. J. 55, 68–69 (1989).

257. Thompson, *supra* note 2, at 185–88.

258. *Id.* at 201. Thompson also claims to have evidence of underenforcement by private agencies, where the private enforcers fail to bring suits that would benefit the common good. *Id.* at 199–203.

259. Brodley, *supra* note 3, at 1.

260. *Id.* at 11.

may deviate from antitrust goals, and the strong penalties and litigation advantages available to private litigants magnify the mischief such litigation may cause."[261] Joseph A. Gunderfest wrote to urge the Securities and Exchange Commission to administratively limit implied private securities class actions on the grounds that in their effort to enforce the investor protection goals of the federal securities laws, private class action litigants

> may therefore do much more than simply supplement federal enforcement efforts by bringing more of the same type of cases that the government would bring if it had the resources. In particular, private parties may pursue cases that the government would refuse to bring even it [sic] had infinite resources.[262]

All of these astute commentators have readily acknowledged the proposition that excessive and unsupervised private enforcement may compromise important social goals. After all, the statutes that permit the use of private enforcers to supplement Government prosecution, whether expressly or implicitly, enlist the aid of private enforcers in the pursuit of lofty social priorities. However, no one has empirically confirmed that when left to their own devices, private attorneys general will seek to serve their own personal interests, regardless of the impact they may have on the public good.

This Article demonstrates the overwhelming impact of a "real life" example of the divergence between private and public interests.[263] It offers the theory of moral hazard as an explanation for that divergence in the particular instance of *qui tam*[264] litigation. Finally, based on the root incentives that cause the divergence, the Article offers a proposal to close the gap between the motivations that drive private and public enforcers. The lessons learned herein will, I believe, reverse the harms currently being visited upon the social good by excessive and excessively independent *qui tam* enforcement of the FCA. Moreover, as legal scholars look to broaden the public-private partnership described by the *qui tam* section of

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261. *Id.* at 15.

262. Grundfest, *supra* note 4, at 970. Grundfest also observed that the converse is true; private plaintiffs may fail to bring cases under the federal securities law that the government would pursue if it had the resources. *Id.*

263. Notably, J. Randy Beck has traced accounts of actual *qui tam* abuses that occurred in English legal history from before the American Revolution until Parliament abolished the tool in the mid-twentieth century. J. Randy Beck, *The False Claims Act and the English Eradication of Qui Tam Legislation*, 78 N.C. L. REV. 539 (2000).

264. *See supra* note 9.

the FCA,[265] these reforms will limit the chance that moral hazard problems will be exported broadly. Finally, the ideas presented here may also be applied to inform the public and private enforcement concerns that arise under securities class action enforcement, private antitrust actions, civil rights litigation, and citizen suits brought to force compliance with environmental laws and regulations.

265. *See, e.g.*, Bucy, *supra* note 42, (advocating expansion of a reformed version of the *qui tam* model to introduce private enforcement in protecting the environment and financial markets); *see also* Jill E. Fisch, *Class Action Reform, Qui Tam, and the Role of the Plaintiff*, LAW & CONTEMP. PROBS., Autumn 1997, at 167, 198–202 (suggesting the *qui tam* "enforcement partnership" as a way to reform class action lawsuits to enforce securities law).