THE IMPACT OF 2010 HEALTH CARE LEGISLATION ON FALSE CLAIMS ACT LITIGATION

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In 2009, Congress passed the first significant amendment of the False Claims Act ("FCA") since 1986. The 1986 Amendments had revitalized the Act by significantly expanding the ability of whistleblowers to receive monetary rewards for prosecuting *qui tam* actions against persons who had defrauded the federal government. Not surprisingly, after a generation of litigation under the 1986 Amendments, Congress determined that revisions were necessary to improve the operation of the FCA. Congress displayed particular concern about misguided court decisions which, in the opinion of the Senate Judiciary Committee, were contrary to the intent of Congress when it passed the 1986 Amendments.[1] These decisions limited the types of claims that could be brought under the FCA and made it difficult for relators to prevail in *qui tam* litigation.

The Fraud Enforcement and Recovery Act of 2009 ("FERA"), which enacted the 2009 revisions to the FCA, was passed by Congress with overwhelming bipartisan support.[2] According to the Senate Committee Report, the impetus for the bill was to combat the types of fraud that caused the financial crisis in 2008—mortage fraud, securities fraud, and financial institution fraud—and to protect against fraud in the programs Congress created to counter the consequences of the financial collapse, i.e. the federal stimulus package.[3] The Senate Committee report for FERA, however, has no references to health care fraud or Medicare—surprising omissions since the largest settlements under the FCA at the time the legislation was

[1] *See* S. Rep. No. 111-10 (March 23, 2009) at 10-12 (specifically identifying *Allison Engine v. United States ex rel. Sanders*, 553 U.S. 662 (2008), and *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004), among others, as cases which erroneously interpreted the 1986 Amendments to the FCA).

[2] The Senate vote was 92-4. The House vote was only slightly less lopsided, 367-59.

[3] S. Rep. No. 111-10 at 3.

passed were in connection with claims of Medicare and Medicaid fraud. Moreover, FERA's changes to the FCA principally concerned amendments of 31 U.S.C. § 3729, the statute that defines the elements of a False Claims Act violation, and §3733, the statute concerning civil investigative demands. FERA left largely untouched the statute that sets forth the procedural and jurisdictional requirements for bringing a *qui tam* claim under the FCA, 31 U.S.C. §3730.[4]

Congress turned its attention to these matters in 2010 when it passed the Patient Protection and Affordable Care Act[5] and the Health Care and Education Affordability Reconciliation Act (collectively, "PPACA").[6] Perhaps it was not surprising that in the legislation that enacted a sweeping overhaul of the health care system, Congress also made a number of changes that will significantly affect the litigation of health care False Claims Act cases (and non-health cases as well). This paper will examine three provisions of the PPACA that affect False Claims Act practice:

(1) the complete revision of the public disclosure bar under 31 U.S.C. §3730(e)(4);

(2) new provisions of the Social Security Act that concern recovery of overpayments made to Medicare and Medicaid providers; and

(3) amendments to the Anti-Kickback Statute that expressly state that kickbacks that result in the submission of Medicare and Medicaid claims are "false claims" under the FCA.

The paper will also examine whether these amendments can be applied retroactively.

CHANGES TO THE PUBLIC DISCLOSURE BAR

The Public Disclosure Bar Under the 1986 Amendments

Throughout the long history of the False Claims Act there has always been tension between the goal of incentivizing relators to bring forward actionable fraud claims which would not otherwise be recompensed and the principle that relators should not be permitted to pursue "parasitic" claims—claims which the government already knew about and which it was otherwise investigating or pursuing. The public disclosure bar, which was codified at 31 U.S.C. §3730(e)(4)(A), is the balance Congress struck in 1986 between these two goals. If the allegations or transactions that are the basis of a *qui tam* action have been publicly disclosed, as defined in the statute, the action is barred unless the relator qualifies as an "original source."

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[4] FERA made minor changes to §3730(h), the subsection of the statute that creates a private right of action for persons who have been retaliated against due to their attempts to enforce the provisions of the False Claims Act. But FERA did not make any changes to the requirements for actions brought by the United States or relators to hold defendants liable for violations of §3729.

[5] Pub. L 111-148 (March 23, 2010).

[6] Pub. L 111-152 (March 25, 2011).

Prior to the PPACA, the statute stated:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
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> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

When faced with a public disclosure challenge, courts have engaged in a multi-step analysis to determine whether the action is barred. The First Circuit defines the analysis as follows:

> (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).[7]

The amendments to subsection (e)(4)[8] should not change the first or third steps of the First Circuit's analysis. PPACA does not alter how courts determine whether the allegations of a *qui*

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[7] *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 728 (1st Cir. 2007).

[8] 31 U.S.C. 3730(e)(4) now states:

> (4) (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed-
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> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and

tam complaint have previously been made public,[9] nor does it modify the nature of the comparison that must be made to determine whether the bar applies between the "allegations or transactions" contained in the relator's complaint and what has been publicized.[10] The PPACA amendments, however, significantly change the second and fourth steps. [11] And it adds procedural changes that will lead to fewer cases running afoul of the public disclosure bar.

The List of Public Disclosures Has Been Narrowed

The public disclosure bar does not apply to all types of public disclosure—the disclosure must occur through one of the channels enumerated in the statute.[12] If the information that is the basis of the allegations of fraud was publicized in some other way, such as a book or a public speech, there is no "public disclosure" under the False Claims Act. Thus, extensive litigation has ensued regarding the breadth of the specific fora identified in subsection (e)(4)(A). Does disclosure of allegations or transactions in a local administrative hearing constitute "public disclosure"? Or if the allegations are contained in a complaint filed in state court between private parties? What about a local governmental report?

All of these questions have been decided in favor of defendants, resulting in dismissal of *qui tam* actions.[13] The most prominent of these decisions is the Supreme Court's 2010 opinion in *Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson,* 130 S. Ct. 1396 (2010), which was decided only seven days after the PPACA was signed into law.[14]

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who has voluntarily provided the information to the Government before filing an action under this section.

[9] *See e.g. United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 55 (1st Cir. 2009).

[10] *See e.g. United States ex rel. Poteet v. Bahler Medical, Inc.*, 619 F. 3d. 104, 114-115 (1st Cir. 2010).

[11] In the Fourth Circuit, however, the analysis of the third step will also change. Unlike every other circuit, the Fourth Circuit ruled that a relator's action is "based upon" a public disclosure only if the complaint's allegations were "derived from" the prior disclosure. *United States ex rel. Siller v. Becton Dickinson & Co.,* 21 F.3d 1339, 1348 (4th Cir. 1994). Every other circuit held the words "based upon" in §3730(e)(4)(A) should be interpreted to mean "substantially similar." *See United States ex rel. Ondis v. City of Woonsocket*, 587 F. 3d 49, 57 (1st Cir. 2009) (holding that an FCA complaint is "based upon" a public disclosure when the "relator's allegations are substantially similar to information disclosed publicly" and summarizing the interpretations of "based upon" used in each of the other circuits). PPACA removed the words "based upon" from the statute, and the statute now states that the complaint should be dismissed "if substantially the same allegations or transactions. . . were publicly disclosed," the majority test currently applied in every circuit but the Fourth.

[12] *United States ex rel. LeBlanc v. Raytheon Co., Inc.*, 913 F. 2d 17, 20 (1st Cir. 1990).

[13] *See e.g. United States ex rel. Poteet v. Bahler Medical, Inc.*, 619 F. 3d. 104, 113-114 (1st Cir. 2010) (disclosure through state or local administrative proceeding is a public disclosure under §3730(e)(4)(A)); *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 694 F. Supp. 2d 48, 60 (allegation in product liability complaint filed in state court is a "public disclosure"); *Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson,* 130 S. Ct. 1396 (2010) (local administrative report and state report constituted "public disclosures").

[14] Although noted in the first footnote and the last paragraph of the decision, the amendment of subsection (e)(4)(A) had no effect on the Court's decision. The statutory change did not directly affect the decision of the case because there was no retroactivity provision in the legislation. 130 S. Ct. at 1400, fn. 1. See also text *infra* at notes 49-51.

Graham County examined whether a local audit and a state agency's report constituted "a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation." The relators, and the Solicitor General argued, and the Fourth Circuit below had agreed, that in the context of a federal statute devoted to combating federal fraud where the terms "congressional" and "Government Accounting Office" could only be understood to relate to federal sources, the term "administrative" should be interpreted to mean only federal administrative agencies, not state or local entities. Indeed, given that the policy behind the 1986 amendment of §3730 was to encourage the bringing of more *qui tam* actions and that state materials had not previously been a basis for barring an action under the older, more restrictive version of the False Claims Act, such an interpretation was eminently reasonable. The Court did not agree. Rejecting arguments based on legislative history or policy, it saw no reason why the term "administrative" should not encompass state or local administrative bodies regardless of the fact that federal officials responsible for fraud detection are much less likely to learn of disclosures in state or local administrative reports.[15]

The PPACA amendments reverse *Graham County* and other decisions of that ilk. The amendment is clear that only "federal" sources will initiate the public disclosure bar. Indeed, "administrative" reports, hearings, audits and investigations are no longer enumerated as the types of disclosures which constitute public disclosure. The amendment also significantly narrows the type of hearings that will trigger the public disclosure bar. Now, only hearings in which the "Government or its agent is a party" will constitute "public disclosure." This surely eliminates from the public disclosure bar private lawsuits in which the details of the fraud happen to get disclosed, such as wrongful termination actions or product liability actions.

However, there will undoubtedly be litigation over who will be deemed an "agent" of the Government. If a state Medicaid agency holds hearings or participates in an adversary proceeding that concerns Medicaid fraud, is the state agency considered an agent of the Centers for Medicare and Medicaid Services ("CMS") because Medicaid is a jointly administered federal/state program? Is every state or private agency that receives a federal grant a "Government agent" for FCA "public disclosure" purposes? No Congressional committee report enlightens us as to what Congress had in mind by this term, so only exacting analysis of the relationship between the United States and the alleged agent (and evolving litigation) will determine who falls under this new FCA term.

The amendment also fails to deal directly with the most prominent controversy currently being litigated under the public disclosure bar: whether an agency's production of documents under the Freedom of Information Act constitutes a "report" or "investigation" for the purposes of the public disclosure bar. The First, Third and Fifth Circuits have ruled that an agency's mere collection of requested documents in response to a FOIA request can constitute a "report" or

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Nor did the Court consider the amendment to be an expression of what Congress originally intended when the public disclosure bar was added to the False Claims Act in 1986. The majority rejected consideration of any post-enactment "legislative history" as a tool to understand what Congress originally intended. 130 S. Ct. at 1409.

[15] 130 S. Ct. at 1406-11.

"investigation" for the purposes of subsection (e)(4)(A),[16] while the Second and Ninth Circuits have reached the opposite conclusion.[17] The United States Supreme Court accepted certiorari on the defendant's appeal of the Second Circuit decision, and the case, *Schindler Elevator v. United States ex rel. Kirk*, was argued on March 1, 2011.

As in *Graham County*, PPACA will have no direct effect on the outcome of the *Schindler Elevator* case because the amendment cannot be retroactively applied to the pending action. However, it is difficult to square the intent of the PPACA amendments with a decision that the mere collection of documents in response to a FOIA request could effectuate "public disclosure." The guiding philosophy of the public disclosure amendments appears to be that the public disclosure bar should only be invoked when there is a reasonable likelihood that federal officials will learn of the public disclosures that would otherwise bar relators from bringing an action. A subordinate's assembly of non-investigatory agency documents in response to a FOIA request from a private person is hardly the type of federal oversight that would normally alert a diligent administrator of the existence of fraud, especially if the documents necessary to establish the fraudulent conduct are collected from various federal offices. Had the FOIA decisions been on the radar of the drafters of the §3730(e)(4)(A) amendment, it is hard to believe they would not have addressed it. The decisions that hold that a response to a FOIA request constitutes a "public disclosure" go at least as far to returning the jurisdictional bar to its pre-1986 posture as the court decisions expressly identified in the legislative history as having misinterpreting the public disclosure bar. Yet, if the Supreme Court does hold that a response to a FOIA request is a "public disclosure" under §3730(e)(4)(A),[18] nothing in the PPACA amendments directly overrules such a holding, and it is doubtful that many District Courts will be willing to overturn a Supreme Court ruling without an explicit change in the statutory language.

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[16] *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 55 (1st Cir. 2009); *United States ex rel. Mistick PBT v. Hous. Auth. of Pittsburgh*, 186 F.3d 376, 383 (3d Cir. 1999); *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 175-76 (5th Cir. 2004).

[17] *United States ex rel. Kirk v. Schindler Elevator Corp.*,601 F.3d 94 (2d Cir. 2010); *United States ex rel. Haight v. Catholic Healthcare West*, 445 F.3d 1147 (9th Cir. 2006).

[18] The author is not willing to handicap the Supreme Court's likely decision in *Schindler Elevator*. For those who are playing Fantasy Judiciary, however, it should be noted that due to the Solicitor General's participation in the case (on behalf of the relator), Justice Kagan is not participating. Ordinarily, one might expect that her recusal is one less vote for affirming the Second Circuit's decision to not apply the public disclosure bar, but Court's liberal-conservative division is not usually determinative in False Claims Act cases. For example, Justices Stevens and Ginsberg were the only dissenters in *Rockwell Int. Corp. v. United States*, 549 U.S. 457 (2007), which narrowed the scope of the original source exception to the public disclosure bar under §3730(e)(4)(B), but they both joined the majority in *Graham County*, which expanded the scope of the public disclosure bar, and Justice Stevens authored the majority opinion.

Changes to the Definition of "Original Source"

Even when there has been a public disclosure, a *qui tam* action may still go forward if the relator is an "original source." Original source is a statutorily defined term. In the pre-PPACA version of 31 U.S.C. §3730(e)(4)(B) a relator qualified as an original source if he or she had "direct and independent knowledge of the information on which [False Claims Act] allegations are based" and who had "voluntarily provided the information to the Government" before filing an FCA action.[19]

After the PPACA amendments there are now two ways a relator may qualify as an "original source." A relator will survive a public disclosure under §3730(e)(4)(A) if he or she disclosed the information on which the allegations or transactions in the *qui tam* complaint are based before a public disclosure,[20] or if he or she "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions."[21] In practice there will be very little difference between the two types of original sources. A source who provides information to the government before a public disclosure occurs obviously has information independent of the public disclosure. And unless the disclosure is almost identical to the information provided to the Government, the relator probably has information in addition to the facts disclosed in the subsection (e)(4)(A) public disclosure. Thus, most of the plaintiffs who will qualify under the first category of original source but not the second are those who publicize their discovery of fraud after they have informed the appropriate federal authorities—a very small subset of relators.

Congress may have created two categories of original sources to eliminate a split between the circuits under the old definition. Although there was no textual support for such a position, a number of circuit courts had interpreted the prior version of §3730(e)(4)(B) to require disclosure of the information supporting the fraud allegations before the public disclosure under subsection (e)(4)(A). The First, Fourth, Seventh and Eighth Circuits rejected this approach,[22] but the Second and Ninth Circuits ruled that the relator must directly or indirectly be the source of the public disclosure,[23] while the D.C and Sixth Circuits required the relator to provide the relevant information to the United States before the public disclosure.[24] By clarifying that the relator does not have to provide information to the Government before the public disclosure, the amendment legislatively overrules these minority positions.

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[19] 31 U.S.C. §3730(e)(4)(B) (1986).

[20] 31 U.S.C. §3730(e)(4)(B)(i).

[21] 31 U.S.C. §3730(e)(4)(B)(ii).

[22] See *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 21-28 (1st Cir. 2009).

[23] See *United States ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13, 16 (2d Cir.1990) and *United States ex rel. Wang v. FMC Corp.*, 975 F.2d 1412, 1419 (9th Cir.1992).

[24] See *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 690 (D.C. Cir. 1997); and *United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 942-43 (6th Cir. 1997).

The PPACA amendment also eliminates the "direct knowledge" requirement of the original source definition. This had been the source of considerable litigation, as courts struggled to determine the limits of "direct" knowledge. Some courts stated that the relator had to have firsthand knowledge of the fraudulent transactions,[25] while others granted original source status to relators who had performed original research that uncovered the fraud, even if they had no personal involvement in the underlying transactions.[26] Other questions have arisen regarding whether a relator's knowledge was sufficiently direct if the relator learned it through its agents, a necessity for a corporate or organizational relator, who can only obtain knowledge through its agents.[27]

For cases filed subsequent to the PPACA amendments, all of these distinctions are no longer relevant. Now, in addition to being "independent" an original source only has to have information that "materially adds to the publicly disclosed allegations or transactions" (and, of course, disclosed such information to the Government before filing suit). Most non-parasitic relators should be able to meet this hurdle.

Almost all of the changes to the definition of original source have broadened the definition and made it easier for relators to survive the public disclosure bar. In one small area, however, the changes to the original source definition will eliminate some claims that would have survived pre-PPACA. The exceptions to the general rule are relators who discover a fraud and then publicize it instead of going straight to the Government (or an attorney knowledgeable about the FCA). A citizen may discover, for example, that a product or a real estate project does not meet its announced specifications, or a health care provider is not providing services for which she is billing. Unaware that the product, real estate or services were paid for by the federal government, in whole or in part, the citizen may think that the best way to expose the fraud is to go to the media or to file a lawsuit if she is affected directly. If subsequently she learned that the same transactions resulted in the U.S. being defrauded, despite the public disclosure, she would have survived the public disclosure bar (assuming proper notification of the Government prior to filing a *qui tam* suit) because her knowledge was both "direct" and "independent." She was an original source in both the legal and literal senses of the term. Under PPACA, unless she saved some material facts from her public disclosure for use in a *qui tam* complaint, our original source is no longer an "original source". The change in definition becomes a trap for the unwary. This trap will mostly spring on unsophisticated relators barring worthy claims that could have otherwise been pursued.

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[25] *United States ex rel. Aflatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 525 (9th Cir. 1999).

[26] *Kennard v. Comstock Resources, Inc.,* 363 F.3d 1039, 1045-46 (10th Cir. 2004).

[27] *Compare United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995) (union who collected information regarding fraud from its members and executives did not have direct information) with *Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1048-50 (8th Cir. 2002) (nursing association had "direct" knowledge through the observation of its members). *But see* 31 U.S.C. §3730(e)(4)(B) which defines an "original source" as "an individual," not "a person" or a "relator."

The Public Disclosure Bar is No Longer Jurisdictional

Another important change enacted by PPACA is Congress' revision of the first five words of §3730(e)(4). Where previously the statute commanded that "No court shall have jurisdiction. . ." the statute now states that "The court shall dismiss. . ." By these words, Congress has transformed the public disclosure bar from a jurisdictional hurdle to an affirmative defense. On the surface this may appear to be a modest change—if there has been a public disclosure and the relator is not an original source, the relator is still going to lose—but the administration of the statute and its jurisprudence will significantly change.

A jurisdictional defense is far more formidable than an affirmative defense, especially one as complex as the public disclosure bar. Where a defense is jurisdictional, the plaintiff bears the burden of establishing all elements necessary to establish jurisdiction.[28] Thus, all close cases are decided in the defendant's favor. Nor can the defense be waived or eliminated by a party's concession.[29] A jurisdictional defense, of course, can be raised at any level of the proceeding, even if the defendant did not raise it, and relators who were able to establish jurisdiction at the initiation of the proceeding may lose jurisdiction as allegations evolve or more facts are developed about what had been previously disclosed.[30]

Perhaps most importantly, because the former version of subsection (e)(4) was jurisdictional, courts were compelled to construe it strictly, and all doubts were resolved against federal jurisdiction.[31] When confronted with competing interpretations of the public disclosure bar or the definition of original source, courts frequently felt compelled to rule in favor of the defendant and the more restrictive jurisdictional approach.[32] Tracing the jurisprudence over the years, it is evident that the types of events that triggered the public disclosure bar expanded over time while the understanding of what constituted an original source narrowed. Removing the jurisdictional label from the public disclosure defense will certainly limit the application of the defense in the future and probably arrest the momentum that kept increasing the breadth of the bar.

[28] *Murphy v. United States*, 45 F.3d 520, 522 (1st Cir.1995).

[29] *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 467 (2007).

[30] In *Rockwell Int. Corp. v. United States*, 549 U.S. at 473-476, the relator was an original source of claims he brought when he initiated the litigation. However, after the United States intervened, the complaint was amended and the case was narrowed for trial, new claims were added for which the relator was not an original source and the claims for which he was an original source were jettisoned. On appeal after a jury verdict in favor of the United States and the relator, the Supreme Court ruled that the relator had lost his original source status as the case's allegations evolved and consequently the Court lost jurisdiction over the relator's claim. The judgment in his favor was reversed.

[31] *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 552 (10th Cir.1992).

[32] *See e.g. United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 92 (D. Mass. 2001) where Judge Saris adopted a broader interpretation of the public disclosure bar because jurisdictional statutes are required to be construed narrowly and all doubts are resolved against federal jurisdiction.

The United States Can Throw The Relator a Lifeline

All of the discussion above might be mooted by a final change: that the United States can unilaterally overrule any defendant's attempt to impose the public disclosure bar. Before describing the exact contour of the public disclosure bar, subsection (e)(4)(A) now states:

> The court shall dismiss an action or claim under this section, unless opposed by the Government, . . .

The underlined language was inserted by PPACA and grants the United States the unilateral right to decide whether the public disclosure bar should apply to a case or not.

As a policy decision, this amendment makes sense. The public disclosure bar was not designed to protect defendants, but to protect the public treasury. Awards should not be paid to relators on cases the Government knew about and intended to prosecute on its own. It therefore makes sense for the government to have a voice in determining whether the public disclosure at issue truly alerted the government to actionable fraud. The United States' opinion as to whether the "public disclosure" provided adequate notice had no role in the operation of the former version of the statute.

However, as a procedural device for deciding the validity of a litigation defense, the amendment implements a mechanism that is unorthodox to say the least. The United States has been given an unreviewable veto over the application of the public disclosure bar in any individual case. In this way, the governmental veto is comparable to the veto the FCA provides the United States with regard to any dismissal in connection with a proposed settlement between the defendant and the relator.[33] In the latter situation, the Attorney General is required to provide his reason in writing. To defeat the public disclosure bar in any particular case the Government need only oppose the defendant's motion.

It will be interesting to see how the Government elects to use the discretionary power granted by the PPACA amendment, and whether it will publicize its guidelines for exercising its veto. On purely policy grounds, it makes sense for the Government to always oppose a motion to enforce the public disclosure bar when it has elected not to intervene; defeating the motion keeps the relator's claims alive and allows for a possible future recovery on a matter that the United States was not intending to pursue in the first place. On the other hand, it might make monetary sense for the Government not to oppose such motions in intervention cases. The public disclosure bar only affects the relator's claim; it has no application against the United States.[34] Accordingly, in a case the United States is committed to pursuing, elimination of the relator's rights could save the United States up to 25% of the recovery. However, it does not appear that the United

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[33] 31 U.S.C. §3730(b)(1).

[34] The current and former versions of § 3730(e)(4)(A) expressly exempt actions brought by the Attorney General from the ambit of the statute. The Supreme Court has held that this language also applies to the Government's rights when it intervenes in a *qui tam* case. *See Rockwell Int. Corp. v. United States*, 549 U.S. at 478-79.

States Attorney's Office makes its decisions relating to *qui tam* participation solely on being able to avoid paying relator shares, and it is doubtful it would base its decisions under §3730(e)(4) on such a basis either.

FAILURES TO REFUND MEDICARE AND MEDICAID OVERPAYMENTS ARE NOW SUBJECT TO THE FALSE CLAIMS ACT

In 2009, Congress, through its passage of FERA, modified the definition of "obligation,"[35] in connection with reverse false claims under 31 U.S.C. §3729(a)(1)(g). The amended definition expressly included the retention of an overpayment as an "obligation" under the FCA, and FERA created an express basis for FCA liability if the recipient knowingly concealed such an overpayment from the United States or knowingly and improperly avoided or reduced the overpayment.[36] FERA, however, did not establish a specific deadline when such overpayments had to be returned to the United States in order to avoid FCA liability.

Through an amendment of Title XI of the Social Security Act, PPACA establishes such a deadline with respect to Medicare and Medicaid overpayments. 42 U.S.C. § 1320a-7k(d) requires overpayments to be reported and returned "within 60 days after the date on which the overpayment was identified" or the date any corresponding cost report is due, whichever is later. Subsection (d)(3) of the statute expressly states that an overdue overpayment shall be considered to be an "obligation" for the purposes of the reverse false claims provision of the FCA.[37] The statute expressly limits this deadline for refunding overpayments to funds received under Medicare and Medicaid.[38]

This amendment may not significantly change FCA litigation after FERA regardless of whether Medicare or Medicaid claims are at issue or other types of overpayments. After the enactment of FERA all overpayments, whether made under a federal health care program or otherwise, were obligations subject to FCA liability if the recipient knowingly failed to repay. One could easily argue that once a recipient identified a federal overpayment, improper concealment or avoidance of a federal obligation occurred if the repayment was not made within 30 days. Adding a 60 day deadline does not significantly broaden FCA liability because a failure to repay an indentified overpayment within 60 days was probably already actionable before PPACA, although the amendment will eliminate any litigation over the issue of how long is too long in the Medicare and Medicaid context.

Further, the PPACA amendment only applies 60 days after the overpayment "is identified." If the recipient maintains substandard systems that fail to flag overpayments, it could take months to "identify" the overpayment. During such an extended period, there is no

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[35] 31 U.S.C. §3729(b)(3).

[36] 31 U.S.C. §3729(b)(3).

[37] 42 U.S.C. §1320a-7k(d)(3).

[38] 42 U.S.C. §1320a-7k(d)(4)(B).

FCA liability under §1320a-7k(e) (unless a cost report is due during the period) because the overpayment had never been identified and the 60 day grace period has not started to run.

The enactment of § 1320a-7k(d) does not reach the problem of the Medicare or Medicaid provider who maintains inadequate systems that do not alert the provider to the receipt of overpayments. In these cases, liability may have already existed under the pre-PPACA version of the statute. Even when the recipient does not subjectively recognize that it has received an overpayment, there could be "knowing" avoidance of repayment under the FCA. Under 31 U.S.C. §3729(b)(1)(A)(iii), a defendant has acted "knowingly" if it acts "in reckless disregard of the truth or falsity of the information." Operating a system that cannot adequately identify overpayments may qualify as sufficiently reckless.

CHANGES TO THE ANTI-KICKBACK STATUTE

Under the Medicare and Medicaid anti-kickback statute, 42 U.S.C. § 1320a-7b ("AKS"), it is a felony to offer or receive remuneration, in cash or kind, directly or indirectly, to induce or provide patient referrals or the purchase or lease of any good, facility or service item, if the payment for such service or product is made in whole or in part under a federal health care program.[39] Violations of the AKS have frequently formed the basis of FCA complaints. Where the person who sought payment from Medicare or Medicaid either paid or accepted the kickback, courts have recognized that an actionable FCA violation exists.[40]

In many kickback scenarios, however, the person who files the claim with the government has no connection with the unlawful conduct. When a drug company provides valuable goods and services to reward physicians who have been high prescribers of its drugs, or a medical device company gives a surgeon a free junket to encourage the doctor to use its surgical device, the entity that seeks reimbursement for the product purchased as a result of the kickback often never received any payment. In the prescription context, it is usually a pharmacy which submits the claim to the government for the drugs prescribed because the physician received kickbacks, while hospitals, not physicians or device manufacturers, are frequently the persons who seek reimbursement for devices used during surgery. In a number of cases involving these scenarios, courts have found that there was nothing "false" about the claim submitted by the innocent party[41]—the claim sought reimbursement for a medically necessary service or product which was not tainted by the claimant's payment or receipt of a kickback. The claimant was not required to certify that other parties affiliated with the provided services or products did not participate in kickbacks.

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[39] 42 U.S.C. §1320a-7b(b).

[40] *See United States ex rel. Pogue v. Diabetes Treatment Ctrs. Of Am.*, 565 F. Supp. 2d 153 (D.D.C. 2008); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28 (D.D.C. 2003); *United States ex rel. Thompson v. Columbia/HCA Healthcarecorp, Inc.*, 125 F.3d 899 (5th Cir. 1997); *United States ex rel. Pogue v. Am. Healthcorp*, 914 F. Supp. 1507 (M.D. Tenn. 1996).

[41] *United States ex rel. Rost v. Pfizer, Inc.*, 736 F. Supp 2d 367, 377-78 (D. Mass. 2010); *United States ex rel. Hutchinson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 66 (D. Mass. 2010); *United States ex rel. Thomas v. Bailey*, 2008 WL 485630 (E.D. Ark. Nov. 6, 2008).

In some cases, kickback claims have been ruled non-actionable under the FCA even when the recipient of the kickback did file the claim seeking reimbursement. In *United States ex rel. Westmoreland v. Amgen, Inc.*, [42] the Court dismissed an FCA claim against a drug manufacturer for causing false claims to be presented to the United States when physicians who had allegedly received kickbacks sought Medicare and Medicaid reimbursement for administering the company's drug. But even though the claimant's conduct was not innocent, the District Court still ruled there was no "false" claim because the reimbursement claim itself did not expressly state that the claimant had complied with the federal anti-kickback statute.[43] Further, the Court refused to accept that a claimant implicitly represented that he had complied with the AKS by the mere filing of the claim because no statute or regulation required compliance with the AKS as a condition of payment.[44]

Changes to the AKS enacted by PPACA should change the result in cases like *Westmoreland*. Section 6402(f) of PPACA added a new subsection (g) to the AKS which states:

> In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes (the FCA).

This amendment provides the express statutory directive, which the Court in *Westmoreland* said was lacking, that establishes that all Medicare and Medicaid claims which evidence payment for goods or services influenced by kickbacks are "false claims." Accordingly, subsequent to the amendment, all Medicare and Medicaid reimbursement claims implicitly certify that the goods and services described therein were not purchased as a result of an AKS violation, and the claim will be "false" if such a certification is untrue.

Although not without some room for debate, it appears that this amendment should also change the result in cases where the party seeking reimbursement had no connection to a kickback. The amendment applies to any "claim that includes items or services resulting from a violation of this section." So long as the claim includes such an item or service, the claim should

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[42] 707 F. Supp 2d 123 (D. Mass. 2010) ("*Westmoreland I*").

[43] 707 F. Supp. 2d at 134-37. The relator and several states that had intervened in the relator's case also argued that when the doctors who received kickbacks applied to participate in Medicare and Medicaid they falsely certified that they would not accept kickbacks. Judge Young rejected that argument because the plaintiffs had not pled sufficient facts to establish that the doctors had known that they never intended to honor the representations in their applications when they applied to the federal programs. *Id.* at 136. Subsequently, the relator amended her complaint to include facts showing that numerous physicians were already accepting kickbacks when they filed their application forms, and the Court found that the amended complaint did state a cause of action under the FCA. *United States ex rel. Westmoreland v. Amgen, Inc.*,738 F. Supp. 2d 267, 275-76 (D. Mass. 2010).

The intervening states did not seek leave to amend after the decision in *Westmoreland I* and several of them have appealed the dismissal of their complaints to the First Circuit. That appeal, and a companion case decided at about the same time, *United States ex rel. Hutchinson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48 (D. Mass. 2010), are scheduled to be argued before the First Circuit on April 6, 2011.

[44] 707 F. Supp. 2d at 137-39.

be actionable under the FCA regardless of who actually submitted it. If the party who submitted the claim is unaware of the kickback, it would not be liable because it did not knowingly present the claim, but FCA claims against the parties who paid and accepted the kickbacks should be viable because they caused the presentation of the false claim to the Government.

Of course, defenses still remain to a kickback based FCA claim. If the relator or the Government relies on subsection (g) to establish the falsity of a reimbursement claim, they will still need to establish that the reimbursed service or product "resulted" from the alleged kickback. While proof of a "resulting" claim will be relatively simple where the physician or kickback recipient never used a product before receipt of the kickback, it such proof may be harder to establish when a manufacturer or supplier provides items of great value as a reward for past uses or prescriptions. The defendant will argue that the reward did not result in a subsequent use of a product or service—the provider would have used the product or service regardless. Although at odds with the clear intent of subsection (g), some courts may find this argument compelling if there is no alternative product or service on the market that does the same thing. Then the defendant will argue that the "reward" made no difference, the physician would have had to use the product or service to treat the patient in any event.

There is one other amendment to the AKS enacted by PPACA that may be of interest. Prior to passage of PPACA, there was a split in the circuits regarding the necessary intent to establish a criminal violation of the AKS. Criminal violations under the statute must be "knowing or willful." The Ninth Circuit Court of Appeals has applied a heightened scienter requirement – ruling that a violation must stem from a specific intent to disobey the AKS.[45] Other circuits disagree, ruling that the defendant only has to know that the conduct at issue was unlawful, rather than knowing that the conduct specifically violated the AKS.[46]

PPACA codifies the latter interpretation, clarifying that the government need not show that a defendant had actual knowledge of AKS or specific intent to violate it.[47] It also added substantially similar language to the Health Care Fraud Statute, so that specific intent to violate that statute (making it a crime to knowingly or willfully defraud a federal health care program) is not required.[48] These changes do not directly affect practice under the FCA.

APPLICABILITY OF THE PPACA AMENDMENTS TO NEW AND EXISTING CASES

The PPACA amendments to the FCA may be unique in having been interpreted by the United States Supreme Court only a week after their enactment. When the Court ruled on the pre-PPACA version of the public disclosure bar in *Graham County*, it observed that the relevant

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[45] *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995); *see United States v. Weinbaum*, Case No. 03-CR-1587-L at *14 (S.D. Cal. 2005).

[46] *United States v. Starks*, 157 F.3d 833, 837-39 (11th Cir. 1998); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Jain*, 93 F.3d 436, 439-41 (8th Cir. 1996).

[47] 42 U.S.C. §1320a-7b(h).

[48] 18 U.S.C. §1347.

statute, 31 U.S.C. §3730(e)(4), had only recently been amended by Congress. It nonetheless ruled that the amendment had no application to the case at bar because there was no mention of retroactive application in PPACA, a prerequisite for applying an amended statute to pending cases when the amendment narrowed a party's substantive defense.[49] *Graham County* definitively establishes that the PPACA amendments to the FCA will only apply to cases filed after the statute's effective date, March 23, 2010.

Additional Supreme Court precedent makes it clear that the amended provisions are also limited to conduct that occurred after the statute's enactment. In *Hughes Aircraft Co. v. United States ex rel. Schumer*,[50] the Court examined a *qui tam* action under the FCA which was only viable under the 1986 Amendments. The action was brought years after the effective date of the amendments, but concerned pre-1986 conduct. The 1986 Amendments, like the PPACA Amendments, contained no provision authorizing retroactive application. The Court ruled unanimously that because the 1986 Amendments made substantive changes to a party's defenses under the statute, without explicit statutory language authorizing retroactive application, the new statute could not be applied to conduct that occurred prior to the enactment date.[51] *Hughes Aircraft* applies as fully to the PPACA Amendments as it did to the 1986 Amendments.

Thus the PPACA Amendments are only applicable to action filed after March 23, 2010 that concern conduct that occurred after that date. Given the mandatory sealing of *qui tam* complaints under the FCA and the length of time it generally takes for the U.S. Attorney to investigate alleged violations of the FCA, it may still be another year or two before the first decisions under the PPACA Amendments are made by the District Courts.

CONCLUSION

PPACA addresses some of the most contentious issues currently being litigated and deliberately changes the results. Like FERA, almost all of these changes assist relators in pursuing claims under the FCA and shuts down trends in the jurisprudence that have been growing more and more favorable to defendants over the years. Due to the lack of a retroactivity provision in the legislation and the slow gestation of FCA cases, however, it could be years before the PPACA amendments to the FCA and related statutes are actually applied by the Courts to the cases before them.

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[49] *Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010).

[50] 520 U.S. 939 (1997).

[51] *Id.* at 947-52.