PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 15-3548

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UNITED STATES OF AMERICA, EX REL ANTHONY R. SPAY

v.

CVS CAREMARK CORPORATION; CAREMARK RX, LLC, f/k/a Caremark RX, Inc.; CAREMARK, LLC, f/k/a Caremark, Inc.; SILVERSCRIPT, LLC, f/k/a Silverscript Inc.

Anthony R. Spay,
Appellant

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Appeal from the United States District Court
for the Eastern District of Pennsylvania
(No. 2-09-cv-04672)
District Judge: Honorable Ronald L. Buckwalter

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Argued
November 10, 2016

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Before: SMITH, *Chief Judge*, McKEE, and RESTREPO, *Circuit Judges*.

(Opinion Filed: November 16, 2017)

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OPINION OF THE COURT

McKEE, *Circuit Judge*.

We are asked to consider the viability of two potential defenses to an alleged False Claims Act violation that arise in the context of the Medicare Part D Program: the government knowledge inference, which can defeat a finding of scienter in certain circumstances, and the element of materiality.[1] The District Court relied upon the government knowledge inference doctrine in dismissing the claims. Although we disagree with the court's reliance on that doctrine, we nevertheless affirm the court's dismissal of this suit because the misrepresentations it is based upon were not material to the government's decision to pay the underlying claims.

I. FACTS AND PROCEDURAL HISTORY

A. The Medicare Part D Program

[1] The False Claims Act, and the qui tam actions they give rise to, are explained in more detail below.

Part D of the Medicare program is a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees.[2] The Part D program operates as a public-private partnership between the Centers for Medicare and Medicaid Services ("CMS") and government contractors. CMS contracts with private insurance companies called "Sponsors" that administer prescription drug plans. The Sponsors, in turn, subcontract with "first-tier entities," such as Pharmacy Benefit Managers ("PBM"s), that provide administrative and healthcare services, including claims processing. PBMs then contract with the pharmacies that actually dispense prescription medications to Medicare enrollees. Defendant Caremark Rx LLC[3] was one of the largest PBMs in the United States from 2006 to 2007.

Unlike many other government healthcare programs, Medicare Part D is not a fee-for-service program, in which the healthcare provider is reimbursed for providing specific services. Instead, a Sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered, and CMS—after calculating average costs—prospectively compensates Sponsors for their anticipated costs through regular monthly payments.[4] At the end of the year, CMS undertakes a reconciliation process, wherein it compares actual costs to payments made to Sponsors during the past calendar year.[5] This suit stems from plaintiffs' claim that Sponsors intentionally submitted false information about their costs during the reconciliation process. According to plaintiffs, this false information resulted in CMS paying Sponsors more than they were actually entitled to during the reconciliation.

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[2] The Medicare Part D program was enacted as part of the Medicare Modernization Act of 2003 and began on January 1, 2006. 42 U.S.C. § 1395w-101(a)(2).

[3] "On March 22, 2007, Caremark Rx LLC merged with CVS Corporation to form Defendant CVS Caremark Corporation. The Defendants are various subsidiaries of Defendant CVS Caremark Corporation." *U.S. ex rel. Spay v. CVS Caremark Corp.*, No. 09-4672, 2015 WL 5582553, at *3 (E.D. Pa. Sept. 22, 2015).

[4] 42 C.F.R. §§ 423.265, 315.

[5] 42 C.F.R. § 423.343.

1. Part D Claims Processing

Processing payments and claims under Medicare Part D involves (1) the pharmacy claim, which the pharmacy submits to its PBM, and (2) the Prescription Drug Event ("PDE") record, which the Sponsor submits to CMS.

Before a pharmacy dispenses drugs to a Medicare recipient, it first submits an electronic pharmacy claim to the recipient's Part D Sponsor (or the Sponsor's agent). The pharmacy claim contains information about the patient and the patient's prescription. If the pharmacy claim is accepted, the PBM transmits its approval to the pharmacy, and the drug is dispensed to the Medicare recipient. If the pharmacy claim is rejected, the PBM sends the pharmacy a "Reject Code" that explains why it was rejected. Once the pharmacy claim is approved and the medication dispensed, the Sponsor reimburses the pharmacy for the cost of the prescription, minus the amount of any copay that the pharmacy may have received from the Medicare recipient. This process is called the claims "adjudication." Although it sounds rather laborious and time-consuming, modern technology allows the adjudication to occur in real-time, and PBMs typically inform pharmacies whether a claim has been approved or rejected within seconds—while the Medicare recipient waits at the pharmacy counter.

Additionally, throughout the year, Sponsors submit PDE records to CMS for all prescriptions dispensed to Medicare recipients under Part D. Sponsors often submit those records to CMS through PBMs that act as the Sponsor's agent. These PDE records are created electronically. They consist of summary extracts that include at least 34 mandated data fields about each prescription that was filled and the drug that was dispensed. Sponsors are required to give CMS a PDE for all of the prescriptions dispensed to a Part D Medicare recipient.[6] From 2006 to 2007, the PDEs were only used for the end-of-year reconciliation. This dispute focuses on two of the 34 data

[6] Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4307 (Jan. 28, 2005) (to be codified at 42 C.F.R. pt. 423).

fields on the PDEs: the Prescriber ID and the Prescriber ID Qualifier.

The Prescriber ID was a unique number issued to an individual with prescribing authority such as a physician, dentist, or nurse practitioner. The PDE's layout allowed for entry of any of four compatible sources of a Prescriber ID: (1) a National Provider Identifier ("NPI");[7] (2) a Universal Provider Identification Number ("UPIN"); (3) a state license number; or (4) a Drug Enforcement Agency number. The Prescriber ID Qualifier specified which of these four types of numbers was being submitted. The automated system that CMS used to process the PDEs would reject any PDE with a blank Prescriber ID or blank Prescriber ID Qualifier field. As a result, the dispensing pharmacy would not be paid for the corresponding prescription.

2. Dummy Prescriber IDs

In March 2006, Caremark employees identified approximately 4,500 PDEs that had been authorized for payment by Caremark, but not yet submitted to CMS, that had "errored out" due to the lack of a compatible Prescriber ID.[8] In an attempt to resolve the problem, Caremark used a dummy Prescriber ID (AA0000000) for all of the corresponding data fields on each of those 4,500 PDEs. Caremark then programmed that dummy Prescriber ID into its computer system. Thereafter, when any claim with a missing or incorrectly formatted Prescriber ID was processed, the system would default to the dummy Prescriber ID, which the computer would enter into the appropriate data field. This allowed Caremark to submit for payment PDEs that would have otherwise had missing or incorrectly formatted Prescriber IDs, without trigging CMS error codes that would have resulted from an incorrect, or nonconforming, value in the Prescriber ID data field. Caremark later began to use additional dummy Prescriber IDs, all of which served the same purpose. In 2006–

[7] "In 2006–2007, few prescribers used the NPI since there was no universal form of Prescriber ID issued to all prescribers in the United States." *Spay*, 2015 WL 5582553, at *8.

[8] *Spay*, 2015 WL 5582553, at *15.

2007, Caremark generated PDE records containing 56 different dummy Prescriber IDs, none of which identified the actual prescriber, or corresponded to anyone with actual prescribing authority.

B. Procedural History

Appellant Relator Spay is a former pharmacist and co-founder of a company that audits pharmacies. In 2007, during an audit of one of Caremark's[9] insurance company clients, Spay identified six categories of alleged discrepancies in Caremark's pharmacy claims processing. One of these categories was the use of "dummy" Prescriber IDs. After discussion with Caremark, its client dropped all six issues identified in the audit, collected no recovery from Caremark, and did not pay Spay for the audit.

In 2009, Spay filed this qui tam[10] lawsuit based on those same six audit issues. Spay's claims included an allegation that Caremark populated the Prescriber ID field on a large number of its PDE records with a dummy identifier and then falsely certified the accuracy of the PDEs. Spay alleged this constituted a violation of the False Claims Act ("FCA"), because those inaccurate PDEs were used to support requests for reimbursement for prescriptions that had been filled for

[9] In 2006-2007, Caremark served as a PBM for 39 different Part B Sponsors.

[10] "*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means 'who pursues this action on our Lord the King's behalf as well as his own.'" *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 768 n.1 (2000) (citation omitted). A *qui tam* lawsuit is a private enforcement action under the False Claims Act where the private party bringing the suit referred to as the "relator." *U.S. ex rel. Eisenstein v. City of N.Y.*, 556 U.S. 928, 932 (2009) (citation omitted).

Medicare recipients at various pharmacies.[11] The government declined to intervene in the suit.[12]

The District Court denied Caremark's subsequent motion to dismiss, and granted Caremark's motion for summary judgment in its entirety.[13] In reviewing the dummy Prescriber ID claim, the court concluded that Caremark had established sufficient government knowledge to preclude finding the required element of scienter.[14] In arriving at this conclusion, the District Court first reviewed the law governing the "government knowledge inference" doctrine.[15] The District Court noted that "at least six" circuit courts have adopted this doctrine.[16] The court explained that doctrine as follows: "when the government knows and approves of the facts underlying an allegedly false claim prior to presentment, an inference arises that the claim was not knowingly submitted, regardless of whether the claim itself is actually false."[17] The District Court

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[11] Specifically, Spay alleged that Caremark failed to comply with 42 C.F.R. § 423.505(k), which requires, as a condition for payment, that Part D Sponsors certify the "accuracy, completeness, and truthfulness of all data related to payment."

[12] "When a relator initiates [a *qui tam*] action, the United States is given 60 days to review the claim and decide whether it will 'elect to intervene and proceed with the action.'" *Eisenstein*, 556 U.S. at 932 (quoting 31 U.S.C. §§ 3730(b)(2), (b)(4)).

[13] Spay also moved for partial summary judgment, which was denied in its entirety.

[14] The District Court did not address Caremark's additional arguments for why Spay's dummy Prescriber ID claim failed: (1) the dummy Prescriber IDs were not deceptive and, therefore, not "false;" (2) Spay could not prove the "knowledge" element; and (3) Caremark did not make a false certification. *Spay*, 2015 WL 5582553, at *23.

[15] *Id.* at *23–*25.

[16] *Id.* at *24.

[17] *Id.* (citing *U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 951 (10th Cir. 2008); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 683-84 (5th Cir. 2003) (en banc) (Jones, J., concurring); *U.S. ex rel. Becker v. Westinghouse Savannah*

then pointed out that, although this Court has not yet addressed the government knowledge inference doctrine, several district courts both within the Third Circuit[18] and outside the Third Circuit[19] had dismissed FCA claims on the basis of the government knowledge inference. Based on "the consistency in the federal case law, and the absence of any jurisprudence suggesting that the government knowledge inference should not be used," the District Court relied on that doctrine to dismiss the complaint.[20]

The District Court concluded that (1) CMS knew about the use of dummy Prescriber IDs; (2) it paid all of the claims submitted on PDEs containing dummy Prescriber IDs anyway; and (3) it has never sought repayment from Caremark for any of those claims.[21] Accordingly, the District Court reasoned that "no jury could reasonably find that the Defendants acted with the requisite scienter of falsely submitting a claim," and granted summary judgment.[22] This appeal followed.

River Co., 305 F.3d 284, 289 (4th Cir. 2002); *U.S. ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999); *U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993); *U.S. ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991)).

[18] *Id.* (citing *United States v. Educ. Mgmt. LLC*, No. 2:07-cv-00461, 2013 WL 3854458, at *11 (W.D. Pa. May 14, 2013); *U.S. Dep't of Transp. ex rel. Arnold v. CMC Eng'g Inc.*, 947 F. Supp. 2d 537, 545 (W.D. Pa. 2013), *aff'd*, 567 F. App'x 166 (3d Cir. 2014); *U.S. ex rel. Watson v. Conn. Gen. Life. Ins. Co.*, No. Civ.A.98-6698, 2003 WL 303142, at *8 (E.D. Pa. Feb. 11, 2003)).

[19] *Id.* (citing *S.F. Bay Area Rapid Transit Dist. v. Spencer*, No. C 04-4632, 2007 WL 1450350, at *8 (N.D. Cal. May 14, 2007); *Boisjoly v. Morton Thiokol, Inc.*, 706 F. Supp. 795, 809 (D. Utah 1998); *U.S. ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 988 (E.D. Wisc. 1998)).

[20] *Id.* at *25.

[21] *Id.* at *44.

[22] *Id.*

Taxpayers Against Fraud Education Fund ("TAFEF"), a nonprofit organization "dedicated to combating fraud against the government and protecting public resources through public-private partnerships" and "committed to preserving effective anti-fraud legislation at the federal and state levels;"[23] and Senator Charles E. Grassley, "the leading sponsor of the 1986 and 2009 amendments" to the FCA, filed amicus briefs in support of Spay's claims and arguing against the continued viability of the government knowledge inference.[24]

II. JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction over Spay's FCA claims under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331. We have jurisdiction pursuant to 28 U.S.C. § 1291. "We review an order granting summary judgment de novo, applying the same test the district court employed."[25] Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[26] "We must view the record and draw inferences in a light most favorable to the non-moving party."[27] We can affirm the District Court's grant of summary judgment on any basis supported by the record.[28]

III. DISCUSSION

"The False Claims Act was adopted in 1863 and signed into law by President Abraham Lincoln in order to combat

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[23] TAFEF Br. 1. Caremark notes that Spay's counsel is a major donor to TAFEF and sits on its Advisory Board. Appellees' Br. 43.

[24] Grassley Br. 2.

[25] *In re Ikon Office Solutions, Inc.*, 277 F.3d 658, 665 (3d Cir. 2002).

[26] Fed. R. Civ. P. 56(a).

[27] *Knopick v. Connelly*, 639 F.3d 600, 606 (3d Cir. 2011) (internal quotation marks omitted).

[28] *Fairview Twp. v. U.S. Envtl. Prot. Agency*, 773 F.3d 517, 525 n.15 (3d Cir. 1985).

rampant fraud in Civil War defense contracts."[29] The frauds included the government paying for artillery shells filled with sawdust instead of explosives,[30] uniforms made of "shredded, often decaying rags, pressed . . . into a semblance of cloth" that "would fall apart in the first rain,"[31] and the same horses being sold "two and three times to the Union cavalry."[32] Congress hoped that enacting the FCA would combat these dishonest government contractors, who had become "bands of conspirators . . . knotted together . . . for the purpose of defrauding and plundering the Government."[33]

The FCA's qui tam provision allows individuals to bring claims on behalf of the government, and rewards successful plaintiffs with potentially very substantial recoveries. Though the precise awards to qui tam plaintiffs have changed since the statute's inception, the current iteration of the False Claims Act imposes civil penalties and treble damages on defendants who submit false or fraudulent claims to the government. Individual relators can receive between 15% and 30% of those swollen recoveries.[34] Because the

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[29] *Kellogg Brown & Root Sers., Inc. v. U.S., ex rel. Carter*, 135 S. Ct. 1970, 1973 (2015) (quoting S. Rep. No. 99-345, at 8 (1986), 1986 U.S.C.C.A.N. 5266, 5273). *See also* Act of Mar. 2, 1863, ch. 67, 12 Stat. 696 (1863).

[30] Cong. Globe, 37th Cong., 3d Sess. 955 (1863) (statement of Sen. Howard).

[31] Ron Soodalter, *The Union's 'Shoddy' Aristocracy*, N.Y. Times Opinionator (May 9, 2011, 9:30 PM), http://opinionator.blogs.nytimes.com/2011/05/09/the-unions-shoddy-aristocracy. *See also* James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. Cin. L. Rev. 1261, 1264–65 (2013) (listing reports of misappropriated war funds and collecting sources).

[32] 132 Cong. Rec. H6482 (daily ed. Sept. 9, 1986) (statement of Rep. Berman).

[33] Cong. Globe, 37th Cong, 3d Sess. 955 (1863) (statement of Sen. Howard).

[34] 31 U.S.C. §§ 3730(d)(1)–(2) (outlining the award to a qui tam plaintiff to be "at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the

statutory scheme of the FCA offers the potential for very lucrative damages, individuals have long attempted to take advantage of the potential for substantial awards, [35] and Congress has repeatedly amended the statute in response to past abuses.[36]

For example, because the original FCA did not prohibit relators from bringing qui tam actions even when the government prosecuted the identical fraud, Congress enacted a government knowledge bar in 1943.[37] This bar prohibited "qui

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claim" when the Government intervenes and "not less than 25 percent and not more than 30 percent" when the Government does not intervene); 3729(a)(1) (providing for treble damages and civil monetary penalties for FCA claims). Under the original FCA, individuals bringing qui tam suits were entitled to half of the government's recovery. Act of Mar. 2, 1863, ch. 67, 12 Stat. 696, § 6 (1863).

[35] *See U.S. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 332 (5th Cir. 2011) (explaining that court's holding would prevent qui tam relators from "arbitrarily select[ing] a large group of defendants in any industry in which public disclosures have revealed significant fraud, in hopes that [their] allegations will prove true for at least a few defendants"); James F. Barger, Jr., Pamela H. Bucy, Melinda M. Eubanks, Marc S. Raspanti, *States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts*, 42 False Cl. Act and Qui Tam Q. Rev. 15 (2006) ("Because the FCA's damages and penalty provisions tend to generate exceptionally large judgments, relators' taxable recoveries involve substantial sums.").

[36] *See Graham Cty. Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 310 (2010) (Sotomayor, J., dissenting) (citing S. Rep. No. 99–345, at 10–11) ("To be sure, Congress was also concerned in 1986, as in 1943, with guarding against purely opportunistic, 'parasitic' *qui tam* relators.").

[37] 145 Cong. Rec. E1546-01 (daily ed. July 14, 1999) (statement of Rep. Berman). The government knowledge bar was a response to the Supreme Court's decision in *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), where the Court "upheld the relator's recovery even though he had discovered

tam suits based on information already in the Government's possession" in an attempt to deter "parasitic suits" that allowed relators to recover even if they "contributed nothing to the discovery of this crime."[38] As we explained in *United States ex rel. Cantekin v. University of Pittsburgh*:

> The implicit logic of the [government knowledge bar] was that if the government had the relevant information before the plaintiff initiated suit, then the government must be aware of the false claims and didn't need the assistance of private parties to ferret them out. And if the government knew about the information yet did nothing, then the government probably thought the suit meritless, and any private action was apt to be spurious, driven only by the lure of the Act's sizable damages.[39]

Although the government knowledge bar merely attempted to curb bogus FCA suits, the limitation it created undermined the Act's usefulness.[40] It so "significantly limited the number of FCA cases that were filed" that "[b]y the 1980s, the FCA was no longer a viable tool for combating fraud against the Government."[41] In response, in 1986, Congress amended the FCA yet again, "specifically overturned the Government knowledge bar . . . and replaced it with a new

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the fraud by reading a federal criminal indictment—a quintessential 'parasitic' suit." *Graham Cty.*, 559 U.S. at 294.

[38] *Id.* (quoting *Marcus v. Hess*, 317 U.S. at 545). The pre-1986 version of the FCA barred jurisdiction over any claim "whenever it shall be made to appear that such suit was based upon evidence or information in the possession of the United States, or any agency, officer, or employee thereof, at the time such suit was brought." 31 U.S.C. § 232(C) (1943).

[39] 192 F.3d 402, 408 (3d Cir. 1999), *superseded by statute*, FERA, Pub. L. No. 111-21, *as recognized in U.S. ex rel. Hill v. Univ. of Med. & Dentistry of N.J.*, 448 F. App'x 314, 317 n.4 (3d Cir. 2011).

[40] *See id.*

[41] S. Rep. No. 110-507, at 3 (2008).

mechanism referred to as a 'public disclosure bar.'"[42] The public disclosure bar was enacted "in an effort to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits."[43] Under this new standard, a qui tam suit would only be barred if it was based on information that was "publicly disclosed at various hearings, in certain types of reports, or by the media."[44] "Once public disclosure became the linchpin of the jurisdictional scheme, the effect of government knowledge on the viability of an FCA claim was thrown to the courts to decide."[45]

Meanwhile, courts were inquiring into whether the FCA included a materiality element requiring any alleged falsehoods to be material to the government's decision to pay, and what the proper standard for measuring materiality might be.[46] Though "nearly every court to have considered the issue [of materiality] had imposed such a requirement," courts "did not agree on what the standard for materiality was."[47] In 2009, Congress passed the Fraud Enforcement and Recovery Act, which again amended the FCA and provided a uniform definition of materiality.[48] As explained in the corresponding Senate Report, these amendments "corrected and clarified" certain FCA provisions, the effectiveness of which had

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[42] *Id.* at 5.
[43] *Graham Cty.*, 559 U.S. at 295.
[44] *Cantekin*, 192 F.3d at 408 (internal quotation marks omitted) (citing 31 U.S.C. § 3730(e)(4)(A) (1994)). The public disclosure must have occurred "in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media . . ." 31 U.S.C. § 3730(e)(4)(A) (1994).
[45] *Lamers*, 998 F. Supp. at 988 (citing *U.S. ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 326 (9th Cir. 1995)).
[46] *See* James B. Helmer, *False Claims Act: Whistleblower Litigation* 247–48 n.873 (6th ed.) (2012) (cataloguing pre-2008 circuit cases imposing materiality requirement).
[47] *See id.* at 248 (discussing circuit split on materiality standard).
[48] Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21 (2009).

"recently been undermined by court decisions which limit the scope of the law and, in some cases, allow subcontractors paid with Government money to escape responsibility for proven frauds."[49]

With this background in mind, we will first address Spay's argument that the District Court's decision here created "an unprecedented 'industry practice' government knowledge inference that undermines the purpose of the FCA."[50] We will then more generally address the issue of materiality under the FCA.

A. Government Knowledge Inference.

Though we have never recognized a "government knowledge inference" defense that would defeat the scienter requirement under the FCA, the District Court quite correctly noted that six of our sister circuit courts of appeals have.[51] Just as the Court of Appeals for the Fourth Circuit did before us, "[t]oday, we join with our sister circuits and hold that the government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation."[52]

While the government knowledge bar that Congress overturned in 1986 (in favor of the public disclosure bar) "focused on the government's knowledge of the fraud to preclude the relator from bringing suit," the current government knowledge inference "focuses on the effect the government's knowledge has on the defendant's mental state

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[49] S. Rep. No. 111-10, at 4 (2009). The Report later clarifies that the amendments were meant to "clarify and correct erroneous interpretations of the law that were decided in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008) and *United States ex rel. Totten v. Bombadier Corp.*, 380 F.3d 488 (D.C. Cir. 2004)." *Id*. at *10.

[50] Appellant's Br. 15.

[51] *Arnold*, 567 F. App'x at 170 n.9 (explaining that the Third Circuit had not yet adopted the government knowledge inference in 2014); *Spay*, 2015 WL 5582553, at *24 (collecting circuit cases).

[52] *Becker*, 305 F.3d at 289.

in order to determine if the defendant acted knowingly."[53] "The 'government knowledge inference' helps distinguish, in FCA cases, between the submission of a false claim and the *knowing* submission of a false claim—that is, between the presence and absence of scienter."[54] The government knowledge inference may arise "when the government knows and approves of the facts underlying an allegedly false claim prior to presentment"[55] and the defendant knows that the government is aware of the false information in a claim. In other words, there is a two-prong test that must be met before the government knowledge inference can preclude liability. The two-prong test requires that (1) the government agency knew about the alleged false statement(s), and (2) the defendant knew the government knew.[56]

A "classic example" of the government knowledge inference occurs "when the government, with knowledge of the facts underlying an allegedly false claim, authorizes a contractor to make that claim."[57] For instance, in *United States ex rel. Durcholz v. FKW, Inc.*,[58] officers at a naval facility directed the defendant general contractor to use incorrect line-items in order to expedite the bidding process. The officers did so because "[they] were more interested in speed than cost and made their decisions in accordance with these priorities."[59] The

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[53] 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, 47 (2008) (citations omitted).
[54] *Burlbaw*, 548 F.3d at 951.
[55] *Id*. at 952.
[56] *See Educ. Mgmt.*, 2013 WL 3854458, at *11; *Southland Mgmt. Corp.*, 326 F.3d at 682 (Jones, J., concurring) ("Most of our sister circuits have held that under some circumstances, the government's knowledge of the falsity of a statement or claim can defeat FCA liability on the ground that the claimant did not act 'knowingly', because the claimant knew that the government knew of the falsity of the statement and was willing to pay anyway.").
[57] *Burlbaw*, 548 F.3d at 952 (citing *Wang*, 975 F.2d at 1421).
[58] 189 F.3d 542 (7th Cir. 1999).
[59] *Id.* at 545.

Court of Appeals for the Seventh Circuit "decline[d] to hold [the defendant] liable for defrauding the government by following the government's explicit directions."[60] The court explained that "[t]he government knew what it wanted, and it got what it paid for."[61] Though such direct and contract-specific authorization is not required to support the government knowledge inference,[62] generally, "[w]here the government and a contractor have been working together, albeit outside the written provisions of the contract, to reach a common solution to a problem, no claim arises."[63] In other words, the easy case in which to apply the government knowledge inference is where the defendant and the government engage in open and ongoing discussions about the purportedly false claims.[64] This is the "easy case" because both prongs are easily met.

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[60] *Id.*

[61] *Id.*; *see also Becker*, 305 F.3d at 289 (applying government knowledge inference where the Department of Energy's "full knowledge of the material facts underlying any representations implicit in [the defendant's] conduct negates any knowledge that [the defendant] had regarding the truth or falsity of those representations").

[62] *See Burlbaw*, 548 F.3d at 953 (applying the government knowledge inference where there was evidence of governmental knowledge and cooperation, the defendant was "completely forthcoming" with the government, and there was no evidence that the information the defendant provided was "materially inaccurate").

[63] *Southland*, 326 F.3d at 682 (Jones, J., concurring).

[64] *See, e.g.*, *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) ("The government knew of all the deficiencies identified by [the relator], and discussed them with [the defendant]. The fact that the government knew of [the defendant's] mistake and limitations, and that [the defendant] was open with the government about them, suggests that while [the defendant] may have been groping for solutions, it was not cheating the government in the effort. Without more, the common failings of engineers and other scientists are not culpable under the [FCA]."), *overruled on other grounds by U.S. ex rel. Hartpence v. Kinetic Concepts*, 792 F.3d 1121 (9th Cir. 2015); *Butler*, 71 F.3d at 327 (finding

A two-prong test is necessary because knowledge by the government, without more, cannot negate the scienter requirement. This is so, as noted above, because the elements of the FCA claim focus on the defendant's state of mind. An examination of the cases where government knowledge has not barred recovery drives home that merely showing *some* government knowledge of the alleged false nature of a claim is not enough.

In *Shaw v. AAA Engineering & Drafting, Inc.*,[65] the Court of Appeals for the Tenth Circuit distinguished the decisions of the Court of Appeals for the Ninth Circuit in *United States ex rel. Butler v. Hughes Helicopters, Inc.*[66] and *Wang ex rel. United States v. FMC Corp*.[67] The Tenth Circuit stressed that in *Butler* and *Wang*, the defendants and government had "completely cooperated and shared all information"[68] and "had an ongoing dialogue . . . about the problems."[69] The Tenth Circuit reasoned that, although there was evidence of government knowledge in *Shaw*, the knowledge was not sufficient to "negate the intent requirement under the FCA as a matter of law."[70] In *Shaw*, the evidence showed that (1) the plaintiff relator, and not the defendant government photography contractor, told the government about a failure to use the required film processing method;[71]

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the government's knowledge of allegedly false claims negated defendant's intent where "the only reasonable conclusion a jury could draw from the evidence was that [the defendant] and the Army had so completely cooperated and shared all information . . . that [the defendant] did not 'knowingly' submit false claims").

[65] 213 F.3d 519 (10th Cir. 2000).

[66] 71 F.3d 321.

[67] 975 F.2d 1412.

[68] *Shaw*, 213 F.3d at 534 (emphasis omitted) (quoting *Butler*, 71 F.3d at 327).

[69] *Id.*

[70] *Id*.

[71] In *Shaw*, the defendant government photography contractor was required to provide equipment necessary for silver recovery—a "process by which trace silver is removed from

(2) the defendant was "not forthcoming" about the alleged falsity and "repeatedly evaded government employees' questions on the subject;" (3) there was support for the inference that the defendants did include false information on some work orders; and (4) several government employees were not aware of that false information.[72] Other circuit courts of appeals have also repeatedly stressed "[t]hat the relevant government officials know of the falsity is not in itself a defense."[73]

Thus, it appears the government knowledge inference might be more aptly named a "government acquiescence inference," as knowledge alone on the part of the government is insufficient to establish an FCA defense. To reiterate, there are two prongs to this defense: (1) the government knew about the alleged false statement(s), and (2) the defendant knew that the government knew. This case presents an example where, though there is ample evidence of government knowledge of the industry practice at issue, the evidence to satisfy the second prong is lacking.

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film processing solution"—and to "dispose of the used [solution] and other chemicals in accordance with Environmental Protection Agency . . . guidelines and standards." *Id.* at 527. The plaintiff relator alleged that the contractor failed to do so. *Id.* at 523.

[72] *Id*. at 534–35.

[73] *Kreindler*, 985 F.2d at 1156 (quoting *Hagood*, 929 F.2d at 1421); *see also U.S. ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp., Inc.*, 400 F.3d 428, 454 n.21 (6th Cir. 2005) (explaining that the government knowledge inference is typically applied where "the Government's knowledge was used to demonstrate that what the defendant submitted was not actually false but rather conformed to a modified agreement with the Government," and that, because the defendant had neither altered the Government's understanding of reimbursement nor disclosed all pertinent information, that inference was not available in this case), *superseded by statute*, FERA, Pub. L. No. 111-21 (2009), *as recognized in U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.*, 842 F.3d 430, 436 (6th Cir. 2016).

B. The Government Knowledge Inference Does Not Apply Here.

Spay alleges that Caremark's false certifications violated three sections of the pre-2009 FCA.[74] Those sections prohibit (1) "knowingly present[ing] . . . a false or fraudulent claim for payment or approval" to the government;[75] (2) "knowingly mak[ing] . . . a false record or statement to get a false or fraudulent claim paid or approved by the Government;"[76] and (3) "knowingly mak[ing] . . . a false record or statement to conceal, avoid, or decrease an obligation to pay . . . the Government."[77] The FCA defines "knowingly" to mean that a person "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information."[78] However, "no proof of specific intent to defraud is required."[79]

The District Court exhaustively reviewed the evidence in this case and concluded that it was clear that CMS knew of, and accepted, the industry-wide practice of using dummy Prescriber IDs on PDE records. The court explained:

> [T]he evidence is clear that (a) CMS officials knew, in 2006–2007, that Sponsors and PBMs were having trouble obtaining the unique physician identifier number necessary to populate the associated field on the PDE; (b) CMS prioritized the filling of valid pharmacy

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[74] As we explained at the outset, the False Claims Act was amended in 2009. Those amendments were deemed to "take effect on the date of enactment of this Act [May 20, 2009] and shall apply to conduct on or after the date of enactment." Pub. L. 111-21 at § 4(f). Because the alleged conduct in this case occurred before 2009, we will use the pre-2009 version of the FCA to assess the claims here, just as the District Court did. 2015 WL 5582553, at *21 n.10.

[75] 31 U.S.C. § 3729(a)(1) (1994).

[76] *Id*. at § 3729(a)(2).

[77] *Id*. at § 3729(a)(7).

[78] *Id*. at § 3729(b)(1)–(3).

[79] *Id*. at § 3729(b).

> claims over the administrative requirement of populating the physician identifier field and did not want valid claims rejected due to the absence of that number; (c) CMS knew that, in order to submit PDEs for valid pharmacy claims, Sponsors and PBMs were submitting PDEs containing dummy prescriber identifiers, yet never sanctioned any Sponsor, terminated any Sponsor, or required the submission of any PDE from 2006 or 2007 as a result of this practice; (d) although CMS preferred the use of a unique identifier, CMS affirmatively instructed Sponsors and PBMs to submit dummy prescriber IDs when a unique number was not available; (e) only after the 2006–2007 time frame did CMS issue affirmative instructions mandating the use of a unique identifier; (f) Defendants understood that CMS permitted the use of dummy prescriber IDs in 2006–2007; and (g) Defendants' certifications of the accuracy of the data were filed during the period when CMS clearly knew of dummy prescriber usage.[80]

The record clearly supports these conclusions.[81] It is therefore clear that CMS knew that many Sponsors and PBMs were using dummy Prescriber IDs on PDE records so that those records would not be rejected in the approval process. Accordingly, Caremark has adduced evidence to establish the first prong of the government knowledge inference.

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[80] *Spay*, 2015 WL 5582553, at *26.

[81] Spay and Sen. Grassley argue that the District Court incorrectly applied agency principles when relying on the statements of CMS employees who testified individually, but not on behalf of the government, to infer government knowledge. Appellant's Br. at 28–39 (citing 2015 WL 5582553, at *26 n.17); Grassley Br. at 21–24. As Caremark correctly points out, circuit courts routinely rely on government employee testimony as evidence of what relevant government officials knew about the alleged conduct in FCA cases, and do not require that the employee testify on behalf of the government. *See, e.g.*, *Huston v. Proctor & Gamble Paper Prods. Co.*, 568 F.3d 100 (3d Cir. 2009).

The evidence of Caremark's knowledge that CMS knew of the dummy Prescriber IDs practice, however, is lacking. Caremark understood that CMS seemed to allow the use of dummy Prescriber IDs on the PDEs. But Joe Mulenex, Caremark's manager responsible for PDE submission, did not recall any conversation where he or anyone else from Caremark asked CMS about inputting default Prescriber IDs. He was not aware of any written guidance from CMS regarding how to proceed in the absence of an actual Prescriber IDs.

Our review of the record shows there is no evidence of the kind of cooperation and collaborative problem-solving that exists in the easy case where the government knowledge inference is invoked. While it is true that both the government and contractors throughout the industry knew what was happening, there is no evidence of any explicit approval from the government to Caremark of this temporary work-around. More importantly, this evidence of what was occurring in the industry does not establish that Caremark knew that CMS was aware of the practice of using dummy Prescriber IDs. Indeed the record shows that Caremark was simply hopeful that its use of the dummy IDs would be acceptable. Thus, the circumstances here are somewhat different than the usual case where the government knowledge inference has been applied. Drawing reasonable inferences in Spay's favor, as we must, the evidence does not demonstrate Caremark's knowledge for purposes of the second prong. We agree with Spay and the amici that the District Court erred in relying upon the government knowledge inference in dismissing these claims based on the dummy Prescriber IDs.

There is one more point we must address. The District Court's application of the government knowledge inference is premised, at least in part, on the incorrect assertion that "the crux of an FCA violation is intentionally deceiving the government. Where the government has not been deceived, no violation can exist."[82] The FCA itself, however, states "no proof of specific intent to defraud is required."[83] Though we

[82] 2015 WL 5582553, at *43.
[83] 31 U.S.C. § 3729(b)(1)(B).

agree that there was no evidence of an intent to deceive the government here, Spay was not required to prove there was.

In sum, the government knowledge inference is not applicable here because Caremark failed to establish the second prong of the two-prong test.[84]

C. Materiality in the FCA Before 2009

While this case was on appeal, the Supreme Court decided *Universal Health Services, Inc. v. Escobar*,[85] which confirmed that materiality is an essential element of a False Claims Act violation that "descends from common law antecedents."[86] Spay correctly points out that the *Universal Health* decision dealt with the post-2009 version of the FCA, and the Court explicitly stated that it had not considered "whether pre-2009 conduct should be treated differently."[87] The disputed conduct here all occurred before the 2009 amendments were enacted. Accordingly, we must decide whether materiality was a requirement under the FCA prior to the 2009 FERA amendments.[88]

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[84] The evidence in this case demonstrates that Caremark was stuck between a rock and a hard place at the inception of the Part D Program. Caremark hoped its approach of using dummy Prescriber IDs when they did not have the Prescriber's actual ID—an approach which fit into the Prescriber ID validation algorithm—was a valid, non-fraudulent PDE submission given the circumstances at that time that allowed it to be paid for prescriptions needed by Medicare clients. Thus, Caremark did not act with the scienter necessary for liability to attach under the FCA.

[85] 136 S. Ct. 1989 (2016).

[86] *Id.* at 2002 (citations omitted).

[87] *Id.* at 1998 n.1.

[88] The Court of Appeals for the D.C. Circuit, when similarly evaluating pre-2009 conduct, "assume[d]—as the parties have done—that *Universal Health*'s materiality standard applies to the instant dispute." *U.S. ex re. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 n.5 (D.C. Cir. 2017). Here, Spay contends that *Universal Health*'s materiality standard does not apply to pre-2009 conduct, and we therefore address this question directly.

The impact of the 2009 amendments and the decision in *Universal Health* on the materiality element can best be understood by focusing on the three sections of the FCA at issue here: Sections 3729(a)(1), (a)(2), and (a)(7). As we noted above in summarizing Spay's arguments, those three sections create liability for any person who:

> (a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
>
> (a)(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . . . or
>
> (a)(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government[.][89]

When Congress amended the FCA in 2009, it included a materiality requirement in two of the seven predicates for FCA liability, both of which are at issue here: Sections 3729(a)(2) and (a)(7). Specifically, the amended Section 3729(a)(2) now imposes liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false or fraudulent claim."[90] Similarly, Section 3729(a)(7) now imposes liability on a person who "knowingly makes, uses, or causes to be made or used, a false record or statement *material* to an obligation to pay or transmit

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[89] 31 U.S.C. §§ 3729(a)(1), (2), (7) (1994). In 2009, Congress renumbered these sections, so that Section 3729(a)(1) became Section 3729(a)(1)(A), Section 3729(a)(2) became Section 3729(a)(1)(B), and Section 3729(a)(7) became Section 3729(a)(1)(G). Pub. L. No. 111-21, § 4. For clarity, we refer to these Sections in the text by their pre-2009 labels.

[90] 31 U.S.C. § 3729(a)(1)(B) (emphasis added).

money or property to the Government . . . ."[91] The 2009 FERA amendments did not, however, add an explicit materiality requirement to Section 3729(a)(1).[92] As we discuss below, *Universal Health* dealt with an alleged violation of that section.[93] The 2009 FERA amendments also added a provision defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[94] As the history of the materiality requirement demonstrates, these changes did not inject a new materiality standard into the FCA. Rather, the changes merely made explicit and consistent that which had previously been a judicially-imposed, and oftentimes conflicting, standard.

By 2009, several circuit courts had already acknowledged the implicit materiality requirement in the FCA.[95] Importantly, none of those cases limited the materiality

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[91] 31 U.S.C. §3729(a)(1)(G) (emphasis added).

[92] *Compare* 31 U.S.C. § 3729(a)(1) (1994) ("knowingly presents, or causes to be presented, to [the Government] a false or fraudulent claim for payment or approval"), *with* 31 U.S.C. § 3729(a)(1)(A) (2009) ("knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval").

[93] 136 S. Ct. at 2001, 2002, 2004 (discussing 31 U.S.C. § 3729(a)(1)(A) as relevant provision).

[94] 31 U.S.C. § 3729(b)(4).

[95] *U.S. ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 307 (1st Cir. 2010) ("We have long held that the FCA is subject to a judicially-imposed requirement that the allegedly false claim or statement be material."); *U.S. ex rel. Berge v. Bd. of Trustees of the Univ. of Al.*, 104 F.3d 1453, 1459 (4th Cir. 1997) ("[W]e now make explicit that the current civil False Claims Act imposes a materiality requirement."); *U.S. ex rel. Longhi v. U.S.*, 575 F.3d 458, 468–70 (5th Cir. 2009) (discussing "proper standard for assessing the materiality of a false statement under the FCA's civil-liability" provisions); *United States v. Bourseau*, 531 F.3d 1159, 1170–71 (9th Cir. 2008) (holding "that the FCA includes a materiality requirement"); *A+ Homecare, Inc.*, 400 F.3d at 442 (concluding "that false statements or conduct must be material to the false or fraudulent claim to hold a person

requirement to the two sections amended in 2009. Indeed, the Court of Appeals for the First Circuit noted that the 2009 FERA amendments had not changed the FCA's general requirement that a relator "prove falsity, materiality, and scienter."[96]

Although prior to *Universal Health*, we had never decided whether the FCA contained a materiality requirement, the Supreme Court's analysis in *Universal Health* resolves any hesitation we may have otherwise had.[97] In *United States ex rel. Cantekin v. University of Pittsburgh*, we declined to decide whether materiality was an element of the pre-2009 FCA.[98] We there expressed doubt that the FCA included a materiality requirement based on a footnote in *Neder v. United States*, a Supreme Court case holding that there is a materiality requirement in the federal mail, wire, and bank fraud statutes.[99] We explained that the *Neder* Court noted that "the term 'false statement,' unlike 'fraudulent statement,' does not imply a materiality requirement."[100] Although we expressly refrained from deciding the issue, we did observe that "[g]iven that the False Claims Act prohibits merely making a knowingly false

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civilly liable under the FCA"); *U.S. ex rel. Costner v. U.S.*, 317 F.3d 883, 887 (8th Cir. 2003) (acknowledging that a materiality requirement exists but refraining from deciding "the precise contours of the materiality requirement"); *Lamers*, 168 F.3d at 1019; *U.S. v. TDC Mgmt. Corp., Inc.*, 24 F.3d 292, 298 (D.C. Cir. 1994) ("To prevail under the False Claims Act, the government must prove either that [the defendant] actually knew it had omitted material information from its monthly progress reports or that it recklessly disregarded or deliberately ignored that possibility.").

[96] *Loughren*, 613 F.3d at 306–07 n.7–8 ("We need not decide whether the FERA applies retroactively here because under either the former or amended version of Section 3729(a)(2), our analysis of Relator's claims . . . will be the same.").

[97] *But see U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017) (joining "the many other federal courts that have recognized the heightened materiality standard after *Universal Health Services*.").

[98] *Cantekin*, 192 F.3d at 415.

[99] 527 U.S. 1, 25 (1999).

[100] *Cantekin*, 192 F.3d at 415.

claim and does not require a specific intent to defraud, perhaps *Neder* argues against a materiality requirement."[101] But the subsequent Supreme Court decision in *Universal Health*, and its reliance on *Neder*'s definition of materiality in interpreting how the FCA's materiality requirement should be enforced, resolves the doubts that we previously entertained in *Cantekin*.[102] Thus, contrary to the concerns expressed there, *Universal Health* clarified that *Neder*'s footnote did not suggest the absence of a materiality requirement in the FCA.

Moreover, the real issue that divided the circuit courts before 2009 was not whether materiality was an element of a cause of action under the FCA. Rather, it was the proper standard for determining whether the falsity underlying such a claim was material.[103] Thus, including a formal definition of "material" in the statutory text in 2009 was merely an attempt to resolve those disagreements, and nothing more should be read into it.[104] It was not intended to add a new element to FCA claims.[105]

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[101] *Id.*

[102] *See Universal Health*, 136 S. Ct. at 2002 (explaining that the FCA's post-2009 statutory definition of materiality uses "language that we have employed to define materiality in other federal fraud statutes," like the language in *Neder*).

[103] *See Longhi*, 575 F.3d at 470 (noting the circuit split between the Fourth, Fifth, Sixth, and Ninth Circuits, which used the "natural tendency test" for materiality, and the Eighth Circuit, which used the "more restrictive 'outcome materiality test'").

[104] *See id.* (explaining that, with the 2009 FERA amendments, "Congress embraced the [materiality] test as stated by the Supreme Court and several courts of appeals").

[105] The legislative history of the 2009 FERA also indicates that the original FCA included a materiality requirement, and that Congress enacted the amendments contained in the FERA to restore that original requirement. Indeed, the title of the FCA section of the FERA was "Clarifications to the False Claims Act to Reflect the Original Intent of the Law." FERA, Pub. L. No. 111-21, § 4. The Senate Report on the FERA explains that the 2009 amendments were enacted in response to certain Supreme Court decisions that "r[an] contrary to the

Finally, although the Supreme Court's decision in *Universal Health* addressed only post-2009 conduct, it nevertheless informs our analysis of conduct that occurred before 2009. First, *Universal Health* interprets a section of the FCA—Section 3279(a)(1)—that did not have an explicit materiality requirement before 2009, and, unlike other sections of the FCA, still does not have an explicit requirement.[106] Despite the lack of a materiality requirement, the Supreme Court had no trouble finding that the FCA's materiality requirement also applied to this section.[107] Second, although

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clear language and congressional intent of the FCA." S. Rep. No. 111-10, at 10. Accordingly, the revised text contained in Sections 3729(a)(1)(A) and (a)(1)(G) scaled back the more strenuous intent requirement created by the Supreme Court in *Allison Engine*, 553 U.S. 662 (2008). *See* S. Rep. No. 111-10, at 12 ("To correct the Allison Engine decision, [the FERA] contains three specific changes to existing section 3729(a)(2) and (a)(3). In section 3729(a)(2) the words 'to get' were removed striking the language the Supreme Court found created an intent requirement for false claims liability under that section. In place of this language, the Committee inserted the words 'material to' a false or fraudulent claim."). The Senate Report further explained that the newly-added definition of "material" was "consistent with the Supreme Court definition, as well as other courts interpreting the term *as applied to the FCA*." *Id.* (emphasis added). In other words, the legislative history explains that courts had previously been applying a materiality requirement to FCA claims, and these amendments simply (1) made the formerly implicit materiality requirement explicit, and (2) provided a standard definition of "material."

[106] *Compare* 31 U.S.C. § 3729(a)(1) (1994) (creating liability for anyone who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval"), *with* 31 U.S.C. § 3729(a)(1)(A) (2009) (creating liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval").

[107] *Universal Health*, 136 S. Ct. at 2002 (discussing "§ 3729(a)(1)(A)'s materiality requirement").

the 2009 amendments did include a definition of "material," *Universal Health* held that it "need not decide whether § 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law" because both employ the same standard.[108] The unavoidable conclusion based on the Court's analysis is that: (1) Section (a)(1) has a materiality requirement, even though that requirement has never been expressed in the statute, and (2) the standard used to measure materiality did not change in 2009 when Congress amended the FCA to include a definition of "material." Accordingly, we conclude that the FCA has always included a materiality element (and that the 2009 provisions merely made this element explicit). We also conclude that the definition of "material," which is derived from the common law and was enshrined in the statute itself in 2009, has not changed.[109]

D. The False Claims Alleged in This Case Were Not Material

The Supreme Court has explained that "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."[110] That is precisely the situation here. As the District Court succinctly concluded:

> The crucial facts underlying the false claims here are that (1) CMS was well aware of the difficulty many pharmacies and PBMs were having

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[108] *Id.*

[109] Furthermore, in support of its statement that "[m]ateriality . . . cannot be found where noncompliance is minor or insubstantial," the Supreme Court cites to two cases: a Supreme Court case from 1943 and a New York Court of Appeals case from 1931. 136 S. Ct. at 2003 (citing *Marcus v. Hess*, 317 U.S. at 543; *Junius Const. Corp. v. Cohen*, 257 N.Y. 393, 400 (N.Y. 1931)). The 1943 Supreme Court case, *Marcus v. Hess*, dealt specifically with the FCA. 317 U.S. at 539. This further supports the existence of a materiality element in the FCA long before 2009.

[110] *Universal Health*, 136 S. Ct. at 2003-04.

> obtaining a proper physician identifier; (2) CMS was concerned with filling valid prescriptions and did not want claims rejected at the point of service for absence of a valid identifier; (3) PDE records could not be submitted without some type of number that satisfied the requisite algorithm in the physician identifier field; (4) CMS knew that many PBMs were submitting PDEs with dummy numbers in the physician identifier field in the 2006 and 2007 time period; (5) CMS could easily recognize dummy prescriber identifier numbers; and (6) CMS took no action to deny payment on such claims during the 2006–2007 time period.[111]

Nevertheless, Spay claims that, because the government explicitly advised the parties that the individual CMS employees did not speak for CMS and that CMS did not endorse their testimony, the testimony of those CMS employees cannot be used at summary judgment to establish that CMS as an agency knew of and affirmatively authorized a general industry use of false prescriber identifiers on PDE claims. Although that argument may well preclude reliance on the government inference doctrine, it does not undermine our belief that the misstatements here were simply not material to the government's decision to pay the claims substantiated by the challenged PDEs. The government did not pay for services that were not provided, and the Sponsors did not receive any compensation for prescriptions that were never given to Medicare recipients.

CMS knew that dummy Prescriber IDs were being used by PBMs, that it routinely paid PBMs despite the use of these dummy Prescriber IDs, and that CMS only "signaled [a] change in position" well after 2007.[112] Spay does not contest

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[111] *Spay*, 2015 WL 5582553, at *34.

[112] *See Spay*, 2015 WL 5582553, at *37–*39 (discussing CMS's post-2007 efforts to prohibit use of dummy identifiers and concluding that "[c]onsidered collectively, this evidence creates the sole reasonable inference that CMS did not previously have a clear prohibition on the use of dummy

that CMS employees knew that dummy identifiers were being used on PDEs or the reason for using them. Nevertheless, CMS paid for those prescriptions. Moreover, CMS can hardly be faulted for paying even though it knew the information identifying the prescribers was not accurate. CMS was concerned with making sure that the medications were dispensed to Medicare recipients and that pharmacies were paid for those prescriptions. Had the payments stopped, the prescriptions would not have been dispensed, and the pharmaceutical needs of Medicare recipients would not have been addressed. The misstatements that gave rise to this qui tam action allowed patients to get their medication, and they are precisely the type of "minor or insubstantial" misstatements where "[m]ateriality . . . cannot be found."[113]

The Supreme Court has instructed that "[t]he False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[114] It is difficult for us to disagree with the District Court's conclusion that, "[a]t base, this case appears to be nothing more than an effort to convert an unprofitable private audit—performed at a time when Part D regulations were new and not as explicit in their instructions—into a successful recovery of funds under the guise of a qui tam action."[115] The dummy Prescriber IDs were intended as one thing, and one thing only: they were intended as a technical, formulaic way of preventing a computer program from denying legitimate claims for reimbursement and payment for prescriptions that were actually disbursed to Medicare recipients. Those recipients needed the prescriptions the claims were based on, and nothing here suggests that the prescriptions or the workaround that prevented legitimate claims for payment from being improperly rejected by a computer code served anything other than the practical purpose of facilitating that payment and disbursement of those prescriptions. The workaround could arguably be described as "creative," or a "common sense

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identifiers. By first 'clarifying' its policies [in 2010], then 'revising' its prior policy and regulation text [in 2011 and 2012], CMS effectively indicated that, prior to these efforts, dummy identifiers were permissible").

[113] *Universal Health*, 136 S. Ct. at 2003.

[114] *Id.* (quoting *Allison Engine*, 553 U.S. at 672).

[115] *Spay*, 2015 WL 5582553, at *65.

solution" to a very real and perplexing problem. But we see nothing that would justify calling it "fraud." The claims themselves were neither false nor fraudulent. Nothing in the text or history of the FCA leads us to conclude that Congress intended conduct such as this to morph into an actionable fraud against the government.

V. CONCLUSION

For the foregoing reasons, we will affirm the District Court's order granting summary judgment in favor of Defendants.