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The Dark Side of the Boom: The Peculiar Dilemma of Modern False Claims Act Litigation

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THE DARK SIDE OF THE BOOM: THE PECULIAR DILEMMA OF GOVERNMENT SPOLIATION IN MODERN FALSE CLAIMS ACT LITIGATION

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Spurred by treble damages, substantial penalties, and lucrative relator awards, litigation under federal and state False Claims Act ("FCA") statutes has exploded in recent years. Much of that explosion stems from aggressive and creative legal theories that challenge controversial industry practices or even well-known loopholes or waste in government policy. Evidence from governmental entities can be critically important in litigating these FCA claims. Unique aspects of False Claims Act actions, however, can aggravate the risk of losing this important evidence, leaving the parties, judges, and juries without the evidentiary record necessary to equitably adjudicate these disputes. Defendants can face the risk of treble damages, substantial penalties, or worse without the opportunity to build their defense before evidence is destroyed. Calling on his first-hand experience litigating FCA cases, the author highlights the risk of government spoliation in FCA cases and provides recommendations for courts and counsel to address this escalating problem.

I. INTRODUCTION

On a near-daily basis, the legal press brings word of a new, novel theory of liability under the False Claims Act ("FCA"), a federal law imposing liability on persons and companies who defraud the government. In this environment, alleged malfeasance with any feasible connection to government funds could invite exposure to treble damages, substantial statutory penalties, or worse under the FCA and its state law companions. Government contractors face potential FCA liability on all matters of contractual disputes, including those related to the costs of shipping, feeding overseas troops, the pricing for computer software, and providing nonconforming parts to the military.[1] Banks face FCA claims ranging from alleged failures to follow mortgage approval standards to assertions that inflated foreign exchange rates defrauded pension funds.[2] Pharmaceutical and medical device

[1] *See, e.g.*, Helen Christophi, *UPS Worker Defends FCA Claims In Shipping Overcharge Suit*, LAW360.COM (Feb. 20, 2013), http://www.law360.com/articles/417034/ups-worker-defends-fca-claims-in-shipping-overcharge-suit; *see, e.g.*, Bibeka Shrestha, *US Highlights KBR Kickbacks In $41M Contract Fight*, LAW360.COM (Feb. 2, 2012), http://www.law360.com/articles/305333/us-highlights-kbr-kickbacks-in-41m-contract-fight; *see, e.g.*, Erin Fuchs, *US Appeals Relators' $8M Share Of $48M Cisco FCA Deal*, LAW360.COM (Nov. 14, 2011), http://www.law360.com/articles/285596/us-appeals-relators-8m-share-of-48m-cisco-fca-deal; *see, e.g.*, Keith Goldberg, *Oracle To Pay Record $200M To End Software FCA Suit*, LAW360.COM (Oct. 6, 2011), http://www.law360.com/articles/276624/oracle-to-pay-record-200m-to-end-software-fca-suit; *see, e.g.*, Megan Stride, *Kaman To Pay $4.8M To End False Claims Suit: DOJ*, LAW360.COM (Dec. 21, 2011), http://www.law360.com/articles/295504/kaman-to-pay-4-8m-to-end-false-claims-suit-doj.

[2] *See, e.g.*, Lana Birbrair, *Citi Closes Door on DOJ's Reckless-Mortgage Suit for $158M*, LAW360.COM (Feb. 15, 2012), http://www.law360.com/articles/310131/citi-closes-door-on-doj-s-reckless-mortgage-suit-for-158m; *see, e.g.*, Keith Goldberg, *BNY Mellon Can't Shake*

manufacturers face myriad FCA allegations, from promoting the "off-label" use of drugs and misreporting drug prices to alleged violations of FDA regulations in connection with securing drug approvals and misrepresenting the efficacy of drugs.[3] Even alleged recruiting violations and misstatements in accreditation certifications by educational institutions can give rise to FCA claims.[4] And these are just a handful of seemingly endless possibilities.

The FCA promotes new targets and theories with substantial financial awards for those who formulate them. FCA actions are typically filed in the first instance by private citizen "relators"—often former corporate employees or other "industry insiders"—who stand to recover 15 to 30% of any recovery.[5] The risks posed by treble damages, substantial penalties, and threats of exclusion from government programs or criminal liability has led to breathtaking settlements in recent years that run into the hundreds of millions and even billions of dollars. With these monetary incentives, recent pro-plaintiff amendments to the FCA, and an increased willingness by many courts to expand the FCA's reach, there is little reason to expect a recession in what some have called the "fastest growing area of federal litigation."[6]

The FCA's rampant expansion has been well chronicled. But unique challenges presented by this expansion in the actual litigation setting—including the

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Forex Pricing Fraud Suit, LAW360.COM, (Feb. 14, 2012), http://www.law360.com/articles/309898/bny-mellon-can-t-shake-forex-pricing-fraud-suit.

[3] *See, e.g.*, Gavin Broady, *Maryland AG Hits GSK With Avandia False Claims Suit*, (Feb. 21, 2013), LAW360.COM, http://www.law360.com/lifesciences/articles/417188?nl_pk=73bc6751-854f-4e1b-b0b7-c14b2c3fb270&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences; *see, e.g.*, Daniel Wilson, *Warner Chilcott Falsely Promoted Drugs, FCA Suit Says*, LAW 360.COM (Feb. 22, 2013), http://www.law360.com/health/articles/418015?nl_pk=6078e50c-0f0a-4b00-aabb-bf91df385cfd&utm_source=newsletter&utm_medium=email&utm_campaign=health; *see, e.g.*, Rachel Slajda, *J&J To Pay $1B To Settle Risperdal Civil Claims: Report*, LAW360.COM (Jan. 5, 2012), http://www.law360.com/articles/297732/j-j-to-pay-1b-to-settle-risperdal-civil-claims-report; *see, e.g.*, Richard Vanderford, *Drug Co. Dava Pays $11M To End Medicaid Rebate Suit*, LAW 360.COM (Feb. 8, 2012), http://www.law360.com/articles/307884/drug-co-dava-pays-11m-to-end-medicaid-rebate-suit; *see, e.g.*, Roxanne Palmer, *Takeda Hid Gout, GERD Drug Interactions: Whistleblower*, LAW360.COM (Jan. 25, 2012), http://www.law360.com/articles/303346/takeda-hid-gout-gerd-drug-interactions-whistleblower.

[4] *See, e.g.*, Brian Mahoney, *9th Circ. Reinstates Kaplan FCA Suit Over Fake Enrollments*, LAW360.COM (Feb. 14, 2013), http://www.law360.com/articles/415383/9th-circ-reinstates-kaplan-fca-suit-over-fake-enrollments; *see, e.g.*, Rachel Slajda, *DOJ Pans For-Profit College Co.'s Bid To Nix Fraud Suit*, LAW360.COM (Dec. 8, 2011), http://www.law360.com/articles/291748/doj-pans-for-profit-college-co-s-bid-to-nix-fraud-suit; *see, e.g.*, Abigail Rubenstein, *U. of Phoenix Settles Qui Tam Suit For $78.5M*, LAW360.COM (Dec. 14, 2009), http://www.law360.com/articles/139280/u-of-phoenix-settles-qui-tam-suit-for-78-5m.

[5] Joseph P. Giffith, Jr., *Guide to Federal False Claims Act (FCA) for Whistleblower & Qui Tam Plaintiffs & Their Lawyers*, AVVO.COM, http://www.avvo.com/legal-guides/ugc/highlights-of-the-federal-false-claims-act-fca-for-whistleblowersqui-tam-plaintiffs--lawyers (last visited April 26, 2013).

[6] ABA CLE Program Guide, *The Eighth Annual National Institute on the Civil False Claims Act and Qui Tam Enforcement* (June 2-4, 2010), *available at* http://new.abanet.org/calendar/civil-false-claims-act-and-qui-tam-enforcement-2010/Documents/cen0cfc_Website_Brochure_5-7-10.pdf.

preservation of evidence—have been largely underappreciated and unresolved. Many of today's largest FCA cases involve established industry practices or controversial government reimbursement policies. Other cases turn on the interpretation of rules and regulations drafted by government agencies or contracts negotiated with government officials. Nearly all involve a fact-intensive inquiry into the monetary impact of allegedly false or fraudulent claims, statements, or conduct on government expenditures. It should come as no surprise, then, that data, documents, and testimonial evidence from government entities could be very relevant in these types of FCA actions. Unique aspects of FCA cases, however, aggravate the risk that this evidence may be lost, creating an unbalanced playing field where the government and relators can gather fresh evidence while defendants are left, often years later, to pick through stale evidentiary scraps.

This Article explores the peculiar dilemma of spoliation in FCA cases. Section I traces the FCA's evolution from the relatively unused "Informer's Law" to the powerful force that it and state law FCA statutes have become today. Section II highlights the growing importance of evidence from government entities in the types of FCA cases being litigated today. Section III discusses the particular challenges faced in FCA cases to preserving an adequate factual record. Section IV concludes with recommendations to courts and practitioners to help mitigate these challenges.

II. CAPTAINING THE FALSE CLAIMS ACT INTO UNCHARTED WATERS

A. The Explosion of the False Claims Act

Originally known as the "Informer's Law," the FCA was enacted during the Civil War as a vehicle for prosecuting suppliers of shoddy war supplies, such as passing sand for gun powder.[7] Under the original law, defendants were subjected to double damages, as well as civil and criminal penalties, and whistleblower "relators" could receive up to half of any damages or penalties awarded in the action.[8] Partially because of legal amendments enacted in 1943 to limit parasitic suits and decrease the monetary awards to relators, however, the FCA fell into relative obscurity over the next century.[9]

This began to change in 1986, when Congress repealed certain of the earlier amendments and increased the relator's award and statutory penalties available under the False Claims Act.[10] Over the last two decades, the FCA has become the government's primary weapon of combating fraud against the government. The numbers tell a remarkable story. In 1987, only 30 new *qui tam* suits were initiated

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[7] *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, 125, 129 (2001).

[8] Edward P. Lansdale, *Use as Directed? How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing*, 41 NEW ENG. L. REV. 159, 168-69 (Fall 2006).

[9] *See id*; *see* Congressional Research Service, *Qui Tam: The False Claims Act and Related Federal Statutes* (Aug. 6, 2009), *available at* http://www.fas.org/sgp/crs/misc/R40785.pdf (discussing the historical development of the FCA).

[10] Lansdale, *supra* note 8, at 169-70. The 1986 amendments increased the penalty from $2,000 to $5,000 to $10,000 (now $5,500 to $11,000) for each FCA violation, provided for treble damages, and increased the relator's award from 15 to 30 percent of the government's recovery. 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3730(d)(2).

under the FCA.[11] By 1997, that number had increased to 547.[12] In 2011, 638 new *qui tam* suits were filed and nearly $3 billion was collected through settlements and judgments; two-thirds of the recoveries related to the healthcare industry alone.[13] All told, since 1987, over $30 billion has been collected through FCA settlements or judgments.[14] Actions are proliferating rapidly under state FCA statute, as well. Spurred by federal incentives, twenty-nine states and eleven municipalities, including the District of Columbia, have now enacted state False Claims Act statutes.[15]

In short, state and federal FCA claims have become big business for state and local governments, relators, and their attorneys. Recent amendments to the FCA, further strengthening the plaintiff's hand, promise only to expand their use.[16]

B. Novel and Expansive Legal Theories Continue to Emerge

FCA actions have traditionally focused on allegations like "double-billing," billing for services or products never provided or delivered, "upcoding" healthcare services to gain a higher reimbursement rate, performing inappropriate or unnecessary medical care, "unbundling" of services required by program rules to be "bundled" into one reimbursement rate, and billing at doctor rates for services provided by nurses or interns.[17] Such claims continue in full force today.

In recent years, however, relators and government prosecutors have looked to expand the FCA's reach, often beyond the entities or individuals who actually submitted claims to those who allegedly "caused" others to submit "false or fraudulent" claims.[18] In many cases, these efforts involve employing the FCA to

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[11] *Civil Div., U.S. Dep't of Justice, Fraud Statistics, Oct. 1, 1987-Sept. 30, 2011*, TAF.ORG, http://www.taf.org/DoJ-fraud-stats-FY2011.pdf (last visited April 1, 2013).

[12] *Id.*

[1] *Id.*

[14] *Id.*

[15] *States With False Claims Acts*, TAF.ORG, *available at* http://www.taf.org/states-false-claims-acts (last visited April 26, 2013). States that pass laws meeting certain federal standards are entitled to receive an additional 10% of any recoveries of federal Medicaid funds recovered through litigation filed by the state. *see* 42 U.S.C. § 1396h; *see also* State False Claims Act Reviews, OIG.HHS.GOV, *available at* http://oig.hhs.gov/fraud/falseclaimsact.asp; Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48, 552 (Aug. 21, 2006).

[16] *See* R. Christopher Cook, Nolan S. Young, Lee Perla, Heather O'Shea, Stephen G. Sozio, Frank E. Sheeder III, Suzanne C. Jones, Martha Boersch, *Fraud Enforcement Recovery Act of 2009 Becomes Law, Expanding Exposure Under the False Claims Act and Funding Anti-Fraud Enforcement*, JONESDAY.COM, June 2009, *available at* http://www.jonesday.com/fraud-enforcement-recovery-act-of-2009-becomes-law-expanding-exposure-under-the-false-claims-act-and-funding-anti-fraud-enforcement-06-03-2009 (discussing the impact of the amendments to the FCA implemented by FERA).

[17] *See False Claims Act Overview*,TAF.ORG, *available at* http://www.taf.org/resource/fca/false-claims-act-overview (last visited April 6, 2013).

[18] *See FY 2012 Is Record Year for FCA Recoveries*, TAF.ORG, *available at* http://taf.org/blog/fy-2012-record-year-fca-recoveries (last visited April 26, 2013); *FY 2011 False Claims*

correct perceived, yet politically sensitive, imperfections in government reimbursement policies. For example, one commentator observed:

> [H]ealth care fraud enforcement offers significant advantages to the government. [E]nforcement may achieve a quicker "fix" to a problem than would be possible in the legislative or regulatory arenas. If those processes have failed to resolve the issue--as with Medicare drug reimbursement, for example--prosecutors may regard enforcement as the only practical method of achieving the "right" result. When politics and inertia stymie the development of necessary regulations, litigation provides an alternative.[19]

Another commentator stated that FCA "[l]itigation may also reflect the government's desire to recapture 'overpayments' that, because of the political bargains that underlie Medicare and Medicaid, are not available through ex ante regulation."[20] The FCA can even allow the government to have its cake and eat it too, permitting it to recoup "overpayments" from parties who neither submitted nor received payments on claims, while maintaining the allegedly "false"—yet politically sensitive—level of payment to those who submitted the claims.

Some would argue that the practices or payments being challenged in more novel FCA cases represent, at best, government waste, not any effort to defraud the

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Act Settlements, TAF.ORG, *available at* http://www.taf.org/total2011.htm (last visited April 26, 2013).

[19] Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 269 (2004); *see also* Krause, *supra* note 7, at 125 ("The FCA initially was applied in straightforward cases of fraud, such as physicians who billed the government for services they never performed. But gradually, more creative theories have emerged. Since the mid-1990's, the FCA has been used in situations when health care services were in fact provided to patients, but where the defendants may have violated underlying legal requirements in furnishing those services, such as federal anti-referral laws. These cases signal the government's willingness to invoke the FCA against activities that are increasingly far removed from traditional types of government procurement fraud – a controversial position in light of the fact that the majority of FCA cases are resolved through settlement rather than trial."(citations omitted)).

[20] William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387, 411 (2003); *see also* Patric Hooper, *Health Care Fraud Frenzy: An Exercise in Overzealous Law Enforcement*, 1 HEALTH CARE FRAUD REP. (BNA) 799, 799 (Nov. 19, 1997) ("Rather than making the kind of hard, and often politically unpopular, decisions . . . such as rationing health care or increasing costs to beneficiaries, politicians have embraced the politically popular notion that rising health care costs are due primarily to rampant fraud in the health care industry."); s*ee also* United States v. NHC Healthcare Corp., 115 F. Supp.2d 1149, 1152 (W.D. Mo. 2000) (remarking on the government's more expansive use of the FCA, the court stated that " [a]lthough extensive regulatory authority exists for punishing unscrupulous facilities, the Government has increasingly opted for the expedited results of lawsuits under the FCA's powerful threats of significant fines, treble damages, and costly litigation fees. The health care industry has vigorously resisted this movement by the Justice Department on a variety of fronts, not the least of which is that the FCA was never intended to be a regulatory tool. . . . Until this issue works its way through the appellate system it will remain unclear whether the Government's movement towards increased scrutiny of care facilities through FCA lawsuits is a bona fide exercise of prosecutorial resources or an improper expansion of this powerful Act.").

government.[21] Nonetheless, any link between an alleged regulatory violation or disfavored industry practice and a request for government funds, may prompt relators and government prosecutors to create a new FCA theory. Many of these legal theories are left unproven, as the mere risk of draconian damages, penalties, and exclusion from government programs can force settlements.[22]

Regardless of how one views the merits of the FCA's expansion, there is little reason to expect a change in direction. In the last three years, the DOJ has established numerous teams and task forces to raise the stakes on alleged fraud.[23] These teams face mounting expectations, as government recoveries over the last few years have set an enormously high bar. Sustaining such recoveries will require new legal theories and new targets, which predictably will include a continued focus on policy imperfections and loopholes that have long vexed regulatory officials.

III. THE HEIGHTENED IMPORTANCE OF EVIDENCE FROM GOVERNMENT ENTITIES

In traditional FCA cases, factual disputes typically focused on the defendant's conduct and state of mind. Evidence from the government's files and witnesses typically carried little importance. But the situation can be altogether different in many of today's high-stakes FCA cases, particularly those that challenge sensitive reimbursement policies.

Evidence sought from government entities and witnesses is often referred to—in some cases inaptly—as "government knowledge" evidence.[24] This terminology is

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[21] *See* Congressional Budget Office, Statement of Paul N. Van de Water, Assistant Director Budget Analysis Division Congressional Budget Office, before the Committee on Finance United States Senate, *Fraud, Waste and Abuse in Medicare* (July 31, 1995) (finding "no clear line separates abusive activities from fraud.").

[22] *See, e.g.*, Krause, *supra* note 7, at 126-27 (noting "[w]ithin the industry, there is a growing concern that the Act's large penalties may force health care providers to settle cases that could not be proven in court, such as allegations of falsity stemming from good faith interpretations of ambiguous regulations. While settlement is an efficient way to dispose of FCA allegations, it also removes crucial legal issues from judicial scrutiny-including the falsity of the claim and the defendant's fraudulent intent." (citations omitted)); Robert Salcido, *Recent False Claims Act Prosecutions Fall Flat: Did Previous Large Settlements in FCA Cases Result from Rampant Abuse or Government Leverage?*, NAT'L L.J., at S1-S2 (July 4, 2005) (stating defense lawyers "assert that the government's recoveries typically reflect not the strength of the government's case but the lever it possesses under its ability to exclude companies from participation in Medicare if they are defeated at trial").

[23] Attorney General Eric Holder, U.S. Dep't of Justice, Remarks on New Medicare Fraud Initiative at a Press Conference with HHS Secretary Sebelius (May 20, 2009) (transcript available at http://www.justice.gov/ag/speeches/2009/ag-speech-090520.html); Financial Fraud Enforcement Task Force, *About the Task Force*, STOPFRAUD.GOV, *available at* http://www.stopfraud.gov/about.html (last visited April 6, 2013).

[24] United States' and Relator's Memorandum in Support of Their Motion for a Comprehensive Case Management Order at 7-10, Dkt. No. 3108, *In re* Pharm. Indus. Average Wholesale Price Litig., MDL 1456 Civ. Action No. 01-CV-12257-PBS (D. Mass. Sept. 15, 2006) (attempting to stay discovery against government officials under the notion that it would not be relevant to a "government knowledge" defense); Hearing Transcript, *In re* Pharm. Indus. Average Wholesale Price Litig., MDL 1456 Civ. Action No. 01-CV-12557-PBS (Oct. 26, 2006) at 14 (defense attorney: "[T]the point I'm trying to make is that this isn't about government knowledge. It's about government policy."); *id*. (denying government's

partially a historical artifact. Prior to the FCA's 1986 amendments, the government's prior knowledge of the facts—government knowledge—underlying a *qui tam* suit formed an affirmative defense barring the claim.[25] The 1986 amendments, however, removed that jurisdictional bar and replaced it with the more forgiving "public disclosure" bar; this meant the government's prior knowledge of the underlying facts was not an "automatic bar" to the suit.[26] The 1986 amendments did not mean, however, that the government's knowledge would now be irrelevant to the FCA claims. Instead, the 1986 amendments "le[ft] open what would be the effect of government knowledge of the facts underlying the suit."[27]

Although government knowledge of the underlying facts no longer serves as an automatic bar to a suit, courts, litigants, and commentators often still employ the government knowledge nomenclature to generally describe evidence from government entities and witnesses. This can create confusion about the discoverability and admissibility of evidence from government entities. Often, defendants are not seeking to discover or introduce this evidence solely, or even primarily, in connection with a strict government knowledge affirmative defense. Rather, as discussed below, evidence from government entities can also be relevant to, among other things, challenging the fundamental elements of plaintiff's FCA claim (falsity, *scienter*, causation, materiality, and damages) and, of course, the public disclosure.

Courts recognize that evidence from government entities may be highly relevant to *scienter* in FCA cases.[28] This would include, for example, evidence of situations where the defendant discussed deviations from contracts or regulations with government officials and were led to believe that the government accepted the changes. Evidence from government files might also be relevant to the court's interpretation of an arguably ambiguous regulation, an increasingly common issue in FCA cases that can implicate both the *scienter* and falsity analysis.[29] Documents and testimony concerning how government officials themselves interpreted the regulation might admit the regulation is ambiguous or support the defendant's interpretation as correct or at least objectively reasonable.[30] Many courts have

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request to stay discovery directed against government entities, commenting: "Why can't they get what you guys [the government] know and did?").

[25] *See* Michael J. Davidson, *The Government Knowledge Defense to the Civil False Claims Act: A Misnomer by Any Other Name Does Not Sound As Sweet*, 45 IDAHO L. REV. 41, 46 (2008); 31 U.S.C. § 3730(b)(4) (LexisNexis 1982) ("unless the Government proceeds with the action, the court shall dismiss an action brought by the person on discovering the action is based on evidence or information the Government had when the action was brought.").

[26] *See* Davidson, *supra* note 5, at 46-47; Butler v. Hughes Helicopters, Inc., 71 F.3d 321, 326 (9th Cir. 1995).

[27] *Butler*, 71 F.3d at 326.

[28] *See, e.g.*, *id.* at 326-27; United States *ex rel*. Hagood v. Sonoma Cnty. Water Agency, 929 F.2d 1416 (9th Cir. 1991); JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 2.06[E] (3d ed. 2010).

[29] *See* BOESE, *supra* note 8, at § 2.03[B].

[30] *See* United States *ex rel*. Walker v. R&F Properties of Lake Cnty, Inc., 433 F.3d 1349, 1356-58 (11th Cir. 2005) (considering Medicare manuals, Medicare bulletins, seminar programs, and expert testimony to "show the meaning of the language in the regulation and on the

recognized—often in dealing with allegedly ambiguous regulations—that the "falsity and *scienter* requirements are inseparable."[31]

Evidence from government entities relating to what it knew and/or allegedly "would have done" but for the alleged wrongdoing can be highly relevant issues of materiality, causation, damages, and penalties.[32] Moreover, courts generally hold that if the "government knew what [defendant] was doing and implicitly approved of [defendant's] actions," the FCA claims fail.[33] The strength of that defense, however,

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HCFA 1500 form and the reasonableness of [defendant's] claimed understanding of that language," rejecting district court's holding that evidence was "irrelevant . . . because none of it held the force of law"); Minn. Assoc. of Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1053-54 (8th Cir. 2002) (relying on HCFA memorandum, a bulletin published by a HCFA fiscal intermediary, and an industry publication to determine whether defendant's interpretation of regulation was objectively reasonable).

[31] United States *ex rel*. Morton vs. A Plus Benefits, Inc., 139 Fed. Appx. 980, 982 (10th Cir. 2005); *see also* United States *ex rel*. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 377 (4th Cir. 2008) ("'[I]mprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA'") (quoting United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999)); United States v. Southland Mgmt. Corp., 326 F.3d 669, 682 n.26 (5th Cir. 2003) (en banc) (Jones, J. concurring) (besides scienter, government knowledge "is also bound up with whether the claim itself was false"); Massachusetts v. Mylan, 608 F. Supp. 2d 127, 148 (D. Mass. 2008) ("Government knowledge could conceivably be relevant to two elements of the FCA: the falsity of the claim and the defendant's state of mind."); United States v. Prabhu, 442 F. Supp.2d 1008, 1032 (D. Nev. 2006) ("Finally, Dr. Prabhu's claims cannot be false, as a matter of law, because under the undisputed facts there is no articulated, objective standards that dictates that the documentation underlying the claims is false, inaccurate, or incomplete."); BOESE, *supra* note 28, at § 2.03[F] (citing cases where courts have indicated government knowledge is relevant to issue of falsity).

[32] *See Hagood*, 929 F.2d at 1421 ("It may be, as the district court observed, that no damages were suffered when officers of the United States knowledgeably decided to proceed with the contract."); *Cf.* United States *ex rel.* Butler v. Hughes Helicopter Co., 1993 WL 841192 (C.D. Cal. 1993) (finding, as a matter of law, that there was no "causal connection between the allegedly false or incorrect statements made by MDHC and the government's decision to purchase the Apache aircraft" and that, "[c]onsequently, actual damages . . . could not have been found as a matter of law"); *see* United States *ex rel*. Bunk v. Birkart Globistics GmBH & Co., Nos. 1:02cv1168 (AJT/TRJ), 1:07cv1198 (AJT/TRJ) (E.D. Va. Nov. 10, 2010) ("[T]he extent of the government's knowledge and its conduct in light of what it knew remains relevant considerations to the Court in considering an appropriate civil penalty."); Neal J. Wilson, *The Government Knowledge "Defense" to Civil False Claims Actions*, 24 PUB. CONT. L.J. 43, 60-61 (1994) ("[T]he Government knowledge defense may not be successful in precluding False Claims Act liability in every instance, even where the facts permit. The defense, however, should nonetheless be recognized as an effective means of precluding, or greatly reducing, the measure of actual damages under the Act, perhaps the paramount concern of targeted individuals or contractors." (collecting cases)).

[33] Englund v. Los Angeles County, 2006 WL 3097941, at *12 (E.D. Cal. 2006); *see also Southland Mgmt. Corp.*, 326 F.3d at 682 n.8 (Jones, J. concurring) ("[t]he governments knowledge and acquiescence in its contractor's actions" is 'highly relevant' to determining FCA liability"); *Mylan Labs.*, 608 F. Supp.2d 127, 152 (D. Mass. 2008) ("a government knowledge defense is viable because the government decided to continue using WACs as a policy matter"); United States *ex rel*. Gudur v. Deloitte, 512 F. Supp.2d 920, 932 (S.D. Tex.

"rests upon the depth of the government's knowledge of the facts underlying the allegedly false claims and the degree to which the government invites the claim."[34] A valid inquiry into the depth of the government's knowledge, acquiescence, or decision-making, of course, requires a reasonably complete factual record from the files of relevant governmental entities.

The subject matter underlying the allegations of three recent areas of FCA activity—pharmaceutical pricing, the "off-label" marketing of pharmaceuticals, and disputes over Medicaid program funding—demonstrates the increased relevance of evidence from government entities in today's expanding FCA environment.

A. Average Wholesale Price Litigation

The "average wholesale price," or "AWP," benchmark reportedly was created in the late 1960's by two pharmacists working for the state of California as a way to more efficiently process pharmacy claims submitted to the state's Medicaid program.[35] While a novel concept, a list of AWPs did not actually exist at the time.[36] Shortly thereafter, a publication called the Drug Topics *Red Book* filled the void by being the first to publish AWPs; the publication stated the AWP prices had been "independently obtained and calculated by *Red Book*'s editorial staff from a representative group of wholesalers located throughout the country."[37] Despite the "average wholesale price" moniker, over the next two decades those within the pharmaceutical industry—including government officials—came to understand that AWPs represented "list prices" which did not account for discounts that most pharmacists and physicians negotiated with drug manufacturers and wholesalers.[38] Intense price competition in the generic drug industry led to increasingly large discounts, widening the "spread" between reported AWPs and actual sales prices

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2007) ("no violation exists where relevant government officials are informed of the alleged falsity, thus precluding a determination that the government has been deceived").

[34] United States *ex rel*. Burlbaw v. Orenduff, 548 F.3d 931, 952 (10th Cir. 2008) (also holding that "neither the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference"); Wilson, *supra* note 32, at 57 ("Successful application of the defense where Government assent is unexpressed obviously turns in large part on the quantum and quality of evidence demonstrating presubmittal consent.")

[35] Michael L. Koon, *AWP Through the Looking Glass: Industry Litigation by Definition*, FOR THE DEFENSE, at 47, October 2005, http://www.shb.com/practiceareas/Pharma/Pubs/IndustrywideLitigation_2005.pdf.

[36] *See id.*

[37] *See id*.

[38] *See generally* Krause, *supra* note 19, at 266; OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., A-06-40216, CHANGES TO THE MEDICAID PRESCRIPTION DRUG PROGRAM COULD SAVE MILLIONS, (Sept. 1984) ("Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price. . . . The use of AWP in determining Medicaid reimbursement for drugs has been a problem that HCFA has recognized for some time. However, efforts to date to control the problem have not been successful.")

paid by pharmacists and physicians.[39] Those in the industry joked that "AWP" meant "Ain't What's Paid."[40]

Nonetheless, third-party payors, including the Medicare and Medicaid programs, continued to base their payments to pharmacies and physicians who provided drugs to patients upon the AWPs reported in the *Red Book* and other pricing "compendia"—but usually with only a small discount, typically 5-10%, off the AWP.[41] The applied discount usually did not reduce Medicare or Medicaid payments to the costs paid by pharmacists and physicians to acquire the drugs.[42] Providers were allowed to pocket the difference, which they argued was appropriate given untimely and inadequate reimbursement provided for related services.[43] Although this state of affairs was generally well known, efforts at the state and federal level to more closely align payments with provider acquisition costs were repeatedly rejected—often with little to no explanation.[44] The situation developed

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[39] OFFICE OF THE INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., A-06-97-00011, MEDICAID PHARMACY—ACTUAL ACQUISITION COST OF GENERIC PRESCRIPTION DRUG PRODUCTS, 5 (Aug. 1997) (finding that generic drugs sold at an average discount of 42.5% off reported AWP).

[40] E.M. Kolassa, *Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents*, J. OF PAIN & SYMPTOM MGMT., May 1994, at 235-43; Bill Alpert, *Hooked on Drugs*, BARRON'S, June 10, 1996.

[41] OFFICE OF THE INSPECTOR GENERAL, *supra* note 39. (finding most common discount used by state Medicaid programs was 10% off of AWP).

[42] *Id.* (calculating savings on generic drugs that could be achieved by state Medicaid programs if they reimbursed at a higher 42.5% discount off of AWP instead of the commonly used 10% discount).

[43] *See, e.g.*, OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., A-06-95-00068, REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES at App. 4, (July 1996) (Montana Medicaid agency: "In Montana we currently believe that the dispensing fee is below the cost to dispense because of the cap on dispensing fees that is currently in place and has been for many years."); OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., A-06-95-00072, REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES at App. 4, (Nov. 1996) (Virginia Medicaid agency: "the acquisition cost is just one factor involved in pharmacy reimbursement policy or methodology").

[44] Krause, *supra* note 19, at 266; OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., A-06-00-00023, MEDICAID PHARMACY—ACTUAL ACQUISITION COST OF BRAND NAME PRESCRIPTION DRUG PRODUCTS at 1-4, (Aug. 2001) (estimating savings of over $1 billion that could be achieved on the 200 brand drugs with the highest Medicaid expenditures if states modified their AWP discount levels); OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., A-06-01-00053, MEDICAID PHARMACY—ACTUAL ACQUISITION COST OF GENERIC PRESCRIPTION DRUG PRODUCTS 5, (March 2002) (estimating savings of $470 million that could be achieved on the 200 generic drugs with the highest Medicaid expenditures if states modified their AWP discount levels). Congress finally changed the reimbursement system for most Medicare drugs in the Medicare Modernization Act of 2003, moving to an "average sales price" system. *See* CONG. RESEARCH SERV., RL31199, MEDICARE: PAYMENTS TO PHYSICIANS 24 (Jan. 2008). At the same time, however, Congress increased the payments to physicians for administering drugs.

into a major policy issue, with President Clinton even commenting on it in a December 1997 radio address.[45]

Intrigued by this flaw in reimbursement policy—something President Clinton referred to as "waste and abuses [that] aren't even illegal"—relators and state and federal prosecutors saw opportunity. Prosecutors saw a mechanism to fix an imperfect reimbursement system. Relators and plaintiffs' counsel saw the potential for huge awards on millions of allegedly "false" claims, as each drug reimbursement claim could be considered a false claim. Plaintiffs set their litigation sights not on the providers who pocketed the drug margin, but instead on upon pharmaceutical manufacturers. While the manufacturers did not typically set the AWP—and there was no statute or regulation defining or establishing duties upon manufacturers in connection with AWP—plaintiffs argued that manufacturers nonetheless controlled the setting of AWP and therefore "caused" the submission of "false" claims by pharmacists and physicians.[46] In addition to statutory penalties, plaintiffs sought the "spread" paid to providers—alleged "overpayments"—as damages from manufacturers. Over the last decade, numerous AWP-related lawsuits were filed, resulting in substantial recoveries.[47] Many suits are still ongoing.

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[45] President Clinton remarked:

> Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system. Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs, overpayments that cost taxpayers hundreds of millions of dollars. Such waste is simply unacceptable. Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price, for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price.

President William Jefferson Clinton, The President's Radio Address at the White House (Dec.13, 1997), *in* 33 WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS 2033, 2033-34 (Dec. 22, 1997), *available at* http://www.gpo.gov/fdsys/pkg/WCPD-1997-12-22/html/WCPD-1997-12-22-Pg2033-2.htm.

[46] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-01-1142T, MEDICARE PART B DRUGS: PROGRAM PAYMENTS SHOULD REFLECT MARKET PRICES (Sept. 21, 2001) ("The term AWP is not defined in law or regulation, so the manufacturer is free to set AWP at any level, regardless of the actual price paid by purchasers.").

[47] The federal government first intervened in AWP-related litigation in 2001, when Bayer and TAP Pharmaceuticals settled criminal and civil claims that included allegations relating to AWP manipulation. Koon, *supra* note 35. Over the next decade, the federal government has settled several other *qui* tam cases relating to AWP. *See, e.g.*, Press Release, U.S. Dep't of Justice, Bayer To Pay $14 Million To Settle Claims For Causing Providers To Submit Fraudulent Claims To 45 State Medicaid Programs (Jan. 23, 2001), *available at* http://www.justice.gov/opa/pr/2001/January/039civ.htm; 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. 2, 2001), *available at* http://www.justice.gov/opa/pr/2001/October/513civ.htm; Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty To Healthcare Crime; Company Agrees To Pay $355 Million To Settle Charge (June 20, 2003), *available at* http://www.justice.gov/opa/pr/2003/June/03_civ_371.htm; Press Release, U.S. Dep't of Justice, Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), *available at* http://www.justice.gov/opa/pr/2007/September/07_civ_782. html; Press Release, U.S. Dep't of Justice, Pharmaceutical Manufacturers to Pay $421.2 Million to Settle False

Pharmaceutical manufacturers have defended plaintiffs' claims on numerous grounds, many that relied principally on evidence—to the extent it still exists—from state and federal government entities.[48] Indeed, in the closing argument of one state AWP case, defense counsel noted that "[m]ost of . . . our defense is built on witnesses from the state."[49] Manufacturers have pointed to widespread knowledge of spreads and concomitant inaction by government entities as evidence that government programs acquiesced in the payment of spreads for a variety of reasons, including the need to subsidize inadequate dispensing fees, encourage the use of certain drugs, or ensure access to care from pharmacy and physician providers who threatened to leave government programs if reimbursements were reduced.[50] One

Claims Act Cases (Dec. 7, 2010), *available at* http://www.justice.gov/opa/pr/2010/December/10-civ-1398.html (Roxane Laboratories, Inc., Abbott Laboratories, Inc., and B. Braun Medical Inc.); Press Release, U.S. Dep't of Justice, Pharmaceutical Manufacturer to Pay $280 Million to Settle False Claims Act Case (Dec. 20, 2010), *available at* http://www.justice.gov/opa/pr/2010/ December/10-civ-1464.html (Dey Inc., Dey Pharm L.P. and Dey L.P. Inc.). Numerous states have also instituted and received significant recoveries in AWP-related actions. *See, e.g.*, Press Release, $89 Million Settlement Reached in Alabama Medicaid Fraud Case (May 22, 2009), *available at* http://www.beasleyallen.com/news/$89-million-settlement-reached-in-Alabama-Medicaid-fraud-case; Press Release, California Office of Attorney General, Brown Settles $21.3 Million Medi-Cal Fraud Suit with Pharmaceutical Giant Schering-Plough (Dec. 17, 2009), *available at* http://www.contractormisconduct.org/ass/contractors/178/cases/1261/1792/schering-plough-albuterol_calpr.pdf; Press Release, Jack Conway, Office of the Kentucky Attorney General, Attorney General Conway Announces $10 Million Settlement With Drug Company (Aug. 13, 2010), *available at* http://migration.kentucky.gov/Newsroom/ag/tevaawpsettlement.htm; Press Release, Hawaii Department of the Attorney General, Hawai'i Reaches $82 Million Settlement with Pharmaceutical Companies (Oct. 6, 2020), *available at* http://hawaii.gov/ag/main/press_releases/2010/2010-21.pdf.

[48] Courts have almost uniformly rejected government attempts to limit discovery from governmental entities in AWP mattes. *See, e.g.*, Agreed Orders on Mot. in Limine, Commonwealth of Kentucky *ex rel.* Jack Conway, Attorney General v. Alpharma NSPD, Inc., No. 04-cr-1487, slip op. (June 24, 2009) (on file with author) (denying Kentucky's motion to exclude "government knowledge evidence" and permitting defendants to introduce "evidence of cross-subsidization" and "evidence that pharmacy participation in the Medicaid program was a concern"); Decision and Order on Plaintiffs Motion Partial Summary Judgment Against Defendants Novartis, AstraZeneca, Sandoz, and Johnson & Johnson, State of Wisconsin v. Abbott Laboratories, No. 04 CV 1708, slip op at 6 (Wis. Cir. Ct. May 20, 2008) (on file with author) ("Plaintiff's argument that '[a]n untrue statement is untrue regardless of whether the listener knows it is untrue' . . . begs the question. How is a statement 'untrue' in the first place, if the speaker and listener are using terms they mutually understand because they have agreed on their meaning- that is, they have together developed the definitions, either expressly or tacitly, such that they have a common understanding?").

[49] Trial Tr. at 3909, Commonwealth of Pa. v. Bristol Myers Squibb Co., No. 212 MD 2004 (Pa. Commw. Ct. Sept. 7, 2010) (on file with author).

[50] *See generally* Defendants Combined L.R. 56.1 Stmt. of Additional Material Facts Pertinent to the U.S.'s Motion for Partial Summary Judgment Against Defendants., No. 6447, *In re* Pharm. Indus. Average Wholesale Price Litig., MDL 1456, No. 01-CV-12257-PBS (D. Mass. Aug. 28, 2009).

commentator has observed that the use of AWP was a "loophole" that the government did "not yet [have] the political will to close."[51]

These contentions raise disputed factual questions potentially relevant to issues of acquiescence, falsity, causation, materiality, and *scienter* for which evidence from government entities would be critical. Evidence from government entities and their contractors has also been vitally important to questions of damages, including as to whether, and the extent to which, reported AWPs actually impacted the government's payment amount (for example, when Medicare based its payment on a "median" of AWPs across many manufacturers' products).

B. Off-Label Marketing of Pharmaceuticals Litigation

Another notable area where relators and government prosecutors have aggressively used the FCA concerns the "off-label" marketing of prescription drugs. "Off-label" refers to any use of a drug that has not been approved by the FDA.[52] Off-label use is both common and legal, the theory being that the physician is in the best position to evaluate the risks and benefits of using the drug to treat a particular condition.[53] But off-label use can be controversial. Some criticize the practice as lacking in scientific evidentiary support, avoiding the clinical testing necessary for FDA approval, and posing unnecessary safety risks.[54]

While off-label use is legal, drug manufacturers are restricted by Food and Drug Administration regulations promoting drugs for off-label use. Starting with the groundbreaking case of *United States ex rel. Franklin v. Parke-Davis*,[55] which involved the drug Neurontin, relators sought to connect manufacturers' alleged violations of the FDA's regulations with the submission by pharmacists and

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[51] *See* Krause, *supra* note 19, at 273; Marc J. Scheineson, *Lessons From Expanded Government Enforcement Efforts Against Drug Companies*, 60 FOOD & DRUG L. J. 1, 7 (2005) (observing that the government's increased efforts to use fraud statutes "to force settlements by drug and device manufacturers for conduct that was, in large part, viewed by FDA and other agencies as acceptable industry practice until DOJ and OIG began to redefine the regulatory landscape"). *Id.*

[52] *See* Joshua Cohen, Andrew Wilson & Laura Faden, *Off-Label Use Reimbursement*, 64 FOOD AND DRUG L. J. 391, 392 (2009) (discussing how off-label uses commonly originate).

[53] *See* Washington Legal Found. v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000) ("the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties"); Gregory Conko & Henry I. Miller, *Off Target On Off-Label Drugs*, FORBES, May 12, 2010 (stating some estimates indicate that off-label uses account for at least 20% of all prescriptions and as many as half of all prescriptions for cancer and cardiac care); Cohen, et al., *supra* note 52, at 392 (citing report by the National Comprehensive Cancer Network finding 50-75% of all uses of anti-cancer therapy are off-label); Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. LEGAL MED. 365, 365 (1999) (indicating that the American Medical Association reported in 1995 that approximately one-half of all prescriptions were written for off-label uses).

[54] Robert Kaufman, *The Neurontin Controversy: The Saga of Off-Label Drug Regulation Continues* (April 27, 2004), *available at* http://leda.law.harvard.edu/leda/data/638/Kaufman.html; Lansdale, *supra* note 8, at 168; Cohen, et al., *supra* note 52, at 393.

[55] United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp.2d 39, 45 (D. Mass. 2001). According to the court's opinion in *Park-Davis*, approximately 50% of Neurontin's sales in 1996 were attributable to off-label uses. *See id.*

physicians of "false" claims to Medicare and Medicaid programs for off-label drug use. Arguing a theory of FCA liability that the court in *Parke-Davis* noted "t[ook] the parties into territory that is not well charted by the existing decisional law,"[56] the relator claimed that Parke-Davis "engaged in an extensive and far-reaching campaign to use false statements to promote increased prescriptions of Neurontin . . . for off-label uses which caused the filing of false claims for reimbursement by the federal government."[57] The relator's theory of liability, however, hinged largely on the debatable premise that Medicaid did not legally permit—or at least knowingly allow—reimbursement for certain off-label uses not recognized as a "medically accepted indication."[58] The case eventually settled for $430 million, $190 million of which was paid to resolve FCA claims.[59] The Neurontin case would be only the beginning of a wave of high-stakes FCA off-label litigation that continues today, many that have resulted in enormous settlements.[60]

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[56] *Id.* at 53.

[57] *Id.* at 45.

[58] *Id.* at 44-45. Federal law requires states to pay for "covered outpatient" drugs used for a "medically accepted indication," meaning the use is specifically approved by the FDA or "supported" by specified drug compendia. 42 U.S.C. § 1395r-8(k)(6), (g)(1)(B)(i). In a subsequent decision, the court in the Neurontin litigation acknowledged an open question as to whether most states are *permitted* under federal law to reimburse off-label uses that are not "supported" by the compendia. *See* United States *ex rel*. Franklin v. Parke-Davis, Civ. A. No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *7-9 (D. Mass. Aug. 22, 2003). The court did signal, however, that it favored the defendant's position that federal law did *not* prohibit reimbursement. *See id*. Subsequently, CMS appears to have rejected the relator's argument in the Neurontin litigation that federal Medicaid law prohibits reimbursement of off-label prescriptions not "supported" by the compendia. *See* Dec. 6, 2007 Letter from CMS to State of Utah (on file with author), *available at* http://psychrights.org/education/ModelQuiTam/071206CMSRepl2 DStallard.pdf. ("Section 1927(d) of the Act authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act), however, it does not explicitly require them to do so. States are responsible for defining this coverage in their app-roved Medicaid State plan and implementing policies."). *See id.* More recently, relators and government prosecutors have argued that alleged "kickbacks" paid by manufacturers to physicians render off-label claims for reimbursement "false," an argument that was recently rejected—at least for pending claims—by a court. *See* United States *ex rel.* Rost v. Pfizer, Inc., Civ. Action No. 03-11084-PBS, 2010 WL 3554719, at *8-10 (D. Mass. Sept. 14, 2010).

[59] Press Release, U.S. Dep't of Justice, Warner-Lambert To Pay $430 Million To Resolve Criminal & Civil Health Care Liability Relating To Off-Label Promotion (May 13, 2004), *available at* http://www.justice.gov/ opa/pr/2004/May/04_civ_322.htm.

[60] *See, e.g.*, Press Release, U.S. Dep't of Justice, Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008), *available at* http://www.justice.gov/opa/pr/2008/September/08-civ-860.html; Press Release, U.S. Dep't of Justice, Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), *available at* http://www.justice.gov/civil/ocl/cases/Cases/Eli_Lilly/Lilly%20Press%20Release%20Final%2009-civ-038.pdf; Taxpayers Against Fraud Education Fund, *Top 100 FCA Cases*, TAF.ORG, *available at* http://www.taf.org/general-resources/top-100-fca-cases (last visited April 6, 2013); Press Release, U.S. Dep't of Justice, Pharmaceutical Giant AstraZeneca to Pay $520 Million for Off-label Drug Marketing (April 27, 2010), *available at* http://www.justice.gov/opa/pr/2010/April/10-civ-487.html; Press Release, U.S. Dep't of Justice, Novartis Vaccines & Diagnostics to Pay More Than $72

Evidence from governmental entities can also play an important role in the off-label marketing cases. Each state's contemporaneous knowledge and policies regarding reimbursement for off-label use—which may depend on the specific drugs at issue—could be determinative to whether claims for off-label prescriptions are considered "false."[61] Moreover, as noted in a recent article, "state Medicaid databases will yield large amounts of information about how and why the drug was prescribed" and "the state may have access to medical records which may yield evidence about the number of actual off-label prescriptions."[62] The article also notes that "depositions of state-employed pharmacists or physician may further undercut the state's claim that the drug is dangerous or ineffective," particularly since state attorneys general typically do not consult with public health officials prior to filing suit.[63] Discovery from the state might also show that the state previously rejected proposals to restrict off-label use, which would appear inconsistent with the plaintiffs' FCA claims. Indeed, even after numerous lawsuits have alleged that Medicaid programs are not permitted to reimburse off-label uses not listed in the compendia, it appears that most Medicaid agencies continue to do so.[64]

Million to Resolve False Claims Act Allegations Concerning TOBI (May 4, 2010), *available at* http://sanfrancisco.fbi.gov/dojpressrel/ pressrel10/sf050410.htm; Press Release, U.S. Dep't of Justice, Two Johnson & Johnson Subsidiaries to Pay Over $81 Million to Resolve Allegations of Off-Label Promotion of Topamax (Apr. 29, 2010), *available at* http://www.justice.gov/opa/pr/2010/April/10-civ-500.html; *New Whistleblower Law on Medicaid Fraud Signed Today by Governor of Georgia*, WHISTLEBLOWER LAWYER BLOG (May 24, 2007), *available at* http://www.whistleblowerlawyerblog.com/2007/05/new_ whistleblower_law_on_medic_1.html ("Many states have taken action against pharmaceutical companies over 'off-label' marketing of drugs.").

[61] A 2009 report published by the Food and Drug Law Journal entitled "Off-Label Use Reimbursement" highlights the importance of such evidence. *See* Cohen, et al., *supra* note 52. Updating a study published 14 years earlier, the authors surveyed 179 third-party payors administering Medicare and Medicaid pharmacy benefits to examine both their coverage, and criteria for covering, of off-label prescriptions. *Id.* at 397. 20 state Medicaid agencies responded to the survey. *Id*. The study found that "most [public] payors reimburse off-label uses," and that "payors vary considerably both in their policies regarding payment off-label uses, as well as the sources used to justify their reimbursement decisions." *Id.*

[62] *See* Brian C. Anderson & Michael E. Stamp, *Shooting the Messenger: 'Off-Label Marketing' Attacks Against Pharmaceutical Companies by State Attorneys General*, AM. ENTER. INST., *available at* http://www.aei.org/files/2008/05/21/20080522_Andersonpaper.pdf (last visited June 10, 2013).

[63] *Id.* at 13-14.

[64] *See* Cohen, et al., *supra* note 52, at 400; Anderson & Stamp, *supra* note 62, at 12 (citing Julie Schmit, *Drugmaker Admitted Fraud, but Sales Still Flourish*, USA TODAY, Aug. 16, 2004, at 1A ("Indeed, four years after the case was settled, only 4 of 50 state Medicaid programs now require pre-approval of Neurontin prescriptions to ensure that it is being used for FDA-approved purposes. . . . It cannot be doubted that states are aware that they are paying for off-label use of Neurontin. Nor can it be doubted that states have it within their power to avoid payment for off-label use of Neurontin if they really believe it improper, but they refrain from doing so.").

C. Federal Funding Challenges

A final example relates to the politically sensitive topic of how the federal government funds Medicaid. Because the federal government pays at least a majority of Medicaid expenditures, Medicaid can be seen as a mechanism of getting federal dollars into the states.[65] Relators and government prosecutors have recently turned to the FCA in an attempt to curb allegedly abusive schemes in this area. For example, in *United States ex rel. Englund v. Los Angeles County*, the relator sued the County of Los Angeles for allegedly conspiring with the state of California to receive unwarranted Medicaid matching funds.[66] The relator claimed that federal Medicaid matching dollars—paid through so-called "intergovernmental transfers" (IGTs) between the state and local governments—were paid to healthcare providers (including the County) at amounts which exceeded the providers' cost of providing services.[67] The surplus was deposited into the County's general funds and was allegedly "expended for non-Medicaid, and even non-healthcare purposes."[68] The

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[65] *See* Robert B. Helms, *Medicaid: The Forgotten Issue in Health Reform*, HEALTH POLICY OUTLOOK (Am. Enter. Inst. for Pub. Policy Research, Washington, D.C.) (Nov. 6, 2009), *available at* http://www.aei.org/article/health/healthcare-reform/medicaid-the-forgotten-issue-in-health-reform/ ("Since no one state ever pays the full cost of its Medicaid program, each state has an incentive to expand its program when the economy is expanding and state revenues are increasing."); Robert B. Helms, *The Medicaid Commission Report: A Dissent*, (Jan. 12, 2007), *available at* http://www.aei.org/article/society-and-culture/poverty/the-medicaid-commission-report/(describing incentives for states to increase Medicaid spending by virtue of the federal match and a "tug of war" between state and federal governments to control schemes to enhance federal matching); James Frogue, *Medicaid's Perverse Incentives*, STATE FACTOR (July2004) ("The federal match that states receive is open-ended. No matter how much a state spends on Medicaid, the federal government will add on the pre-determined match rate. This creates strong incentives for states to not only spend more on Medicaid, but also to be very creative with what constitutes 'Medicaid' spending so that they can maximize their match.").

[66] Englund v. Los Angeles Cnty, 2006 WL 3097941, at *1 (E.D. Cal. 2006).

[67] *Id.* at *2-4.

[68] *Id.* at *4, 8-9. The court described the essential facts as follows:

> Under SB 1255 certain providers of Medicaid services can seek supplemental Medicaid funding. The County is one such provider. Under SB 1255, IGTs from public entities (such as the County) are used for the non-federal share of the supplemental funds. In other words, at the time at issue in this case, the County would transfer money to the State, which in turn, would use that money to apply for matching funds from the Federal government. Providers such as the County could seek up to 175% of uncompensated costs under SB 1255. The idea was that the State would "put up" part of the funds and then the Federal government would "match" the State's contribution.
>
> Once the State made the SB 1255 payment to the County (which consisted of both the State and Federal shares), the "net" amount would go to the hospitals (the gross payment minus the IGT amount) and the amount of the initial IGT would go to the County's general DHS fund.

Id. at *8.

court noted IGTs were a "controversial" mechanism to "'pull down' federal money'" that was "not necessarily popular with Congress and CMS."[69]

A recent case in which the government intervened, *United States ex rel. Baker v. Community Health Systems, Inc*., presents similar issues.[70] There, plaintiffs contend that New Mexico hospitals made legal, but "non-bona fide" donations to various New Mexico counties that resulted in the state of New Mexico submitting false claims for federal matching dollars to the federal government.[71] Plaintiffs alleged that the "64 Forms" submitted by the state for federal reimbursement dollars were false because they failed to deduct the allegedly "non-bona fide" donations, further contending that defendants "devised a fraudulent scheme" to "receiv[e] back Medicaid payments in the amount of their payments plus triple those amounts from the resulting federal financial participation."[72] For their part, defendants claim the suit is a "funding dispute" between the State of New Mexico and the federal government, and that CMS and state officials were "fully informed of and approved the claims at issue in accordance with applicable statutes and regulations."[73]

In both *Englund* and *Community Health Systems*, evidence from government entities is important and, at least in the *Englund* case, dispositive. In *Englund*, the court granted Defendant's motion for summary judgment based upon "extensive evidence that officials on both the State and Federal levels were well aware of the County's actions and understood the alleged 'scheme' to be legal."[74] For example, the Court cited testimony from CMS Administrator Thomas Scully, who testified that "almost every state was doing that [transferring money to the general fund] to some degree," that he "was very aware of what they were doing all along," and that "everybody in Congress understood it was a total scam, but it happened to be a scam Congress authorized."[75] Similarly, in the *Community Health Systems* litigation, the defendants' pleadings suggest that their defense will rely heavily on the fact that state and federal officials were fully aware of and approved the alleged payments that plaintiffs now label "false."[76] In fact, as discussed more fully below, the

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[69] *Id.* at *2, 16.

[70] United States *ex rel.* Baker v. Cmty. Health Sys., Inc., Civil No. 05-279 WJ/WDS, Slip op. at 6-8, 13-14, 18 (D.N.M. July 7, 2010).

[71] *Id.*

[72] *Id.* at 6; *see generally id.* at 7, 13-14, 18.

[73] United States *ex rel.* Baker v. Cmty. Health Sys., Inc., Civil No. 05-279 WJ/WDS (D. N.M. Aug. 28, 2009) (Memorandum of Law in Support of Defendants Motion to Dismiss the Complaint of the United States in Intervention) *available at* 2009 WL 2823668; Answer and Affirmative Defense of Defendant Community Health Systems, Inc. at ¶¶ 411-13, United States *ex rel.* Baker v. Cmty. Health Sys., Inc., Civil No. 05-279 WJ/WDS (D. N.M. July 21, 2010).

[74] U.S. *ex rel.* Englund v. Los Angeles Cnty., No. CIV S.-04282 LKK/JFM, 2006 WL 3097941, at *12-16 (E.D. Ca. Oct. 31, 2006).

[75] *Id.* at *13-14. The court also cited Congressional testimony from CMS's top Medicaid official, who admitted that he was aware of the practice and believed it was "inappropriate, but . . . not illegal." *Id.* at *15.

[76] Answer and Affirmative Defense of Defendant Community Health Systems, Inc. at ¶¶ 411-17, United States *ex rel.* Baker v. Cmty. Health Sys., Inc., Civil No. 05-279 WJ/WDS (D. N.M. July 21, 2010).

defendants in this case successfully filed a motion for sanctions against the government for failing to preserve its files.[77]

AWP, off-label marketing, and federal funding disputes are only a few examples of the increasingly broad and creative ways that relators and government prosecutors have used the FCA to challenge perceived flaws or "loopholes" in government reimbursement policy. Other examples FCA claims relate to Medicare "outlier" payments, suits alleging deceptive practices by pharmacy benefit managers (PBMs) concerning drug "switching" and the retention of Medicaid drug rebates, and cases alleging that healthcare equipment manufacturers overcharged government programs.[78] These actions have also led to substantial settlements.[79] These cases, too, involve allegations where evidence from governmental entities can be critical.[80]

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[77] *See* United States *ex rel.* Baker v. Cmty. Health Sys., Inc., Civil No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 146865 (D. N.M. Aug. 31, 2012).

[78] For a discussion of the Medicare outlier allegations, *see* Elizabeth A. Weeks, *Loop-holes: Opportunity, Responsibility, or Liability*, 35 J.L. MED. & ETHICS 320, 322-23 (Summer 2007); R. Brent Rawlings & Hugh E. Aaron, *The Effect of Hospital Charges On Outlier Payments Under Medicare's Inpatient Prospective Payment System: Prudent Financial Management or Illegal Conduct?*, 14 ANN. HEALTH L. 267 (Summer 2005); *see* DAVID A. BALTO, PROACTIVE LITIGATION AGAINST PBMS (2006), *available at* http://www.ncpanet.o rg/pdf/legal_summary_suits_vs_pbms.pdf (discussing state and federal false claims act claims relating to PBMs); *see What Health Reform Won't Cure*, ZIMBIO.COM (Dec. 18, 2009), http:// www.zimbio.com/BusinessWeek/ articles/tyQqH6BDB7T/WHAT+HEALTH+REFORM+W ON+T+CURE (discussing FCA suit against Siemens for allegedly overcharging the Department of Veterans Affairs for medical equipment).

[79] *See, e.g.*, Press Release, U.S. Dep't of Justice, Tenet Healthcare Corporation To Pay U.S. More Than $900 Million To Resolve False Claims Act Allegations (June 29, 2006), *available at* http://www.justice.gov/opa/pr/2006/June/06_civ_406.html; Press Release, U.S. Dep't of Justice, Largest Health Care System In New Jersey To Pay U.S. $265 Million To Resolve Allegations Of Defrauding Medicare (June 15, 2006), *available at* http://www.justice. gov/opa/pr/2006/June/06_civ_373.html; Press Release, U.S. Dep't of Justice, Houston's Methodist Hospital To Pay U.S. More Than $9 Million To Resolve Allegations Of Over-charging Medicare (Mar. 26, 2009), *available at* http://www.justice.gov/opa/pr/2009/M arch/09-civ-274.html; Press Release, U.S. Dep't of Justice, New Jersey Hospital to Pay $6.35 Million to Resolve Allegations of Inflating Charges to Obtain Higher Medicare Reim-bursement (Mar. 19, 2010), *available at* http://newark.fbi.gov/dojpressrel/pressrel10/nk 031910.htm; Press Release, U.S. Dep't of Justice, Parent Company of Two New Jersey Hospitals to Pay U.S. $7.95 Million to Settle False Claims Act Allegations (Dec. 15, 2009), *available at* http://www.justice.gov/opa/pr/2009/December/09-civ-1350.html; Press Release, U.S. Dep't of Justice, Cathedral Healthcare System to Pay U.S. $5.3 Million to Resolve Allegations Involving Inflated Charges to Obtain Higher Medicare Reimbursement (Mar. 4, 2008), *available at* http://www.justice.gov/opa/pr/2008/March/ 80_civ_167.html; Balto, *supra* note 78 (discussing settlements of FCA cases involving PBMs).

[80] *See, e.g.*, Memorandum of Law in Support of Defendant's Motion for Summary Judgment at 1, 5, States *ex rel.* Thomas v. Siemens Medical Solutions USA, Inc., Civ. No. 99-4414-TJS (E.D. Pa. Oct. 22, 2010) (quoting the court's statement that "the greatest discovery you are going to get is what the government tells you," and arguing that discovery showed "the VA accepted varying interpretations of, and disclosures on, the DPI—after extensive audits and with full understanding of the very pricing information [relator] contends was fraudulently misstated and omitted").

In sum, as FCA allegations and legal theories continue to evolve and expand, evidence on what responsible government officials understood, accepted, and intended becomes increasingly critical to resolving these disputes fairly and in the interests of justice.

IV. UNIQUE ISSUES OF SPOLIATION IN FALSE CLAIMS ACT LITIGATION

The integrity of our judicial system depends on the preservation of relevant evidence. Judge Allegra of the United States Court of Federal Claims put it well: "Aside perhaps from perjury, no act serves to threaten the integrity of the judicial process more than the spoliation of evidence," as "when critical documents go missing, judges and litigants alike descend into a world of ad hocery and half measures—and our civil justice system suffers."[81] While there is no dispute that "[i]t is the duty of the United States, no less than any other party . . . to ensure . . . that documents relevant to a case are preserved,"[82] FCA cases present special challenges.

A. An Unregulated Seal Period and Generous Statute of Limitations Can Delay False Claims Act Cases Indeterminately.

A relator-instituted FCA *qui tam* action must be filed under seal.[83] By statute, the case remains under seal for at least 60 days, during which time the government is supposed to conduct an investigation to decide whether to intervene.[84] While Congress believed this 60-day period would be adequate in "the vast majority of cases,"[85] in practice the government may, and usually does, ask the court to extend the seal.[86] Repeated extension requests—often for six months at a time—are now the rule.[87]

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[81] United Med. Supply Co. v. United States, 77 Fed. Cl. 257, 258-59 (2007). Magistrate J. Schenkier writes:

> Parties and attorneys frequently are called upon to preserve and produce documents that are against their interest in a particular case. And when they do so, the parties and the attorneys uphold the integrity of our litigation system and inspire confidence in it. Conversely, when a charge is made that relevant information has been destroyed, and especially when a charge is made of intentional destruction, it is a charge that strikes at the core of our civil litigation system.

Danis v. USN Commc'ns, Inc., No. 98 C 7482, 2000 WL 1694325, at *1-2 (N.D. Ill. Oct. 23, 2000).

[82] *United Med. Supply*, 77 Fed. Cl. at 274.

[83] *See* 31 U.S.C. § 3730(b)(2).

[84] *Id.*

[85] S. REP. NO. 99-345, at 25 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5290.

[86] 31 U.S.C. § 3730(b)(3).

[87] *See False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits*, U.S. DEP'T OF JUSTICE, https://www.doioig.gov/docs/falseclaimsact.pdf (last visited April 6, 2013).

The FCA's increased popularity, coupled with government staffing shortfalls and other strategic factors, has produced a sizeable backlog of cases sitting under seal.[88] A January 2011 letter from the DOJ to Senator Charles Grassley indicated that there were 1,341 FCA *qui tam* cases under seal still awaiting the DOJ's decision on intervention.[89] Some cases, particularly high-stakes cases, have sat under seal for several years.[90] Congress did not intend this unfortunate backlog. The legislative history to the 1986 FCA amendments states that a "mere[ ] showing that the Government was overburdened" would not justify extending the seal, cautioning that the "Government should not, in any way, be allowed to unnecessarily delay lifting of the seal from the civil complaint or processing of the qui tam litigation."[91]

Courts, and even counsel representing relators, have expressed dismay about inordinate delays in FCA cases. In the AWP litigation, Judge Saris stated:

> These long delays are quite troubling. Evidence spoils, memories fade, and prejudice may result. In my experience, the government routinely files for multiple extensions of time, frequently citing as the reason the size of the case and lack of resources to investigate adequately. At some point, though, the government must fish or cut bait.[92]

Similarly, another court commented that "the multiple interventions [by the government] . . . [which] appear to the Court to have no other justification than to allow the government to investigate and settle the multiple claims at its own pace, selectively carving out those claims that were easiest to settle while keeping the

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[88] *See* Carrie Johnson, *A Backlog of Cases Alleging Fraud, Whistle-Blower Suits Languish at Justice*, WASH POST (July 2, 2008), http://www.washingtonpost.com/wp-dyn/content/article/2008/07/01/AR2008070103071.html ("By its own account, the 75-lawyer unit in Washington that reviews the sensitive lawsuits is overloaded and understaffed. Only about 100 cases a year are investigated by the team, which works out of the commercial litigation branch of Justice's civil division.").

[89] *See* Letter from J. Esquea, Asst. Sec. U.S. Dep't of Health and Human Res. & R. Weich, Asst. Att'y Gen. U.S. Dep't of J. to Sen. Grassley (Jan. 14, 2011), at 13, *available at* http://quitam-lawyer.com/sites/quitam-lawyer.com/files/DOJ-HHS-joint-letter-to-Grassley.pdf.

[90] *See, e.g.*, *In re* Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp.2d 389, 398-99 n.6 (D. Mass. 2007) (action remained under seal for more than ten years); United States v. Baylor Univ. Med. Ctr., 469 F.3d 263, 266 (2d Cir. 2006) (government made sixteen separate requests to extend the seal over an eight-year period); United States *ex rel.* Health Outcomes Techs. v. Hallmark Health Sys.,Inc., 409 F. Supp.2d 43, 50 (D. Mass. 2006) ("The government's investigation dragged on incessantly, and with respect to these particular hospital-defendants seven years, until it chose officially to intervene."); *How the False Claims Act Works*, WARREN BENSON LAW GROUP, *available at* http://www.warrenbensonlaw.com/how-it-works/ ("Your False Claims Act lawsuit will typically remain sealed for up to 2 to 3 years, although we have seen cases sealed for as many as 9 years before the public has access to the case filing.").

[91] S. REP. NO. 99-345, at 24-25 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5289-5290. The legislative history also indicates that, by "providing for sealed complaints, [Congress] did not intend to affect defendants' rights in any way." *Id.* at 8.

[92] *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d at 402 n.6.

remaining defendants in limbo until it chose to act against them."[93] Recently, some courts have become so frustrated with government foot-dragging that they have unsealed the relator's complaint before the government's decision on intervention.[94]

Normally, statutes of limitations serve to prevent stale claims. "Such statutes 'promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence has been lost, memories have faded, and witnesses have disappeared.'"[95] The FCA's statute of limitations, however, is very generous to the government:

> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.[96]

Thus, even before the operation of the "relation-back" doctrine, a defendant could be subject to liability for conduct that occurred ten years ago.[97] But under the relation-back doctrine, liability might reach back even further, particularly in cases with a lengthy DOJ investigation. Prior to the 2009 FERA amendments, courts were split on whether a government's complaint-in-intervention could relate-back to the relator's under seal complaint.[98] But FERA now provides that the government's

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[93] United States v. St. Joseph's Reg'l Health Ctr., 240 F. Supp. 2d 882, 888 (W.D. Ark. 2002). *See also Health Outcomes*, 409 F. Supp. 2d at 50 ("The government's investigation dragged on incessantly, and with respect to these particular hospital-defendants seven years, until it chose officially to intervene."); *War Profiteering And Other Contractor Crimes Committed Overseas: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary*, 110th Cong. 41 (2007) (statement of Alan Grayson, whistleblower attorney) ("To prevent the abuse of this sealing provision, which is only supposed to be in effect for 60 days—but, in this case, 60 days becomes 60 weeks and almost 60 months—there needs to be a firm limit on extensions of the seal. Clearly, 1 year is enough. The seal is meant to help to uncover fraud, not to bury it."); Johnson, *supra* note 88 (noting district court judge hearing FCA case "blasted civil division lawyers for 'doing virtually nothing' to follow up for four years after [relator] brought forward allegations in 1995 about bid rigging on construction contracts in Egypt," which led to 'loss of evidence, fading memories, [and] disappearance of documents'").

[94] *See* Sheri Qualters, *Cases Deluge Boston Court, Federal Judges Have Begun to Unseal Idling False Claims Act Suits*, NAT'L L. J. (Aug. 1, 2011), *available at* http://www.fcaalert.com/uploads/file/Qui%20Tam%20Article.pdf (citing decisions by courts in the District of Massachusetts and the Eastern District of Pennsylvania to unseal, respectively, 25 and 2 cases before the government's decision on intervention).

[95] Burnett v. New York Cent. R.R. Co., 380 U.S. 424, 428 (1965) (citations omitted).

[96] 31 U.S.C. § 3731(b) (2010).

[97] *Id.*

[98] *See, e.g.*, United States v. Baylor Univ. Med. Ctr., 469 F.3d 263, 268 (2d Cir. 2006) (denying relation-back); United States *ex rel.* Miller v. Bill Harbert Int'l. Const., Inc., Civil Action No. 95-1231 (RCL), 2007 WL 851855, at *2 (D.D.C. Mar. 14, 2007) (rejecting Baylor holding) (citations omitted); United States *ex rel.* Sikkenga v. Regence Bluecross Blueshield

complaint will relate back to the relator's complaint so long as the government's complaint arises out of the same conduct, transactions, or occurrences set forth in the relator's complaint.[99] Thus, with the relator's initial complaint serving as a place-holder for statute of limitations purposes, there is little incentive for the government to make its intervention decisions on a timely basis. There is no simply no established mechanism to force the DOJ to "fish or cut bait" in FCA cases.[100]

If anything, the FCA's unregulated seal period encourages government delay. In contrast to non-FCA cases, where defendants will immediately issue document requests, interrogatories, and deposition notices while the evidence is fresh, the government enjoys an open-ended period of one-sided discovery during the seal period. While the defendant in FCA cases has no ability to serve discovery during the seal period, there are no such constraints on plaintiffs. This provides the plaintiff an unparalleled opportunity to build its case while evidence is fresh, including the ability to contact key witness and persuade them with their litigation theories.[101] One court disturbed by this state of affairs commented, "the government appears to be fully engaged in its discovery, without giving the defendants the opportunity even to answer the complaint," including "criss-crossing the country" doing "investigate interviews" with "numerous current and former [defendant] employees and government personnel."[102]

An extended seal period might also allow the government to increase its damages. For example, in the AWP litigation the government sought damages relating to claims submitted (and paid) for several years after the relator filed its initial complaint.[103] Generally speaking, a party is not permitted to recover damages after it becomes aware of the alleged wrongdoing and has had a reasonable

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of Utah, 472 F.3d 702 (10th Cir. 2006) (rejecting argument that FCA action commences when government unseals the complaint and files a complaint-in-intervention); United States *ex rel.* Parikh v. Premera Blue Cross, No. CV01-0476 MJP, 2007 WL 1031724, at *3-4 (W.D. Wash. Apr. 3, 2007) (holding an FCA action commences, and the statute of limitations is tolled, when relator files initial complaint).

[99] 31 U.S.C. § 3731(c) (West 2010).

[100] *In re* Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 389, 402, n.6 (D. Mass. 2007).

[101] Abbott Laboratories Inc.'sMemorandum inSupport of Its Motion For Partial Summary Judgment at 29-30, Dkt. No. 6186, In re Pharm. Indus. Average Wholesale Price Litig., MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. June 26, 2009) (In the federal AWP litigation, the government's motions for extension (eventually unsealed after motions practice) depict substantial discovery efforts by government investigators during the under seal period. These efforts included "pressing defendants to produce responsive documents," "creating an electronic database for storage and review of the thousands of documents," "shar[ing] . . . documents" with Medicaid officials, "conducting witness interviews across the country," and retaining "teams of accounting and data analysis experts.").

[102] United States ex rel. Costa v. Baker & Taylor, Inc., 955 F. Supp. 1188, 1190 (N.D. Cal. 1997).

[103] *See* United States' Common Memorandum of Law in Support of Cross-Motions from Summary Judgement and in Opposition to the Defendants' Motions for Summary Judgment at 36-37, Dkt. No. 6440, In re Pharm. Indus. Average Wholesale Price Litig., MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. Aug. 28, 2009).

opportunity to stop relying on the alleged wrongdoing.[104] But the government might argue that it has no obligation to "mitigate" damages under the FCA and that its knowledge of the fraud (even by virtue of a filed *qui tam* complaint) does not preclude recovery.[105] The mere possibility of continuing treble damages would seem not to promote timely action.[106] Indeed, in the *Community Health Systems* litigation, the defendants have contended that the government suppressed certain reports "in order to create additional damages."[107]

B. The Lack of a Clear "Trigger Date" Can Delay Preservation Efforts.

It is now commonly accepted that "[o]nce a party reasonably anticipates litigation, it is obligated to suspend its routine document retention/destruction policy and implement a 'litigation hold' to ensure the preservation of relevant documents."[108] The duty is triggered "not only during litigation," but also when litigation is "reasonably foreseeable."[109] When, exactly, litigation was "reasonably

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[104] A seminal case on this point is a 1886 case from the Minnesota Supreme Court, which held: "[T]o allow a person who has discovered the fraud while the contract is still wholly executory to go on and execute it, and then sue for the fraud, looks very much like permitting him to speculate upon the fraud of the other party. It is virtually to allow a man to recover for self-inflicted injuries." Thompson v. Libby, 31 N.W. 53, 53 (Minn. 1886). *Accord, e.g.*, Thor Power Tool Co. v. Weintraub, 791 F.2d 579, 585 (7th Cir. 1986) ("[g]enerally, a defrauded party cannot recover damages for the period after the victim discovers the fraud"); Slotkin v. Citizens Cas. Co. of N.Y., 614 F.2d 301, 313 (2d Cir. 1979) (noting that "[t]his rule prevents a plaintiff from recovering damages for 'self inflicted' injury"); Sanitoy, Inc. v. Shapiro, 705 F. Supp. 152, 156 (S.D.N.Y. 1989) ("Many cases have held that if a plaintiff continues to deal with a defendant after discovering the truth of the defendant's misrepresentations, the plaintiff waives any fraud claim for damages arising subsequent to the discovery.").

[105] *See supra* note 103.

[106] The Supreme Court has recognized the perverse incentives that exist in a situation where plaintiff might seek to recover treble damages for ongoing conduct. In holding that the plaintiff in a private antitrust matter could not recover damages after it was aware of the fraud, the Court reasoned that to allow otherwise would "permit plaintiffs who know of the defendant's pattern of activity simply to wait, 'sleeping on their rights,' as the pattern continues and treble damages accumulate, perhaps bringing suit only long after the 'memories of witnesses have faded or evidence is lost.'" Klehr v. A.O. Smith Corp., 521 U.S. 179, 186-88 (1997) (quoting Wilson v. Garcia, 471 U.S. 261, 271 (1985)).

[107] United States *ex rel.* Baker v. Cmty. Health Sys., Civil No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 146865, at *23-24 (D.N.M. Aug. 31, 2012).

[108] Zubulake v. UBS Warburg LLC, 220 F.R.D. 212, 218 (S.D.N.Y. 2003). Even prior to Judge Scheindlen's landmark opinions in *Zubulake*, courts generally required parties to take affirmative action once a duty to preserve evidence was triggered. *See, e.g.*, Danis v. USN Communications, No. 98C7482, 2000 WL 1694325, at *32 (N.D. Ill. Oct. 23, 2000) (duty to preserve must be "discharged actively"); Nat'l Ass'n of Radiation Survivors v. Turnage, 115 F.R.D. 543, 557-58 (N.D. Cal 1987) ("The obligation to retain discoverable materials is an affirmative one; it requires that the agency or corporate officers having notice of discovery obligations communicate those obligations to employees in possession of discoverable materials.").

[109] Silvestri v. Gen. Motors Corp., 271 F.3d 583, 590-91 (4th Cir. 2001); *see also* Blinzler v. Marriott Int'l, Inc., 81 F.3d 1148, 1159 (1st Cir. 1996); The Sedona Conference, The Sedona Conference Commentary on Legal Holds: The Trigger and the Process 5 (2007),

foreseeable" depends on the facts of each case, and courts do not always agree on even general standards. Some courts hold litigation must be "probable" or even "imminent"—not merely "a possibility"—before the duty to is triggered.[110] Other courts reject the "probable" standard in favor of the traditional "reasonably anticipated" standard.[111] Of course, the likelihood of litigation (as opposed to an out-of-court resolution) depends on the parties' respective views of the dispute. If a pre-litigation settlement is unlikely, the duty to preserve would likely attach at an earlier period of time.

Once a FCA *qui tam* case is filed by the relator, not only is litigation "reasonably anticipated," some sort of litigation—which the government may seek to relate back to for statute of limitations purposes—has actually been filed. There is some precedent suggesting that a relator's complaint may trigger a duty on the government to preserve evidence. In *Miller v. Holzmann*, an intervened case relating to bidding on waste water treatments in Egypt, Magistrate Facciola found that the government spoliated various files relating to its investigation of the alleged misconduct. Magistrate Facciola found that "it cannot be seriously argued that [the lost files] did not contain information relevant to this case and there was no duty to preserve it once relator filed his complaint."[112]

The court in the *Community Health Systems* litigation also addressed this question. There, the court tersely rejected the government's claim that its duty to preserve did not arise "until the very day" its notice of intervention was filed on February 20, 2009.[113] The court found that even under the Tenth Circuit's more lenient "imminent" standard, the government had a duty to preserve once the defendants had rejected a settlement offer several months earlier.[114] The court also

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available at http://sos.mt.gov/Records/committees/erim_resources/C%20-%20Legal%20Holds.pdf.

[110] *See* Cache La Poudre Feeds, LLC v. Land O'Lakes, Inc., 244 F.R.D. 614, 621 (D. Colo. 2007) ("While a party should not be permitted to destroy potential evidence after receiving unequivocal notice of impending litigation, the duty to preserve relevant documents should require more than a mere possibility of litigation."); Hynix Semiconductor Inc. v. Rambus, Inc., 591 F. Supp.2d 1038, 1061-62 (N.D. Cal. 2006) (holding litigation must be "probable," rather than "a possibility," and the "path to litigation" must be "clear" and "immediate"); Henkel Corp. v. Polyglass USA, Inc., 194 F.R.D. 454, 456 (E.D.N.Y. 2000) (finding the duty to preserve arises when litigation is "'likely to be commenced'") (quoting Turner v. Hudson Transit Lines, Inc., 142 F.R.D. 68, 73 (S.D.N.Y. 1991)); Turner v. Public Serv. Co. of Colo., 563 F.3d 1136, 1149 (10th Cir. 2009) (applying "imminent" standard).

[111] *See* Goodman v. Praxair Services, Inc., 632 F. Supp.2d 494, 509, n.7 (D. Md. 2009) ("This Court declines to follow the *Cache* ruling, as the law surrounding the duty to preserve is well-settled in the Fourth Circuit."); Samsung Elecs. Co., Ltd. v. Rambus, Inc., 439 F. Supp.2d 524, 568 (E.D. Va. 2006) ("[T]he point at which litigation becomes probable does not necessarily correspond with when a party anticipated, or reasonably should have anticipated, litigation."), *vacated on other grounds*, 523 F.3d 1374 (Fed. Cir. 2008), *cert. denied*, U.S. ----, 129 S. Ct. 279, 172 L. Ed. 2d 149 (2008).

[112] Miller v. Holzmann, No. 95-01231, 2007 WL 172327, at *3-6 (D.D.C. Jan. 17, 2007).

[113] *See* United States *ex rel.* Baker v. Cmty. Health Sys., Civil No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 146865, at *14-20 (D.N.M. Aug. 31, 2012).

[114] *See id.* at *17.

observed that while the government had earlier instructed the defendants to preserve documents, it "did not impose a similar obligation on itself."[115]

Apart from these decisions, however, there is little guidance in written opinions on the extent to which a relator's complaint triggers a duty to preserve evidence. Although the government is the "party in interest" in FCA cases where it has not yet intervened, that does not necessarily mean courts will consider it a "party" or that the government should be deemed to have reasonably anticipated litigation.[116] The DOJ often determines that the relator's claims lack merit and declines to intervene. Many declined cases never mature to active litigation, either because the government moves to dismiss the case or the relator abandons the claim.[117] Other times, the DOJ will simultaneously intervene and settle cases before active litigation begins.[118] Because many relator complaints never mature to litigation, a bright-line rule triggering a duty to preserve evidence once a relator complaint is filed would appear too broad, for both plaintiffs and defendants alike.

At the same time, imposing no duty on the government to preserve evidence until and unless it intervenes can be even more problematic. The duty to preserve attaches once the plaintiff has decided to sue,[119] and this duty is usually "triggered before litigation commences, in large part because plaintiffs control the timing of litigation."[120] Thus, in cases where the government does intervene, an appropriate

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[115] *Id.* at *19.

[116] *See* United States *ex rel*. Farrell v. SKF USA, Inc., 32 F. Supp.2d 617, 618 (W.D.N.Y. 1999) ("If the United States remains a party to every qui tam action, Congress's intent in creating the option provision would be thwarted since the government counsel would have to expend government resources to respond to discovery requests from hundreds of private suits."); United States *ex rel.* Sanders v. Allison Engine Co., 364 F. Supp.2d 716, 719 (citing *Farrell* in holding, "[y]et, because it is not a party to the action, the Government is not bound by the Federal Rules of Civil Procedure as they relate to discovery"); CLAIRE M. SYLVIA, THE FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT § 11:113 (West 2012) ("When the Government declines to intervene in a case, although it remains real party in interest, it is not a party to the case and therefore is not subject to the Rules of Civil Procedure that apply to party discovery.").

[117] *See* United States Dep't of Justice, *False Claims Act Cases: Govt. Intervention in Qui Tam (Whistleblower) Suits* 2, *available at* http://www.justice.gov/usao/pae/Civil_Division/InternetWhistleblower%20update.pdf (last visited April 7, 2013) (indicating "[f]ewer than 25% of filed qui tam actions result in an intervention on any count by the Department of Justice," which includes cases where the government intervenes and simultaneously settles the pending *qui tam*).

[118] *See id.*

[119] *See* Samsung Elecs. Co. v. Rambus, Inc., 439 F.Supp. 2d 524, 559 (E.D. Va. 2006) (holding plaintiff's duty to preserve was triggered once it had "identified the most likely and attractive litigation targets, and had settled on a number of possible legal theories to press against specific targets"); Struthers Patent Corp. v. Nestle Co., 558 F.Supp. 747 (D.N.J. 1981) (holding plaintiff improperly spoliated evidence during the time that it was "actively planning to institute a complex patent action against Nestle.").

[120] Pension Comm. of the Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC, 685 F.Supp.2d 456, 466 (S.D.N.Y. 2010); Cyntegra, Inc. v. Idexx Labs., Inc., No. 06 Civ. 4170, 2007 WL 5193736, at *3 (C.D. Cal. Sept. 21, 2007) (stating that because plaintiffs control when litigation begins, they "must necessarily anticipate litigation before the complaint is filed"); Indemnity Ins. Co. of N. Am. v. Liberty Corp., No. 96 Civ. 6675, 1998 WL 363834, at

trigger date probably lies somewhere between the relator's initial filing and the government's notice of intervention. But short of mind-reading or some admission by the government, defendants cannot easily learn or prove when the government "reasonably anticipated" litigation.

A prolonged "investigatory" period makes it more difficult, and potentially more important, to fix the trigger date. While many of today's multiple-defendant, nationwide FCA actions require more than the standard 60-day investigation, undoubtedly something else beyond staffing shortages is driving the excessive delays seen in recent years. The quasi-political nature of more recent FCA suits probably contributes, as some suits may languish under seal until the right mix of prosecutors, regulatory officials, and political and legal environment comes together to stimulate an intervention. The lack of any effective statute of limitations and the possibility the government might recover ongoing treble damages would also appear to contribute to delay.[121] Finally, while some courts have expressed reservations about the practice, the possibility of a pre-litigation settlement can delay the intervention decision.[122]

The federal AWP litigation, concerning drug payments made by both the Medicare and Medicaid programs, presents an example of this difficulty. There, the relator filed its initial complaint under seal in 1995.[123] More than a decade later, the government finally decided to intervene against certain manufacturers—seeking damages and penalties not only for alleged claims before the relator's complaint, but also on claims submitted for more than a decade thereafter.[124] Despite receiving a request by defendants in 2000 to preserve evidence, the government did not institute a litigation hold ~~or~~ request to the relevant federal or state agencies and contractors until more than a year *after* it first intervened, resulting in what defendants alleged to be a mass spoliation of relevant evidence.[125] While it is untenable to suggest that the

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*4, n.3 (S.D.N.Y. June 29, 1998) (holding that "the following factors demonstrate that plain-tiff was on notice that a lawsuit was likely so as to trigger a duty to preserve the evid-ence: (1) the sheer magnitude of the losses; (2) that plaintiff attempted to document the damage through photographs and reports; and (3) that it immediately brought in counsel as well as experts to assess the damage and attempt to ascertain its likely causes in anticipation of litigation").

[121] *See supra* text accompanying notes 103-107.

[122] *See, e.g.*, United States *ex rel*. Costa v. Baker & Taylor, Inc., 955 F.Supp. 1188, 1191 (N.D. Cal. 1997) (noting that "one cannot help wondering whether the fact that the defen-dants must guess about the case filed against them is not the more significant settlement advantage currently enjoyed by the government," that "Congress enacted the seal provision to facilitate law enforcement, not to provide an extra bargaining chip in settlement negotiati-ons."); *See* United States v. St. Joseph's Reg'l Health Ctr., 240 F.Supp.2d 882, 888 (W.D. Ark. 2002) (stating multiple interventions by the government seemed designed "to allow the government to investigate and settle the multiple claims at its own pace, selectively carving out those claims that were easiest to settle while keeping the remaining defendants in limbo until it chose to act against them").

[123] *See* Abbott Laboratories Inc.'s Memorandum in Support of its Motion For a Finding of Spoliation and For Sanctions at 2, Dkt. No. 6097, *In re* Pharm. Indus. Average Wholesale Price Litig., MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. June 4, 2009).

[124] *Id.* at 4.

[125] *Id.*

government did not "reasonably anticipate" litigation until the moment it filed its intervention papers eleven years after the relator's complaint, establishing the appropriate trigger date presents a challenging issue.

Cases where the government declines to intervene, but the relator decides to go forward, raise additional issues—including whether the government has a duty to preserve evidence and, if so, when. If the government declines intervention, it considers itself a "third party" for discovery purposes and requires that document requests be served through a Rule 45 subpoena.[126] The duty to preserve evidence generally applies to party litigants, not third parties. Nonetheless, the government (as the real party in interest) is plainly not a typical "third party" in such cases. Its agents may be directly involved in the events surrounding the allegations. Under some circumstances, for example in the common situation where the government has decided it will either obtain a large settlement from defendants or intervene, some duty of preservation should attach to the government.[127]

C. The Scope of the Government's Duty to Preserve Evidence in False Claims Act Cases Can Be Unclear.

FCA cases can also pose unique questions on the scope of the government's duty to preserve evidence, including how broad the duty extends across federal and state government entities. Generally speaking, a party must generally preserve evidence within its "possession, custody, or control,"[128] including from the "key players" involved in the subject matter of the dispute. While "possession" and "control" are self-explanatory, the parameters of "control" will depend on the nature of the relationship between the party and the third party possessing the material, as well as the underlying legal standard applied by the court. Some courts have held that "documents are considered to be under a party's control when that party has "'the right, authority, or practical ability to obtain the documents from a non-party to the action.'"[129] Under this "practical ability" test, documents are deemed within the

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[126] *See False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits*, U.S. DEP'T OF JUSTICE, https://www.doioig.gov/docs/falseclaimsact.pdf (last visited April 6, 2013) ("If the United States declines to intervene, the relator and his or her attorney may prosecute the action on behalf of the United States, but the United States is not a party to the proceedings apart from its right to any recovery.").

[127] Although no court appears to have addressed the possibility, defendants could argue that there is a "special relationship" between the relator and the government in FCA cases that triggers a responsibility on the government to preserve evidence. Some states have articulated a test for whether there is a duty to preserve evidence. *See, e.g.*, Smith v. Shipping Utilities, Inc., No. Civ. 05-500-GPM, 2005 WL 3133494, at *2-3 (S.D. Ill. Nov. 23, 2005) (stating the elements of determining whether there is a duty to preserve evidence under Illinois law).

[128] *See In re* NTL Sec. Litig., 244 F.R.D. 179, 195 (S.D.N.Y. 2007).

[129] Shcherbakovskiy v. Da Capo Al Fine, Ltd., 490 F.3d 130, 138-39 (2d Cir. 2007) (noting that a party was entitled to obtain documents if an opposing party "has access to them and can produce them"); *see also In re* Rudolfo Lozano, 392 B.R. 48, 55-56 (Bankr. S.D.N.Y. 2008) (noting that there is a practical ability to obtain documents "if the assignee of the original mortgagee, or the current loan servicer, can by custom or practice in the mortgage business informally request and obtain the original loan file, and any related documents, including a payment history"); Ice Corp. v. Hamilton Sundstrand Corp., 245 F.R.D. 513, 521 (D. Kan. 2007) (noting that defendants had practical ability when they could "simply ask" or "employ their 'right or ability to influence'" so as to gain documents); Steele Software Sys., Corp. v.

party's control if it is able to ask for documents and receive them.[130] Other courts take a more restrictive view of the scope of a party's "control."[131] The question likely turns on the facts of each case.

In many of the more novel FCA cases, potentially relevant information affiliated with the government might reside outside the federal agency that paid the allegedly false claims in question. Additional repositories of relevant information could include other government agencies, government contractors, and state agencies. There should be little dispute that documents held by federal agencies and their government contractors are within the federal government's "possession, custody, or control." Similarly, in state FCA actions, documents held by state agencies and their contractors are likely within the scope of the state's duty to preserve evidence. But what about evidence in the possession of the states (or their contractors) that is relevant to a federal FCA claim—such as the large (and growing) number of FCA claims seeking recovery relating to state Medicaid programs? Is evidence from these "key players" within the federal government's "control?" Similar issues could exist in state FCA actions for payments made by city or county programs funded by state dollars.

These are not merely hypothetical questions. In the AWP, off-label marketing, and intergovernmental transfer FCA actions, evidence from the states is important to a host of issues, including whether the claims were false, whether the government knowingly permitted or acquiesced in paying the alleged "overpayments," *scienter*, and damages.[132] In the federal AWP litigation, the parties disagreed on whether the

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DataQuick Info. Sys., Inc., 237 F.R.D. 561, 564 (D. Md. 2006) (stating that control "has been construed broadly by the courts as the legal right, authority, or practical ability to obtain the materials sought on demand."); Synopsys, Inc. v. Ricoh Co., No. C-03-2289 MJJ (EMC), 2006 WL 1867529, at *2 (N.D. Cal. July 5, 2006) (noting that defendant had practical ability to obtain documents because the third party agreed to be represented by defense counsel for purposes of discovery and defendant was able to secure a search for documents in third party's facility within three days); *In re* NTL Sec. Litig , 244 F.R.D. at 195 (quoting Bank of N.Y. v. Meridien BIAO Bank Tanzania Ltd., 171 F.R.D. 135, 146-47 (S.D.N.Y. 1997)); Bank of N.Y. v. Meridien BIAO Bank Tanzania Ltd., 171 F.R.D. 135, 149 (S.D.N.Y. 1997) (noting that defendant had practical ability to obtain documents from third-party because "[the defendant] ha[d] been able to obtain documents from [the third-party] when it ha[d] requested them," and the third-party readily cooperated with the defendant's requests by searching for and turning over relevant documents from its files); Golden Trade, S.r.L. v. Lee Apparel Co., 143 F.R.D. 514, 525 (S.D.N.Y. 1992) (noting that plaintiff had practical ability to obtain documents from third party because sub-license agreement provided the plaintiff the "right to cooperation" by the third party and prior history of the case suggested such cooperation encompassed "production of documents and other assistance in conducting discovery").

[130] *See id*; *see also* David S. May, *Third-Party Discovery: Who's in Control?*, 25 NAT. RES. & ENV'T 48, 49 (Summer 2010).

[131] *See* Chaveriat v. Williams Pipe Line Co., 11 F.3d 1420, 1427 (7th Cir. 1993) ("[T]he fact that a party could obtain a document if it tried hard enough and maybe if it didn't try hard at all does not mean that the document is in its possession, custody, or control; in fact, it means the opposite."); *Goodman v. Praxair Services, Inc.*, 632 F. Supp.2d 494, 514-15; Bleecker v. Standard Fire Ins. Co., 130 F. Supp.2d 726, 739 (E.D.N.C. 2000) ("Adopting the 'ability to obtain' test would usurp [the principles of Rule 34], allowing parties to obtain documents from non-parties who were in no way controlled by either party.").

[132] In both the *Englund* and AWP cases, key CMS officials acknowledged primary decision-making on Medicaid program issues rested with the states. *See* United States *ex rel.*

federal government had a duty to preserve evidence from the states. The government argued that the states were not "agents" of the federal government and that it had no obligation to produce or preserve material "in the possession of other sovereigns."[133] Defendants pointed to the joint federal-state nature of Medicaid, the federal government's "common interests agreements" with several states relating to drug pricing litigation, the government's history of successfully requesting information from the states during its investigation and prosecution of the case, and the fact that the DOJ eventually did ask the states to preserve evidence.[134] This, defendants argued, demonstrated that the federal government had sufficient control and practical ability to obtain the information from the states.[135] If nothing else, the federal government could—as it did in the *Community Health Systems* litigation—at least "remind" relevant state agencies of their duty to preserve evidence.[136]

In non-FCA cases, of course, a party does not have to rely on the opposing party to assure the preservation of relevant evidence in the hands of third parties. It can issue subpoenas to produce or at least preserve the evidence. But in under-seal FCA actions, the defendant's hands are tied; there is no clear mechanism to assure evidence from government entities and third parties is retained during what could be a lengthy investigation. The free market of discovery, where a defendant can obtain what it believes is important to its defense, simply does not exist.

Englund v. Los Angeles Cnty., No. CIV. S-04282 LKK/JFM, 2006 WL 3097941,, at *4 (E.D. Ca. Oct. 31, 2006) (noting that intergovernmental transfers were controversial, but the "practice of using the savings in any way the State saw fit was well-known"); *Id*. at *27 (citing testimony of former CMS Administrator that "[o]nce [the federal money] was paid for services that were actually being provided at that point our sort of formal jurisdiction over it and interest of what became of the funds ended"); *see also* Defendants Abbott Laboratories Inc., Dey, Inc., Dey, L.P., Dey L.P., Inc., and Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc.'s Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent To the United States' Motions For Partial Summary Judgment Against Defendants at ¶ 20, *In re* Pharm. Indus. Average Wholesale Price Litig., No. 6448, MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. Aug. 30, 2009) (quoting testimony from former CMS Administrator that "governors and Medicaid directors have to deal with community pharmacists, and local pharmacists, and local politics, and that's not the role of, in this administration, anyway, the role of the CMS administrator to go in and tell states what they have to pay"); *see also id*. at ¶¶ 18-22, 60-64.

[133] *See* United States' Sur-Reply in Opposition to Defendants' Motions For a Finding of Spoliation and For Sanctions at 15-16, *In re* Pharm. Indus. Average Wholesale Price Litig., No. 6734, MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. Dec. 4, 2009).

[134] Abbott Laboratories Inc.'s Response To The United States' Response To The Court's Instruction Relating To State Medicaid Claims Data at 2-4, *In re* Pharm. Indus. Average Wholesale Price Litig., No. 6924, MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. Feb. 24, 2010). Because the claims were settled, the issue was never resolved.

[135] *See* Abbott Laboratories Inc.'s Memorandum in Support of its Motion For a Finding of Spoliation and For Sanctions at 9, *In re* Pharm. Indus. Average Wholesale Price Litig., No. 6097, MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. June 4, 2009); *see also* Abbott Laboratories Inc.'s Response To The United States' Response To The Court's Instruction Relating To State Medicaid Claims Data, *supra* note 4, at 2-4.

[136] United States *ex rel.* Baker v. Cmty. Health Sys., Inc., No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 146865, at *14 (D.N.M. Aug. 31, 2012).

D. The Government's Outdated Position on the Relevance of "Government Knowledge" Evidence Can Contribute to Spoliation.

Another formidable challenge in FCA cases is the government's frequent position on the relevance of evidence from government entities. The DOJ typically advocates an absolutist position, arguing that requests for discovery from government entities seeks to support an irrelevant or at least tangentially relevant "government knowledge" defense.[137] And in the DOJ's view, only a showing that the government formally "approved" of the alleged false claims can defeat recovery.[138] Under this reasoning, the DOJ argues the government had no duty to preserve evidence from the government's files because they are legally irrelevant.[139]

Courts have been hesitant to share the DOJ's narrow view, particularly before discovery can reveal the true relevance of government documents on all facets of the FCA claims. Many decisions have looked to what the government understood in deciding whether a claim was "false" or "fraudulent" in the first place.[140] And even if the government's mere "knowledge" of a false claim is insufficient to defeat claims, courts have held that government "acquiescence" or implicit "approval" can defeat claims.[141] Courts also recognize that evidence in the government's files can be relevant to issues of causation, materiality, damages, and penalties.[142] In the federal AWP litigation, for example, the court repeatedly rejected the DOJ's attempts to evade discovery on what it labeled "irrelevant" evidence of "government

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[137] The government typically argues that its knowledge of a false claim does not defeat a FCA claim, and that "government knowledge" evidence can only be relevant to the issue of *scienter*—and then only if the defendant fully disclosed the alleged fraud to the government. *See, e.g.*, *Cmty. Health Sys., Inc.*, 2012 U.S. Dist. LEXIS 146865, at *37-38 ("According to the Government, its own knowledge is irrelevant and Defendants are incorrectly calling their defense a 'government knowledge inference,' when in fact it should be called a 'full disclosure inference.' The Government contends the burden is on Defendants to prove full disclosure on their part and that what the Government knew at any particular time frame is simply not relevant to the litigation."); United States Common Memorandum of Law in Support of Cross-Motions for Partial Summary Judgment and in Opposition to the Defendants' Motions for Summary Judgment at 30-37, *In re* Pharm. Indus. Average Wholesale Price Litig., No. 6303, MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. July 24, 2009).

[138] *See* supra text accompanying note 137.

[139] *See* United States' Memorandum in Opposition to Defendants' Motions for a Finding of Spoliation and for Sanctions at 4-10, Dkt. No. 6270, *In re* Pharm. Indus. Average Wholesale Price Litig., MDL 1456, Civ. Action No. 01-CV-12257-PBS (July 20, 2009).

[140] *See* United States *ex rel*. Morton vs. A Plus Benefits, Inc., 139 Fed. Appx. 980, 982-83 (10th Cir. 2005); United States v. Southland Mgmt. Corp., 326 F.3d 669, 682 (5th Cir. 2003); Massachusetts v. Mylan, 608 F. Supp. 2d 127, 148 (D. Mass. 2008); BOESE, *supra* note 28 at § 2.03[F] (citing cases where courts have indicated government knowledge is relevant to issue of falsity).

[141] *See* United States *ex rel.* Englund v. Los Angeles Cnty., No. CIV. S-04282 LKK/JFM, 2006 WL 3097941, 2006 U.S. Dist. LEXIS 82034, at *37 (E.D. Ca. Oct. 31, 2006) (granting summary judgment for defendants because "the Federal government knew what [defendant] was doing and implicitly approved of [defendant's] actions") (emphasis added); *Mylan*, 608 F. Supp. 2d at 152 (indicating government knowledge might be relevant to extent state continued to use reported prices "as a policy matter").

[142] *See* cases cited *supra* note 32.

knowledge," permitting defendants to take discovery from both state and federal officials.[143] State courts considering AWP actions have likewise largely rejected efforts to stymie the discovery and trial use of evidence from government entities.[144]

The court in the *Community Health Systems* litigation provided particularly pointed comments in rejecting the government's view. Citing a prior refusal to strike the defense of government knowledge, the court noted that "[t]he problem with the Government's view is that it is entirely one-sided. . . . The bottom line is one party's unilateral and arbitrary determination of relevance cannot dictate the timing or the boundaries of the litigation hold."[145]

V. RECOMMENDATIONS

As relators and government counsel press new theories of FCA liability to challenge sensitive issues of government policy, evidence of what responsible governmental officials expected, understood, and accepted surrounding the events in question becomes increasingly important. The duty to preserve evidence in FCA litigation, however, has not kept pace with this reality. Courts routinely grant the government's motions to extend the seal (often for years) without addressing what is normally a threshold issue in any litigation—the duty to preserve evidence.[146] Government counsel do not appear to recognize any duty to preserve evidence while its investigation languishes under seal.[147] Meanwhile, defendants have no effective way to assure relevant evidence from government entities and relevant third parties is preserved. The result can be the rampant, prejudicial spoliation of evidence in cases seeking treble damages and substantial penalties.

There are, however, steps that the courts and parties can and should consider in an effort to mitigate this escalating problem.

A. Increased Court Attention to Spoliation Issues in FCA Actions

Perhaps most importantly, courts should appreciate that many of today's FCA allegations involve "gray areas" between what is "false or fraudulent" conduct by a defendant and what is arguably imperfect government reimbursement policy. In

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[143] *See, e.g.*, *supra* note 24; Order Re: Submitted Documents for In Camera Review at 2, 15, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 5665, MDL 1456, Civ. Action No. 01-CV-12257-PBS (D. Mass. Nov. 5, 2008) (holding that the government's argument that "government knowledge is not a defense to a False Claims Act charge" was "premature" because defendant "has the right during discovery to see documents reflecting the government's knowledge about spreads in order to mount the defense").

[144] *See supra* text accompanying note 48.

[145] United States *ex rel.* Baker v. Cmty. Health Sys., Inc., Civil No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 146865, at *40 (D. N.M. Aug. 31, 2012) (quoting Goodman v. Praxair Services, Inc., 632 F. Supp.2d 494 (D. Md. 2009) ("The argument of an accused spoliator that it did not violate its duty to preserve evidence because it retained the 'relevant' information and only deleted 'irrelevant' information rings particularly hollow. The ultimate decision of what is relevant is not determined by a party's subjective assessment filtered through its own perception of self-interest.").

[146] *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits*, *supra* note 87.

[147] S. REP. NO. 99-345, at 24-25 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5289-5290.

these cases, defendants will predictably argue that responsible government officials were well aware of the alleged wrongdoing and knowingly accepted or acquiesced in what is now claimed to be a "false" claim. Defendants will need government documents to prove their defense.

Instead of rubber-stamping the government's motions to extend the seal period, courts should consider the Congressional intention that the government "should not, in any way, be allowed to unnecessarily delay lifting of the seal from the civil complaint or processing of the qui tam litigation."[148] Courts should take notice of the lessons from one court, which "note[d] with regret that when the earlier extensions were granted in this case, the effects of inertia and the lack of an opposing party may have resulted in a less searching inquiry regarding good cause than is appropriate."[149] Merely requiring the government to make its intervention decision in a timely manner would significantly curtail the risk of spoliation. Alternatively, courts could follow the recent practice of some judges in the Districts of Massachusetts and the Eastern District of Pennsylvania and unseal the relator's complaint when the government unreasonably delays its decision on intervention.[150]

Moreover, in those cases where the government's investigation drags on for years, courts should make clear that the government cannot "speculate upon the fraud of the other party" and recover damages well after it discovers the alleged fraud.[151] This would mitigate any perverse incentive for the government to keep cases under seal, and encourage timely intervention before evidence is lost. It would also allow courts to timely resolve hotly disputed issues of law—such as the proper interpretation of a statute or regulation—thereby avoiding alleged continuing damages in the first place. Courts should also remember that sealed complaints were not intended "to affect defendants' rights in any way."[152] This includes the right to have disputed issues of law decided within a reasonable period of time and with a reasonably complete factual record. Allowing cases that turn on a disputed interpretation of a government regulation—as many modern FCA cases do—to remain under seal for years is neither good policy nor sound law.

Even in those cases with a prolonged government investigation, courts can take steps to encourage the preservation of evidence. When government counsel appears before the court on its motions to extend the seal, the court should inquire about the chances that FCA allegations will be litigated. Once litigation is reasonably anticipated, the court should ask government counsel what material from its files might be relevant and what steps have been taken to preserve that evidence. At the same time, courts should be skeptical of broad-brushed claims that restrict the "legal relevance" of "government knowledge" evidence, including attempts to narrow the disputed issues of material fact to avoid evidence of government polices inconsistent with plaintiff's theories.[153] If the issues are not clear to the court, it should consider

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[148] S. REP. NO. 99-345, at 24-25 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5289-5290.

[149] United States *ex rel*. Costa v. Baker & Taylor, Inc., 955 F. Supp. 1188, 11991-92 (N.D. Cal. 1997).

[150] Qualters, *supra* note 94.

[151] Thompson v. Libby, 31 N.W. 53, 53 (Minn. 1886).

[152] S. Rep. No. 99-345, at 8.

[153] *See* Leon v. IDX Sys. Corp., 464 F.3d 951, 956-57 (9th Cir. 2006) (noting that the district court found "Dr. Leon did not have the authority to make unilateral decisions about

addressing preservation issues with the defendant (who is often made aware, through a partial unsealing approved by the court, of a FCA investigation before it is unsealed). These steps are consistent with the guidance provided by the Federal Judicial Center's *Manual for Complex Litigation*.[154] If there is a dispute as to the relevance of government evidence, that dispute should be decided by the court *before* evidence is lost, not years later in connection with a spoliation motion.

In evaluating the potential consequences of a long seal period, courts—and perhaps legislators—might consider provisions contained in the Private Securities Litigation Reform Act of 1995 (PSLRA). The PSLRA grants an automatic stay of discovery in all private securities actions during the pendency of a motion to dismiss.[155] "At the same time, Congress included a preservation provision in the PSLRA "in recognition that 'the imposition of a stay of discovery may increase the likelihood that relevant evidence may be lost."'[156] The same is true in FCA cases and similar safeguards should be implemented.

Courts should also help assure that efforts to preserve evidence are extended to the "key players," including, where appropriate, state Medicaid agencies. If the federal government is able to gain information from the states during its investigation, fairness dictates that courts should similarly require the federal government to, at least, request that states preserve relevant evidence. If it is unclear whether the federal government can require states to preserve evidence, courts should use their inherent power to regulate and maintain the integrity of their proceedings and order—or have the federal government order—preservation by the states.[157]

Finally, in those cases where the government has failed to satisfy its obligation to preserve evidence, courts should not hesitate to subject the government to the same variety of spoliation sanctions typically imposed on party litigants.[158] When faced

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what evidence was relevant in this case," and affirming district court's spoliation sanctions); Ogin v. Ahmed, 563 F. Supp. 2d 539, 545 (M.D. Pa. 2008) (issuing sanctions for spoliation when defendants "unilaterally made the decision that the driver's logs were irrelevant and destroyed the records"); Diersen v. Walker, No. 00 C 2437, 2003 WL 21317276, at *5 (N.D. Ill. June 6, 2003) (explaining that "A party cannot destroy documents based solely on its own version of the proper scope of the complaint.").

[154] *See* Federal Judicial Center, *Manual for Complex Litig.* § 11.442 (4th ed. 2004).

[155] *See* 15 U.S.C.A. § 78u-4(b)(3)(B) (West 2010).

[156] *In re* Tyco Int'l Ltd. Sec. Litig., No. 00MD1335, 2000 WL 33654141, at *1 (D.N.H. July 27, 2000) (quoting *In re* Grand Casinos, Inc. Secs. Lit., 988 F. Supp. 1270, 1271 (D. Minn. 1997) (quoting S.REP. NO. 104-98, at 14 (1995), *reprinted in* 1995 U.S.C.C.A.N. 679, 693)).

[157] *See* United Med. Supply v. United States, 73 Fed. Cl. 35, 36 (2006) (describing inherent powers of the court to "preserve evidence and issue orders in furtherance thereof"); *cf. In re* Tyco Int'l Ltd. Sec. Litig., 2000 WL 33654141, at *3 (permitting plaintiffs in a securities action to issue document particularized preservation subpoenas to specifically identified third parties under the statutory framework of the Private Securities Litigation Reform Act).

[158] The determination of the appropriate sanctions is "confined to the sound discretion of the trial judge and is assessed on a case-by-case basis." Fujitsu Ltd. v. Federal Express Corp., 247 F.3d 433, 436 (2d Cir. 2001) (citation omitted). Common sanctions for spoliation include (1) permitting further discovery by the aggrieved party, (2) cost-shifting (*e.g.*, payment of attorneys fees for bringing a spoliation challenge), (3) fines, (4) special jury instructions, such

with spoliation challenges, courts should critically evaluate when the government reasonably anticipated litigation and demand explanations in cases that remained under seal for years. Defendants should not be prejudiced when potentially favorable evidence is lost because the government unnecessarily delayed its intervention decision. While the FCA has undoubtedly discouraged fraud and restored ill-begotten funds, courts should remember that severe damages and penalties make a full and fair evidentiary record especially important in FCA actions.

In deciding what sanctions may be appropriate, the court should, as in all cases, attempt to "(1) deter parties from engaging in spoliation; (2) place the risk of an erroneous judgment on the party who wrongfully created the risk; and (3) restore 'the prejudiced party to the same position he would have been in absent the wrongful destruction of evidence.'"[159] Courts should be flexible in fashioning sanctions to meet these remedial goals. For example, if the government did not live up to its obligation to preserve evidence while the case remained under seal, an appropriate remedy might be to disallow relation-back to the earlier complaint. Another possibility, imposed by the court in the *Community Health Systems* litigation, is to override the government's right to withhold otherwise available documents withheld under the deliberative process, attorney-client privilege, or the work-product doctrine.[160] Moreover, if the government is better positioned to explain what evidence has been lost, courts should demand an accounting from the government.[161] Courts should not hesitate to issue jury instructions on spoliation or shift the burden of proof on an issue. Defendants should not have the burden of disproving an element of plaintiffs' claims or proving a defense that relies on evidence rendered incomplete by the government's spoliation.

B. Improved Guidance for Government Attorneys

The author is not aware of any present guidance to government counsel related to the preservation of evidence in government files during the pendency of an FCA investigation. In typical litigation, the parties raise and settle document preservation issues early on, often without court guidance. But this dynamic does not exist during FCA investigations, particularly since so many cases settle before the government

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as an adverse inference or shifting the burden of proof on an issue, (5) preclusion of evidence, and (6) entry of default judgment or dismissal. Pension Comm. of the Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC, 685 F. Supp.2d 446, 469 (S.D.N.Y. 2010) (footnotes omitted).

[159] West v. Goodyear Tire & Rubber Co., 167 F.3d 776, 779 (2d Cir. 1999) (citing Kronisch v. United States, 150 F.3d 112, 126 (2d Cir. 1998); *see also* Nat'l Hockey League v. Metro. Hockey Club, Inc., 427 U.S. 639, 643 (1976) (holding that the District Judge did not abuse his discretion in finding bad faith . . . and concluding that the extreme sanction of dismissal was appropriate in this case by reason of respondents' "flagrant bad faith" and their counsel's "callous disregard" of their responsibilities).

[160] United States *ex rel.* Baker v. Cmty Health Sys., Inc., No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 146865, at *53 (D. N.M. Aug. 31, 2012) ("The Court also finds that any claim of deliberative process privilege as to the 2006 or 2009 FMRs, assuming the privilege even applies, is overridden by the spoliation that has occurred in this case and the effect it has had on Defendants' ability to present their defense of Government knowledge.").

[161] *See United Med. Supply*, 73 Fed. Cl. at 36 (describing past judicial directives to the government to file affidavits concerning the availability of relevant evidence).

instigates litigation. As relators and prosecutors increase their focus on cases where the illegality or wrongfulness of the alleged conduct is less clear, one would expect that more cases will advance toward full-blown litigation. Government counsel will thus need to be more cognizant of the need to preserve evidence during a prolonged investigation.

An overarching issue is the government's position on the relevance of "government knowledge" evidence in a FCA case. Government counsel should accept that—particularly in those cases that raise issues of government policy—evidence from the files of government entities might well be relevant to liability and damage issues. If it is unclear what materials the defendant believes are relevant, government counsel should discuss those issues with the court or defense counsel, not just assume the court will agree with *post-hoc* arguments on relevance. If there is a dispute over the relevance of government evidence, that dispute should be raised at the outset of the litigation and decided by the court.

Furthermore, because many large FCA cases involve the Medicaid program, government counsel should fairly consider how documents from state and perhaps local agencies can be preserved. When evidence from state programs is relevant to a nationwide FCA case, government counsel should make efforts to inform their state counterparts of the need to preserve evidence once litigation is reasonably anticipated. Government counsel can confer with the court about the most effective way to preserve evidence that is not in its direct possession, custody, or control. The government should not wait until the case is unsealed—perhaps many years later—before making that request.

C. Defendants Should Actively Seek to Protect The Preservation of Evidence

Although a defendant facing an FCA investigation lacks ordinary discovery measures, there are steps it can take in an effort to preserve relevant evidence (or at least improve its position in a later spoliation challenge). In non-FCA litigation, a party typically learns—to the extent it does not already know—the types of documents that need to be preserved in connection with document requests.[162] While an FCA defendant cannot issue formal document requests during an FCA investigation, it can advise government counsel, once it becomes aware of an under-seal *qui tam*, the types of government evidence it considers relevant. Thus, once the defendant believes litigation is likely with either the relator, the government, or both, it should consider making a formal written request to government counsel to preserve evidence.[163] Defense counsel, of course, must strike a delicate balance here, as making demands on the government could adversely affect the

[162] Telecom Int'l Am., Ltd. v. AT&T Corp., 189 F.R.D. 76, 81 (S.D.N.Y. 1999) ("Clearly, a party is also put on notice when an opponent has made a specific document request.")

[163] Many courts have considered requests by opposing parties to preserve evidence in deciding when the duty to preserve was triggered. *See, e.g.*, Optowave Co. v. Nikitin, No. 6:05-cv-1083-Orl-22DAB, 2006 WL 3231422, at *10-11 (M.D. Fla. Nov. 7, 2006) (request by opposing party gave "explicit notice of the duty to preserve"); *see* Wiginton v. CB Richard Ellis, 229 F.R.D. 568 (N.D. Ill. 2004) (letter to opposing counsel alerted it to the types of electronic information likely to be requested in discovery); *cf. In re Tyco Int'l Ltd. Sec. Litig*., 2000 WL 33654141, at *2 (finding defendant aware of documents plaintiff believed should be preserved by virtue of parties' discussions); Clark Constr. Grp., Inc. v. City of Memphis, 229 F.R.D. 131, 136 (W.D. Tenn. 2005) ("The trigger date is the date a party is put on notice that it has a duty to preserve evidence.").

government's decision on intervention. Ideally, defendants should not be placed in this position.

If defense counsel does request the government to take action to preserve evidence, counsel should target specific categories of documents from an identified list of "key players" to the extent possible. The government is more likely to respond to targeted and manageable requests—and the loss of documents specifically targeted by defendants would be more difficult for the government to defend. Defense counsel should engage in a dialogue with government counsel to efficiently identify and preserve relevant material. Furthermore, counsel would be well advised to follow-up with the government to understand what efforts, if any, it has taken in response to the defendant's requests. If the government refuses to retain material the defendant believes is clearly relevant, defense counsel should consider bringing the issue to the court. Courts have the inherent power to require even third parties to preserve evidence.[164] If counsel chooses this path, it should obviously be prepared to address why particular documents should be preserved and the resulting burden on the government.[165]

Once the government has made its decision to intervene, the statutory seal no longer protects pleadings filed by the relator or the government while the case was under seal.[166] Even though the government routinely rejects requests to unseal its prior filings in FCA actions after the case is unsealed, courts have generally "considered lifting the seal on the entire record to be appropriate."[167] Because those filings may provide, among other things, information pertinent to when the

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[164] *In re* Napster Copyright Litig., 462 F. Supp.2d 1060, 1068 (N.D. Cal. 2006); Gervis v. Berg, No. 00-CV-3362 (JS)(ETB), 2005 WL 3299436, at *2 (E.D.N.Y. Nov. 29, 2005) (noting it is "not uncommon for courts to grant a plaintiff leave to issue subpoenas that give specified third parties notice of the action and impose on them only a duty to preserve certain relevant evidence in their possession"(citation omitted)); *In re* "Agent Orange" Prod. Liab. Litig., 506 F.Supp. 750, 751 (E.D.N.Y. 1980) (government required to preserve documents despite status as third party and stay of discovery).

[165] *United Med. Supply*, 73 Fed. Cl. at 36 (party seeking issuance of a preservation order must show that "it is necessary and would not be overly burdensome" (citing Pueblo of Laguna v. United States, 60 Fed.Cl. 133, 138 (2004))).

[166] *See* United States *ex rel*. Fender v. Tenet Healthcare Corp., 105 F. Supp. 2d 1228, 1230-31 (N.D. Ala. 2000) (noting the FCA "'makes no mention of the [United States'] right to keep in camera information under seal indefinitely'" following intervention and finding "no authority under the [False Claims Act] or elsewhere to hold information relating to this cause under seal" (citing U.S. Dept. of Defense v. CACI Intern., Inc., 885 F.Supp. 80, 81 (S.D.N.Y. 1995))); United States *ex rel*. McCoy v. Cal. Med. Review, Inc., 715 F. Supp. 967, 969 (N.D. Cal. 1989) ("neither [§3730(b)(2)] nor any other [section] in the FCA provides authority for retaining the civil action under seal once the Government has elected to intervene").

[167] United States *ex rel*. Lee v. Horizon West, Inc., No. C 00- 2921 SBA, 2006 WL 305966, at *2 (N.D. Cal. Feb. 8, 2006) (citing United States *ex rel*. Erickson v. Univ. of Wash. Physicians, 339 F. Supp. 2d 1124, 1126-27 (W.D. Wash. 2004)); United States *ex rel*. Costa v. Baker & Taylor, Inc., 955 F. Supp. 1188, 1191 (N.D. Cal. 1997); United States *ex rel*. Mikes v. Straus, 846 F. Supp. 21, 23 (S.D.N.Y. 1994); *California Med. Review*, 715 F. Supp. at 967); United States v. CACI Int'l. Inc., 885 F. Supp. 80, 83 (S.D.N.Y. 1995) (noting that if the documents simply describe routine or general investigative procedures, without implicating specific people or providing substantive details, then the Government may not resist disclosure).

government reasonably anticipated litigation—and thus had a duty to preserve evidence—defense counsel should seek access to the filings under seal. By describing the government's investigatory efforts, these filings may also help defendants contrast the government's efforts to build its case with a failure to preserve evidence relevant to the defense.

There can be no dispute that the FCA has deterred fraud on the government and recouped millions from unscrupulous defendants. At the same time, relators and government counsel have aggressively expanded the FCA into situations where evidence from government entities becomes necessary for full and fair adjudications. Unless efforts to improve the retention of that evidence is improved, judges and juries will increasingly find themselves without the information they need to fairly resolve FCA disputes. Justice requires a fair playing field in litigating cases under this powerful act.