# **The Salcido Report**

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# Understanding When a Overpayment Can Result in False Claims Liability and Why Current Court Precedent and Regulatory Guidance is Mistaken

#### **Key Points**

- Learn what specific evidence or information triggers a duty for a health care company to investigate whether an overpayment is owed to the government.
- Identify when a health care entity is required to remit an overpayment to the government or incur potential liability under the False Claims Act (FCA).
- Understand why regulators' and courts' current interpretation of the scope of the FCA overpayment provision is mistaken.



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An issue every health care entity that submits claims to the government must frequently confront is when and how to disclose an overpayment to the government. This issue arises when, for example, an employee expresses concern about a claim or an internal audit or review questions a claim, or a Medicare Administrative Contractor inquiries into a claim. Under amendments to the Affordable Care Act (ACA), if an overpayment is not reported to the government within 60 days, the entity could be held liable under the FCA for treble damages and substantial civil penalties.<sup>1</sup>

Yet, notwithstanding the high stakes underlying the issue, one of the most vexing issues confronting any health care entity is the determination of when precisely it has a duty to disclose an "overpayment" to the government. There are at least two reasons for the lack of clarity. First, the limited regulatory guidance and case law that regulators and courts have promulgated are mistaken. They are demonstrably wrong, because they have used the FCA's general intent standard—defining knowledge, at a minimum, to be acting with "reckless disregard" or "deliberate ignorance"—when the FCA's provision governing the repayment of an overpayment requires the higher standard that the person act "knowingly and improperly."<sup>2</sup> Congress used the standard "knowingly and improperly" as a term of art, to proscribe conduct, as Congress described, that is "*malum in se*," or "inherently wrongful," or "willful" and where a person "employed means that are inherently tortious or illegal."<sup>3</sup> This is to be distinguished from the

<sup>&</sup>lt;sup>1</sup> See Pub. L. No. 111-148, 124 Stat. 119 (2010).

<sup>&</sup>lt;sup>2</sup> Compare 31 U.S.C. 3729(b)(1) with 31 U.S.C. §3729(a)(1)(G).

<sup>&</sup>lt;sup>3</sup> See 155 Cong. Rec. S4539–40 (2009); see also S. Rep. No. 111-10, at 15 (2009) (hereinafter S. Rep. 10), reprinted in 2009 U.S.C.C.A.N. 430, 442.

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substantially lower FCA general constructive knowledge standard of "reckless disregard" and "deliberate ignorance." A person knowing that, in light of the evidence, the person's retention of governmental funds is "inherently wrongful" or "*malum in se*" – both in a legal and commonsensical manner—describes a vastly different circumstance than the person being merely recklessly disregardful or deliberately ignorant regarding whether the person possesses an overpayment. These different circumstances trigger different duties to investigate.

Second, because the government's guidance and court precedent have misconstrued the plain statutory language regarding what knowledge standard applies in determining whether there is an obligation to repay an overpayment, there is related confusion regarding when the overpayment is "identified." And, because there is a lack of clarity regarding when an overpayment is identified, there is correspondingly uncertainty regarding when the 60-day period is triggered to report the overpayment.

To adumbrate the root cause of the error in regulatory guidance and court precedent regarding the FCA overpayment provision, the relevant 2009 FCA statutory and legislative history will be chronicled. What this statutory review reveals, consistent with the express statutory language, is that Congress intended that the standard that courts use when assessing whether a health care entity breached its duty to report an overpayment, is whether, in light of the information the entity had, it would be inherently wrongful to not investigate further and not the lower standard of whether it would be recklessly disregardful or deliberately ignorant not to conduct an additional investigation.

#### I. Congress' 2009 FCA Amendments

The legislative path that the FCA's overpayment provision traversed is important to study in detail, because it demonstrates Congress' resolve that a higher, more stringent standard governs FCA overpayments and that the duty to repay does not arise from contingent obligations, but from an "established duty" to repay a debt owed.

#### A. Senate Bill 386 to Amend the FCA

On February 5, 2009, Sens. Patrick Leahy (D-VT) and Chuck Grassley (R-IA) introduced S.386, a bill to improve the enforcement of mortgage, securities, and financial institution fraud and other frauds related to federal assistance and relief programs.<sup>4</sup>

The Senate bill proposed expanding the scope of the reverse false claims provision. Prior to 2009, the FCA lacked an express provision mandating the repayment of a known overpayment and, under the interpretation of a majority of courts, a person had an obligation to pay the government only when it submitted a false record or statement to the government that breached a fixed duty to pay an owed amount to the government. Under the 2009 amendments, Congress sought to enact two significant revisions to close this "loophole": (1) expand the provision so that it would apply to a knowing avoidance to repay an overpayment to the government, and (2) enlarge the provision to apply to merely contingent

<sup>&</sup>lt;sup>4</sup> See 155 Cong. Rec. S.1681 (Feb. 5, 2009).

obligations. Specifically, Congress proposed the following revisions (proposed revisions to the FCA's existing provision in bold and underscored):

(G) 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, or knowingly conceals, avoids, or decreases an obligation to pay or transmit money or property to the Government;

\* \* \*

# (3) the term 'obligation' means a fixed duty, or a contingent duty arising from an express or implied contractual, quasi-contractual, grantor-grantee, licensor-licensee, fee-based, or similar relationship, and the retention of any overpayment.<sup>5</sup>

Thus, under the amendment, the provision would no longer require that a person submit an actual false record or statement, but could apply when a person simply received an overpayment, because the amendment would prohibit a person from "knowingly . . . avoid[ing] . . . an obligation to pay" and an obligation was defined to include the retention of any overpayment.

#### B. DOJ's February 24, 2009, Letter

Approximately three weeks after Sens. Leahy and Grassley proposed their bill, the Department of Justice, on February 24, 2009, wrote to Sen. Leahy to recommend additional revisions to the bill.<sup>6</sup>

As to revisions to the reverse false claims provision, DOJ proposed the following amendment to the Senate's bill:

(G) knowingly makes, uses, or causes to be made or used, a false record or statement **material** to <del>conceal, avoid, or decrease</del> an obligation to pay or transmit money or property to the Government, or knowingly conceals, **or improperly** avoids; or decreases, an obligation to pay or transmit money or property to the Government.

DOJ noted that the apparent purpose underlying the Senate bill's definition of "obligation" was to overrule cases that found that an obligation encompassed only duties that were "fixed in all particulars, including the specific amount owed."<sup>7</sup> However, DOJ also recognized that this amendment created the danger that those who merely sought to avoid or decrease an obligation to pay during an audit process may be subjected inappropriately to FCA liability. Specifically, DOJ noted:

Section 4(a)(1) amends the FCA's reverse false claim provision to make the knowing concealment or avoidance of an obligation to pay a violation, and adds a definition of the term "obligation." The Department supports these changes . . . While the affirmative FCA provisions currently impose liability even in the absence of any false statement or record,

<sup>&</sup>lt;sup>5</sup> *Id.* at S. 1683-84.

<sup>&</sup>lt;sup>6</sup> Letter from M. Faith Burton, Acting Assistant Attorney General, Department of Justice, to The Honorable Patrick J. Leahy, United States Senate, Committee on the Judiciary (Feb. 24, 2009) (hereinafter, "DOJ Letter").

<sup>&</sup>lt;sup>7</sup> *Id*. at 2.

there is no analogue in the reverse false claim context. Additionally, the new definition of obligation would address those cases that unduly narrowed the reverse false claim provision by holding or suggesting that the term "obligation" encompasses only a duty to pay that is fixed in all particulars, including the specific amount owed. *See, e.g., American Textile Mfrs. Inst. v. The Limited, Inc.,* 190 F.3d 729 (6th Cir. 1999); *United States v. Q Int'l Courier, Inc.,* 131 F.3d 770 (8th Cir. 1997).

Although the Department supports the Committee's efforts to revise and clarify the scope of the reverse false claim provision, the Department recommends . . . refinements to ensure that the provision reaches only a party's wrongful attempts to minimize the party's obligations to the Government. [T]he Department recommends inserting the words "or improperly" before the term "avoids" in the last clause of proposed subparagraph 3729(a)(I)(G), as follows: "... or knowingly conceals, or improperly avoids or decreases, an obligation to pay . . . "<sup>8</sup>

#### C. Senate Judiciary Committee Report (March2009)

On March 5, 2009, the Senate Judiciary Committee issued its Report.<sup>9</sup>

As to amendments to the reverse false claims provision, the Committee proposed the following revisions to the amendment that DOJ proposed to create the "knowingly and improperly" standard:

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals, or **knowingly and** improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Further, the Committee proposed an additional revision to the definition of "obligation":

(3) the term "obligation" means a fixed duty, or a contingent duty arising from an express or implied contractual, quasi-contractual, grantor-grantee, licensor-licensee, **statutory**, fee-based, or similar relationship, and the retention of any overpayment;

When comparing the Senate's bill to the actual language in the FCA's reverse false claims provision, the bill reported out of the Committee proposed the following revisions:

(7)G knowingly makes, uses, or causes to be made or used, a false record or statement **material** to <del>conceal, avoid, or decrease</del> an obligation to pay or transmit money or property to the Government, or knowingly conceals **or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government**,

<sup>&</sup>lt;sup>8</sup> Id. For a detailed history of the FCA's reverse false claims provision and a description of its case law, see Robert Salcido, FALSE CLAIMS ACT & HEALTHCARE INDUSTRY: COUNSELING & LITIGATION §§ 1:05; 2:03 (American Health Lawyers Ass'n Supp. 2014); see generally Robert Salcido, FALSE CLAIMS ACT & HEALTH CARE INDUSTRY: COUNSELING & LITIGATION (2d ed. American Health Lawyers Ass'n 2008).

<sup>&</sup>lt;sup>9</sup> S.Rep. 10, at 4, reprinted in 2009 U.S.C.C.A.N., at 433.

As drafted at this point, the Committee's provision would create liability in two situations: (1) when a person knowingly uses or causes to be used, "a false record or statement material" to an obligation to pay, or (2) when a person "knowingly conceals or knowingly and improperly avoids or decreases" an obligation to pay.

Also, at this point, it appears that the Committee envisioned that the reverse false claims provision would apply to merely contingent obligations, such as the creation of false statements to avoid the payment of tariffs:

Further, this legislation addresses current confusion among courts that have developed conflicting definitions of the term "obligation" in Section 3729(a)(7). The term "obligation" is now defined under new Section 3729(b)(3) and includes fixed and contingent duties owed to the Government—including fixed liquidated obligations such as judgments, and fixed, unliquidated obligations such as tariffs on imported goods. It is also noteworthy to restate that while the new definition of "obligation" expressly includes contingent, non-fixed obligations, the Committee supports the position of the Department of Justice that current section 3729(a)(7) "speaks of an 'obligation,' not a 'fixed obligation." By including contingent obligations such as "implied contractual, quasi-contractual, grantor-grantee, licensor-licensee, fee-based, or similar relationship," this new section reflects the Committee's view, held since the passage of the 1986 Amendments, that an "obligation" arises across the spectrum of possibilities from the fixed amount debt obligation where all particulars are defined to the instance where there is a relationship between the Government and a person that "results in a duty to pay the Government money, whether or not the amount owed is yet fixed."<sup>10</sup>

Finally, the Committee addressed the balance that it intended to strike by inserting the prohibition against the "retention of an overpayment" in the statute. Specifically, the Committee noted that it simply intended to capture instances where a person knowingly used estimates to retain governmental funds to which the person was not entitled, but not capture instances like hospital cost reports, where an entity may receive overpayments (or underpayments) as a natural byproduct of the regulatory scheme:

The new definition of "obligation" includes an express statement that an obligation under the FCA includes "the retention of an overpayment." The Department of Justice supported the inclusion of this provision and provided technical advice that the proper place to include overpayments was in the definition of obligation. This new definition will be useful to prevent Government contractors and others who receive money from the Government incrementally based upon cost estimates from retaining any Government money that is overpaid during the estimate process. Thus, the violation of the FCA for receiving an overpayment may occur once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment. The Committee also recognizes that there are various statutory and regulatory schemes in Federal contracting that allow for the reconciliation of cost reports that may permit an unknowing, unintentional retention of an overpayment. The Committee does not intend this language

<sup>&</sup>lt;sup>10</sup> S.Rep. 10 at 14, *reprinted in* 2009 U.S.C.C.A.N., at 441–42 (footnote omitted).

to create liability for a simple retention of an overpayment that is permitted by a statutory or regulatory process for reconciliation, provided the receipt of the overpayment **is not based upon any willful act** of a recipient to increase the payments from the Government when the recipient is not entitled to such Government money or property. Moreover, **any action or scheme created to intentionally defraud the Government** by receiving overpayments, even if within the statutory or regulatory window for reconciliation, is not intended to be protected by this provision. Accordingly, **any knowing and improper retention of an overpayment** beyond or following the final submission of payment as required by statute or regulation—including relevant statutory or regulatory periods designated to reconcile cost reports, but excluding administrative and judicial appeals—would be actionable under this provision.<sup>11</sup>

#### D. April 22, 2009, Floor Statements

On April 22, 2009, on the Senate floor, Sen. Jon Kyl (R-AZ) proposed significant revisions to the Committee's definition of "obligation." The Senate agreed to Sen. Kyl's amendments, and those amendments were ultimately adopted into law unchanged. Specifically, Sen. Kyl proposed the following revision to the definition:

(3) the term "obligation" means a fixed an established duty, whether or a contingent duty not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee, relationship, from a fee-based, or similar relationship, and from statute or regulation or from the retention of any overpayment.<sup>12</sup>

As to the purpose underlying these proposed revisions, Sen. Kyl pointed out that the definition of obligation previously proposed was too broad, because it would include "contingent" obligations, such as a duty to pay a fine upon the commission of some transgression. If the statute were expanded in that fashion, as Sen. Kyl pointed out, a person conceivably could be held liable to pay treble damages for a fine before the duty to pay the fine was established. Thus, he proposed to strike the words "contingent duty" and that the language "established duty" be inserted in its place. By revising the statutory language in this fashion, Sen. Kyl believed that the reverse false claims provision would not be inappropriately expanded to reach contingent obligations like duties to pay penalties or fines:

The bill's new definition of the word "obligation," in particular, posed several problems. The original language spoke of "contingent" obligations. Such contingent or potential duties could include duties to pay penalties or fines, which could arise—and at least become "contingent" obligations—as soon as the conduct that is the basis for the fine has occurred.

Obviously, we don't want the Government or anyone else suing under the False Claims Act to treble and enforce a fine before the duty to pay that fine has been formally established. It is unlikely that Justice would ever have brought suit to enforce a claim of this nature, but the FCA can also be enforced by private relators who often may be motivated by personal gain and not always exercise the same good judgment that the Government usually does.

<sup>&</sup>lt;sup>11</sup> S.Rep. 10 at 15, *reprinted in* 2009 U.S.C.C.A.N., at 442 (footnote omitted) (emphasis supplied).

<sup>&</sup>lt;sup>12</sup> 155 Cong. Rec. S.4539.

To preclude such a reading of the act, my amendment strikes contingent obligations from the FCA's new definition of "obligation."<sup>13</sup>

Also consistent with the limited scope of the provision, Sen. Kyl reiterated prior governmental statements that "overpayments" would be a source of obligation only when a defendant "knowingly and improperly" retains an overpayment. Specifically, Sen. Kyl clarified that this standard applied only when defendant's conduct was "*malum in se*," or inherently wrongful, and does not apply when the defendant is "pursuing in good-faith the exhaustion of a reconciliation procedure":

I might also say a few words about aspects of the definition of obligation that I ultimately concluded that it was not necessary to address in this amendment. At the Judiciary Committee's mark up of this bill, I circulated an amendment that would limit obligations arising out the retention of any overpayment so as to make clear that no obligation arises if the defendant is pursuing some type of administrative, judicial, or other process for reconciliation of alleged overpayments. The sponsors of the bill raised the concern. however, that such a safe harbor might immunize parties that intentionally and maliciously obtain an overpayment, and then spend years exhausting a reconciliation process, all in bad faith and knowing full well that they must repay the money, but earning interest on the overpayment in the interim. Apparently incidents like this have occurred, in cases involving sums that allowed the defendant to earn tens of millions of dollars in interest. The sponsors of the bill also noted to me that, under subparagraph (G)'s modification of the reverse False Claims Act, avoiding or decreasing an obligation is only actionable, in relevant part, if the defendant "knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." Therefore, a good-faith pursuit of a reconciliation process would not be actionable.

I asked my staff to research the meaning of "knowingly and improperly" to confirm that a person who pursues reconciliation of an overpayment in good faith could not be held liable under the reverse False Claims Act. The answer that I received is that the term "knowingly and improperly," though infrequently used in the caselaw, is consistently construed to mean that a person either acted with bad intent or that he employed means that are inherently tortious or illegal.

... In the False Claims Act context, this list may include other **improper means**, but "improper means" must be means that are *malum in se*—that is, means that are inherently wrongful and constitute an independent tort.

\* \*

**Given that the words "knowingly and improperly" have a fixed meaning that, at the very least, requires either improper motives or inherently improper means**, the changes made by this bill cannot be read to make actionable the retention of an overpayment when the defendant is pursuing in good faith the exhaustion of a reconciliation procedure. It is with this understanding that I have declined to insist on further qualification of the bill's predication of liability on the retention of an overpayment.<sup>14</sup>

<sup>&</sup>lt;sup>13</sup> *Id.* (emphasis supplied).

<sup>&</sup>lt;sup>14</sup> *Id.* at S4539–40.

Thus, significantly, Congress' precise intent, as reflected in the plain language it employed, the "knowingly and improperly" standard—rather than to use the FCA's general knowledge standard, reckless disregard and deliberate ignorance—was to ensure that the FCA would **never** be used unless the plaintiff established that the person's conduct in retaining an overpayment was "*malum in se*," or "inherently wrongful," or "willful" and where a person "employed means that are inherently tortious or illegal."<sup>15</sup> Moreover, in another clause of the reverse FCA provision, although Congress struck that language to mandate that the provision would apply only to established duties.

## II. Affordable Care Act Amendments

Consistent with the 2009 FCA revisions, Congress, in 2010, in the Patient Protection and Affordable Care Act,<sup>16</sup> imposed additional duties on health care providers and suppliers to report and remit overpayments within 60 days of when those overpayments were "identified."

Specifically, the provision requires the person to report and return the overpayment "by the later of (A) the date which is 60 days after the date on which the overpayment was identified or (B) the date any corresponding cost report is due, if applicable."<sup>17</sup> Under the ACA, any overpayment retained after this deadline is an "obligation" for purposes of the FCA, and hence, can subject the person to FCA treble damages and civil penalties.<sup>18</sup>

Oddly, although, as noted in detail above, the FCA standard regarding overpayments is "knowingly and improperly," this provision contains only a definition of "knowingly" which it defines as having "the meaning given those terms in section 3729(b) of title 31."<sup>19</sup> Equally oddly, although this subsection defines the words "knowing and knowingly," the subsection itself, addressing "Reporting and returning of overpayments," never uses those words except in the definition.<sup>20</sup>

## III. Regulatory and Case Law Developments

The prior sections have developed how the FCA's overpayment provision contains an overt "knowingly and improperly" knowledge standard, while the FCA generally contains merely a reckless disregard and

<sup>&</sup>lt;sup>15</sup> See 155 Cong. Rec. S4539–40 (2009); see also S. Rep. 10 at 15, reprinted in 2009 U.S.C.C.A.N., at 442.

<sup>&</sup>lt;sup>16</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) [hereinafter, ACA]. Section 6402 of the ACA established a new Section 1128J(d) of the Social Security Act titled "Reporting and Returning of Overpayments." This provision is codified at 42 U.S.C. § 1320a-7k(d).

<sup>&</sup>lt;sup>17</sup> The statute defines an 'overpayment' as "any funds that person receives or retains under title XVIII [Medicare] or XIX [Medicaid] to which the person, after applicable reconciliation, is not entitled under such title." 42 U.S.C. § 1320a-7k(d)(4)(B).

<sup>&</sup>lt;sup>18</sup> 42 U.S.C. § 1320a-7k(d)(3) ("Enforcement—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in Section 3729(b)(3) of title 31").

<sup>&</sup>lt;sup>19</sup> Id., § 1320a-7k(d)(4)(A); see also 77 Fed. Reg. 9179 (Feb. 16, 2012) ("Section 1128J of the Act provides that the terms 'knowing' and 'knowingly' have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). The statutory text, however, does not use this phrase other than in the definitions").

<sup>&</sup>lt;sup>20</sup> See 42 U.S.C. § 1320a-7k(d).

deliberate ignorance knowledge standard. This section will describe why it matters that Centers for Medicare & Medicaid Services (CMS) and courts apply the correct knowledge standard—the knowing and improper standard, not the reckless disregard and deliberate ignorance standard—when construing the FCA's overpayment provision.

#### A. Why Applying the Correct Knowledge Standard Matters

There are different gradations of knowledge that Congress establishes based upon the conduct it intends to regulate. For the FCA's reverse false claim provision, as demonstrated, Congress intended a higher knowledge standard apply. This has significant practical importance in determining whether there is actual FCA liability related to the retention of an overpayment.

#### 1. Knowingly and Improperly

As noted, Congress was clear that it used the standard "knowingly and improperly" as a term of art, to proscribe conduct that is "*malum in se*," or "inherently wrongful," or "willful" and where a person "employed means that are inherently tortious or illegal."<sup>21</sup> When courts have considered what conduct constitutes such willful conduct, such as when considering whether defendants violated the Anti-Kickback Statute (AKS), they have required the government to establish that the defendant knew that its conduct was wrongful.<sup>22</sup>

#### 2. Reckless Disregard and Deliberate Ignorance

Unlike a willful standard, or *malum in se* standard, under both a reckless disregard and deliberate ignorance standard, the person does not consciously need to know that the conduct is wrongful. For example, in FCA actions, courts have instructed jurors that to find that a defendant acted with reckless disregard, they must find that the defendant's conduct amounted to a form of aggravated negligence such as gross negligence plus.<sup>23</sup> Thus, under these circumstances, the person is reckless in not finding the

<sup>&</sup>lt;sup>21</sup> See 155 Cong. Rec. S4539–40 (2009); see also S. Rep. 10 at 15, reprinted in 2009 U.S.C.C.A.N., at 442.

<sup>&</sup>lt;sup>22</sup> See, e.g., United States v. Vernon, 723 F.3d 1234, 1256 (11th Cir. 2013); United States v. Starks, 157 F.3d 833, 837–38 (11th Cir. 1998) (upholding AKS jury instruction that "[t]he word willfully . . . means the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law"); United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996) (affirming AKS jury instruction that "the word 'willfully' means unjustifiably and wrongfully, known to be such by the defendant"); see also United States v. McClatchey, 217 F.3d 823, 829 (10th Cir. 2000) (noting that neither the government nor defendant objected to AKS jury instruction defining willfulness as: "An act is done willfully if it is done voluntarily and purposely and with the specific intent to do something the law forbids, that is, with a bad purpose either to disobey or disregard the law. A person acts willfully if he or she acts unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. Thus, in order to act willfully as I have defined that term, a person must specifically intend to do something the law forbids, purposely intending to violate the law"); United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998) (affirming an AKS jury instruction that willfully "means that the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law"); United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 33 (1st Cir. 1989) (upholding AKS jury instruction explaining that "[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that law forbids").

<sup>&</sup>lt;sup>23</sup> For FCA jury instructions regarding reckless disregard, see, e.g., United States v. Science Applications Int'l Corp., No. CA04-1543, ECF No. 161 at 16 (D.D.C. Feb. 5, 2009) ("I also instructed you that the term 'knowingly' includes acting in 'reckless disregard' or an act's truth or falsity. For purposes of the False Claims Act, reckless disregard can be equated with 'an extreme version of ordinary negligence' or 'gross negligence plus'"); United States ex rel.

relevant facts when acting with gross negligence plus (extreme carelessness), but does not need to have actual knowledge that the conduct is wrongful.

Similarly, as to deliberate ignorance, courts have instructed jurors that, to find that a defendant acted with deliberate ignorance, they must find that the defendant acted with "deliberate blindness" or "willful blindness" or "deliberately closed its eyes" as to what otherwise should be obvious to the defendant.<sup>24</sup> Thus under these circumstances, the person is consciously aware ("**deliberately** ignorant") that material facts are unknown, but does not need to have actual knowledge that the conduct is wrongful. Thus, the fundamental difference between a "knowing and improper" standard and a reckless disregard/deliberate ignorance standard is whether the person actually knew the conduct was inherently wrongful.

#### B. Regulatory and Legal Background Interpreting the FCA's Overpayment Provision

CMS, in its proposed rule implementing the ACA, did not attempt to apply the correct "knowing and improper," *malum in se*, inherently wrongful standard, but, instead, a purported reckless disregard or deliberate ignorance standard, which bordered on asserting that mere negligence could constitute an FCA violation, directly contrary to congressional intent. Courts, thus far, have similarly failed to apply the correct knowledge standard to the FCA's overpayment provision.

*Miller v. Bill Harbert Int'l Constr., Inc.,* No. 95-1231 (D.D.C. May 4, 2007) ("I also instruct you that the term knowingly includes acting in reckless disregard of an act's truth or falsity. The term reckless means gross negligence plus. If a defendant submitted a claim, or caused a claim to be submitted, without properly considering the claim's truth or falsity, that defendant may be found to have acted in reckless disregard of its truth or falsity"); *United States ex rel. Grynberg v. The BOC Grp.*, No. 97-D-2422 (D. Col. Apr. 5, 2004) ("Instruction no. 28. Under the False Claims Act, knowledge may be established if the defendant acted with reckless disregard of the truth or falsity of a statement. The term 'reckless disregard' is an aggravated form of gross negligence of, quote, gross negligence plus, unquote. Stated differently, the term, quote, reckless disregard, unquote, means a lack of care which is so pronounced as to be more than grossly negligent").

<sup>&</sup>lt;sup>24</sup> For FCA jury instructions regarding deliberate ignorance, see, e.g., United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., No. 3:05-2858, ECF. No. 575 at 82 (D.S.C. Aug. 16, 2010) ("Plaintiff can prove deliberate ignorance through proof that a defendant deliberately closed its eyes to what would otherwise have been obvious to the defendant"); United States v. Science Applications Int'l Corp., No. CA04-1543, ECF No. 161 at 16 (D.D.C. Feb. 5, 2009) ("A finding that SAIC purposely avoided learning all the facts or suspected a fact but refused to confirm it also constitutes deliberate ignorance. Stated another way, SAIC's knowledge of a fact may be inferred from willful blindness to the existence of the fact. It is entirely up to you as to whether you find any deliberate closing of the eyes and the inference to be drawn from any such evidence"); United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc., No. 95-1231 (D.D.C. May 4, 2007) ("Plaintiffs can prove deliberate ignorance through proof that a defendant deliberately closed its eves to what would otherwise have been obvious to the defendant. A finding that a defendant purposely avoided learning all the facts or suspected a fact but refused to confirm it. also constitutes deliberate ignorance. Stated another way, a defendant's knowledge of a fact may be inferred from willful blindness to the existence of the fact. It is entirely up to you as to whether you find any deliberate closing of the eyes and the inference to be drawn from any such evidence"); United States ex rel. Grynberg v. The BOC Grp., No. 97-D-2422 (D. Col. Apr. 5, 2004) ("Instruction no. 27. Deliberate ignorance means that BOC closed its eyes to what would have otherwise been obvious to BOC. While deliberate ignorance on the part of BOC cannot be established merely by a demonstration that BOC was negligent, careless, or foolish, knowledge in the form of deliberate ignorance can be inferred if BOC deliberately blinded itself to the existence of a fact").

#### 1. CMS Applies the Wrong Knowledge Standard in the Overpayment Provision

On February 16, 2012, CMS published a proposed rule implementing the ACA's provision mandating that an overpayment be reported and returned within 60 days of when the overpayment was identified or the date any corresponding cost report was due, if applicable.<sup>25</sup>

In proposing the Rule, CMS made two significant mistakes: (1) it misconstrued the overpayment provision's knowledge element; and (2) as a consequence, when it purported to provide concrete examples of alleged violations, it produced a literal hodgepodge of imprecise examples ranging from conduct that would appropriately constitute "knowing and improper" conduct under the correct standard to examples that would only satisfy a mere negligence threshold. Merely negligent conduct is not even actionable under the FCA's general knowledge standard, let alone the heightened knowledge standard governing the FCA's overpayment provision.<sup>26</sup>

In construing the overpayment knowledge element, CMS proposed that an overpayment is identified when a "person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment."<sup>27</sup> The basis for this conclusion is that CMS believed that "Congress' use of the term 'knowing' in the ACA was intended to apply to determining when a provider or supplier has identified an overpayment."<sup>28</sup>

CMS asserted that a "reckless disregard" or "deliberate ignorance" standard is appropriate, because it will provide an incentive to providers and suppliers to exercise "reasonable" diligence:

In some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine

<sup>27</sup> 77 Fed. Reg. at 9182.

<sup>28</sup> Id.

<sup>&</sup>lt;sup>25</sup> See 77 Fed. Reg. 9179 (Feb. 16, 2012).

<sup>&</sup>lt;sup>26</sup> The FCA, everyone would agree, does not reach merely negligent conduct. See, e.g., United States ex rel. Urguilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1058 (11th Cir. 2015) ("Congress did not intend to turn the False Claims Act, a law designed to punish and deter fraud . . . into a vehicle either punish[ing] honest mistakes or incorrect claims submitted through mere negligence or imposing a burdensome obligation on government contractors rather than a limited duty to inquire") (internal quotations and citations omitted); United States ex rel. Owens v. First Kuwaiti, 612 F.3d 724, 726–28 (4th Cir. 2010) ("Congress . . . made plain its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence" and noting that "Congress crafted the FCA to deal with fraud, not ordinary contractual disputes. The FCA plays an important role in safeguarding the integrity of federal contracting, administering strong medicine in situations where strong remedies are needed. Allowing it to be used in run-of-the-mill contract disagreements and employee grievances would burden, not help, the contracting process, thereby driving up costs for the government and, by extension, the American public"); United States ex rel. Farmer v. City of Houston, 523 F.3d 333, 338 (5th Cir. 2008) (noting that the FCA's "mens rea requirement is not met by mere negligence or even gross negligence" and citing to United States v. Krizek, 111 F.3d 934, 941-42 (D.C. Cir. 1997) that at least "aggravated gross negligence" or an "extreme version of ordinary negligence" is necessary under the FCA"); Quirk v. Madonna Towers, Inc., 278 F.3d 765, 767 (8th Cir. 2002) ("innocent mistakes and negligence are not offenses under the Act") (internal quotation and citations omitted); Mikes v. Straus, 274 F.3d 687, 703 (2d Cir. 2001) ("the requisite intent is the knowing presentation of what is known to be false as opposed to negligence or innocent mistake") (internal quotations and citations omitted); Hindo v. Univ. of Health Sciences, The Chicago Med. Sch., 65 F.3d 608, 613 (7th Cir. 1995) ("[i]nnocent mistakes or negligence are not actionable under [§ 3729]").

whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment. On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance to whether it received such an overpayment. For example, a provider that receives an anonymous compliance hotline telephone complaint about a potential overpayment has incurred an obligation to timely investigate that matter. If the provider diligently conducts the investigation, and reports and returns any resulting overpayments within the 60-day reporting and repayment period, then the provider would have satisfied its obligations under the proposed rule. If, however, the provider fails to make any reasonable inquiry into the complaint, the provider may be found to have acted in reckless disregard or deliberate ignorance of any overpayment.<sup>29</sup>

Remarkably, CMS noted that "[w]hen *there is reason to suspect* an overpayment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may be found to have acted in reckless disregard or deliberate ignorance of any overpayment."<sup>30</sup>

CMS' proposed knowledge standard is defective in two respects. First, it never tries to apply the actual knowledge standard that Congress created or provide examples, in light of that standard, of when an individual or entity would possess sufficient knowledge to act "knowingly and improperly" in not conducting an additional investigation. Second, and more significantly, unwittingly or not, it conflates a reckless disregard/deliberate ignorance standard with a mere negligence standard.<sup>31</sup>

Leaving aside CMS' errors in legal interpretation, the examples it provides regarding potential violations of the FCA overpayment provision do provide some practical guidance regarding what conduct would potentially constitute a violation of the FCA overpayment provision under a correct analysis of its knowledge standard.

As noted previously, to constitute a "knowing and improper" retention of an overpayment, the person must know that it is inherently wrongful to retain an overpayment under the circumstances. That is the trigger Congress set for the person to be duty-bound to conduct additional investigation. Under this test, the following examples that CMS provided would likely satisfy the actual standard that Congress created:

<sup>&</sup>lt;sup>29</sup> Id. at 9182. See also id ("We believe defining 'identification' in this way gives providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition, some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research").

<sup>&</sup>lt;sup>30</sup> Id.

<sup>&</sup>lt;sup>31</sup> For example, stating that a person has a duty to investigate further whether there is an overpayment merely if one has "reason to suspect" an overpayment appears to indicate that one will be liable for merely negligent conduct— that is not being reasonable in acting upon information that there may be an overpayment—which is directly inconsistent with Congress' intent in creating a "knowing and improper" standard and also directly inconsistent with the FCA, which, as noted, everyone agrees could never reach merely negligent conduct.

- "A provider of services or supplier reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.
- "A provider of services or supplier learns that a patient death occurred prior to the service date on a claim that has been submitted for payment."
- "A provider of services or supplier performs an internal audit and discovers that overpayments exist."<sup>32</sup>

Under these examples, CMS is clearly correct under even the correct "knowing and improper" standard. If a provider or supplier conducts a review and concludes that claims were actually miscoded, or services were billed when no services were provided, or an internal audit identifies actual overpayments, then it would be inherently wrongful and *malum in se* at that point for the entity to retain governmental funds to which it is not entitled, and that entity could be liable if those funds were not reported and repaid within the time period allotted in the statute.

However, other examples, which CMS states could trigger liability, are clearly wrong, because they would transform the FCA, a statute mandating the award of treble damages and civil penalties, and requires a knowing fraud into a statute that, contrary to congressional intent, reaches merely negligent conduct. For instance, CMS provided the following problematic examples and commentary:

- "[A] provider that receives an anonymous compliance hotline telephone complaint about a potential overpayment has incurred an obligation to timely investigate that matter . . . If . . . the provider fails to make any reasonable inquiry into the complaint, the provider may be found to have acted in reckless disregard or deliberate ignorance of any overpayment."
- "When there is reason to suspect an overpayment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may be found to have acted in reckless disregard or deliberate ignorance of any overpayment."
- "A provider of services or supplier is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry."
- "A provider of services or supplier experiences a significant increase in Medicare revenue, and there is no apparent reason—such as a new partner added to a group practice or a new focus on a particular area of medicine—for the increase. Nevertheless, the provider or supplier fails to make a reasonable inquiry into whether an overpayment exists."<sup>33</sup>

In each bullet, CMS does not provide enough information to address the ultimate question which is whether under the circumstances, it would be "inherently wrongful" for the provider or supplier to fail to conduct a further review. Under the first bullet, under many circumstances, it would not be inherently wrongful for a provider or supplier **not** to conduct an additional review. For example, if you have a hospital

<sup>&</sup>lt;sup>32</sup> Each of these bullets is at 77 Fed. Reg. at 9182.

<sup>&</sup>lt;sup>33</sup> Each of these bullets is at 77 Fed. Reg. at 9182.

system that has a financial relationship with a thousand physicians and you receive a hotline complaint that an unnamed physician is upcoding, it would not be reasonable for a compliance department to conduct any inquiry, because there is no viable lead to pursue. Indeed, under these circumstances, where would you even start to conduct a review? Under these circumstances, no additional review would be needed, let alone it being inherently wrongful to fail to conduct an additional review.

The second, third, and fourth bullets are equally wrong. The second bullet inexcusably conflates what appears to be a negligence standard—having "a reason to suspect"—into a "reckless disregard" or "deliberate ignorance" standard without understanding that each knowledge standard is an entirely different term of art, with its own separate body of case law, which reaches entirely different types of conduct and has entirely separate jury instructions describing the standard.

As to the third and fourth bullets, much turns again on the details regarding what was disclosed to the provider and supplier when the government agency informed the provider or supplier of a "potential" overpayment or understanding what may have resulted in an unexpected spike in revenue. For example, it may be clear to the institution that the government's evaluation, which frequently occurs, is simply wrong and additional review is not necessary, and the institution would be satisfied to defend against any future governmental action if the government later concludes that the "potential" overpayment is an actual overpayment and undertakes some action to recoup the funds. Additionally, there are a multitude of reasons that an institution may experience a spike in revenue, and, offhand, it is difficult to discern why an institution should be subjected to FCA liability if it does not undertake a detailed review if this occurred. But, in any event, again, more fundamentally, these examples are asking the wrong question. Under the law, the question is whether it would be "inherently wrongful" for the provider or supplier to not conduct a further review under the circumstances, and CMS' examples do not provide sufficient facts from which one can reasonably conclude that it would be inherently wrongful not to conduct additional review under the proffered facts.

#### 2. Court Precedent Has Incorrectly Construed the FCA Overpayment Provision

Equally alarming, court precedent has incorrectly construed the FCA overpayment provision, based in part on CMS' mistaken regulatory interpretation.

For example, in *United States ex rel. Kane v. Healthfirst, Inc.*,<sup>34</sup> a district court found that, for purposes of defendants' motion to dismiss, the government adequately pleaded that defendants avoided returning the overpayments, because the complaint alleges that a software glitch was brought to defendants' attention by at least December 2010. Although the defendants tasked the relator with investigating the scope of the issue, when he presented them with a list of potentially affected claims, he was fired, and the government alleges that defendants did nothing further with his analysis and although they repaid certain claims that

<sup>&</sup>lt;sup>34</sup> No. 11 Civ. 2325 (ER), 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

were specifically brought to their attention by the Comptroller, they neglected to repay more than three hundred claims until they received the government's Civil Investigative Demand in June 2012.<sup>35</sup>

The district court, in reaching this conclusion, failed to apply the FCA's actual "knowing and improper" standard related to overpayments but instead applied the FCA's general "knowing" standard that applies to other provisions in the FCA.<sup>36</sup> Because, as noted, the case was merely at the pleading stage, the court had to assume the allegations in the complaint to be true. But if discovery validates defendants' position that the relator did nothing more than identify potential overpayments and that approximately half of all claims the relator identified as potential overpayments ultimately did not constitute overpayments, and the court applies the correct knowing and improper standard, rather than the FCA's general knowledge standard, the defendants can potentially prevail under these facts at summary judgment.

However, the court's failure to apply the correct standard has important implications for the health care industry, because it could potentially lead to a body of case law applying the incorrect standard, which would inevitably lead to more FCA actions and cause health care entities to markedly expand their compliance departments and, under these circumstances, divert needed resources from actual patient care.

#### Conclusion

The stakes are high regarding an appropriate construction of the FCA's overpayment provision. Every large health care entity that submits claims to the government experiences a substantial volume of questions regarding claims submission from internal review, employees, governmental review from multiple organizations (MACs, RACs, etc.), compliance hotlines, and anonymous calls.

An issue that arises is this: If a health care claim is questioned in any fashion, what is a health care provider's duty to investigate or else be accused of committing fraud against the United States by violating the FCA, a statute providing for treble damages and substantial civil penalties and substantially enforced by private, financially self-interested, nonpolitically accountable *qui tam* relators? If the questioned claim is far-fetched or uncorroborated, or it appears unsupported, how much resources must a health care entity dedicate to the issue without being accused of violating the FCA? Moreover, how through must the review be? For example, if questioned claim is worth \$1,000, but to conduct an appropriate medical review of the claim and a regulatory review to determine whether the underlying service was appropriately billed in light of the often conflicting guidance would cost the health care entity

<sup>&</sup>lt;sup>35</sup> *Id.* at \*55.

<sup>&</sup>lt;sup>36</sup> Id. at \*57-59. See also United States ex rel. Keltner v. Lakeshore Med. Clinic, Ltd., No. 2:11-cv-00892-LA (E.D. Wis. Mar. 28, 2013). There, the relator alleged that the defendant clinic conducted audits that revealed that physicians were upcoding consultation services at a high rate and did nothing to determine whether nonaudited services were also upcoded. The district court ruled that the relator could state a plausible claim for relief under the amended reverse false claim provision of the FCA for overpayments withheld after the amendment went into effect, because, if the government overpaid the clinic and the clinic intentionally refused to investigate that possibility, it may have unlawfully avoided an obligation to the government. Id. at \*10. In this case, the court similarly did not apply the correct "knowing and improper" standard.

\$5,000, must the entity spend \$5,000 to learn whether there is a \$1,000 overpayment or violate the FCA?<sup>37</sup> Finally, how much of their scarce resources should health care entities divert from patient care to track down, in detail, every unsupported or uncorroborated concern that an entity may have received an overpayment?

Luckily, for health care entities, the statutory language and legislative history indicate that where Congress drew the line was that the duty to investigate is triggered only when failure to conduct a review—based upon the facts and evidence presented to the entity—demonstrates that it would be inherently wrongful not to conduct a further review. Mere negligence, reckless disregard or deliberate ignorance is insufficient. Instead, the information must be clear enough that the person will know that it is wrongful to retain the funds. Once this is understood, the FCA's overpayment provision will be kept within proper bounds, and health care entities will not be compelled to hire an army of compliance staff to track down every concern or else be subject to suit under the FCA.

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September 25, 2015 - False Claims Act Public Disclosure Alert

#### About the Author

Robert Salcido is a leading FCA practitioner.

Although the United States typically obtains a positive monetary recovery in more than 90 percent of the FCA actions it institutes, *see* Lessons from *Qui Tam* Litigation, 114 COLUM. L. REV. at 1991, Mr. Salcido has been lead counsel in several FCA actions in which he successfully defended clients in FCA actions the government filed at trial or summary judgment, including:

 Salcido was lead counsel for Golden Living in an FCA action where the federal government had sued Golden Living's predecessor company, Beverly Enterprises ("Beverly"), for \$895 million, alleging that Beverly had engaged in an unlawful kickback scheme with McKesson Corp. in violation of the Anti-Kickback Act and the FCA. After 14 days of trial, the court ruled that Beverly and McKesson did not violate the FCA or the Anti-Kickback Act, because their business negotiations were fair, reasonable

<sup>&</sup>lt;sup>37</sup> As one court noted, "Medicare regulations are among the most completely impenetrable texts within human experience." See United States v. Medica-Rents, 285 F. Supp. 2d 742, 770 (N.D. Tex. 2003) (internal quotation and citation omitted), aff'd in relevant part, 2008 U.S. App. LEXIS 17946 (5th Cir. Aug. 19, 2008). Frequently, with conflicting guidance in CMS Manuals, National Coverage Determinations, Local Coverage Determinations, Federal Register statements, statutory provisions and regulatory provisions, there is no simple answer to a coding issue.

and conducted in good faith. See United States of America ex rel. Jamison v. McKesson Corp., 900 F. Supp. 2d 683 (N.D. Miss. 2012).

- Salcido was lead counsel for Aegis Therapies and a Golden Living skilled nursing facility where the federal government had alleged that defendants provided medically unnecessary rehabilitation therapy. The district court granted defendants' summary judgment motion, ruling that the government had used the wrong standard to assess whether the services were medically necessary and failed to prove that defendants' certification regarding medical necessity was objectively false. *See United States ex rel. Lawson v. Aegis Therapies, Inc.*, 2014 U.S. Dist. LEXIS 45221 (S.D. Ga. Mar. 31, 2015).
- Salcido was lead counsel for a defendant physician and multispecialty group practice that the government accused of FCA violations. The district court dismissed all the government's claims on summary judgment. Ultimately, because the United States' action lacked "substantial justification," the United States was ordered to pay defendants more than \$500,000 in legal fees. In making the ruling, the court ruled that Medicare fraud law is an area of expertise and ruled that it was undisputed that Mr. Salcido possessed such expertise. See United States v. Prabhu, 442 F. Supp. 2d 1008 (D. Nev. 2006).
- Salcido was lead counsel for Golden Living in an action where relator and government sued multiple defendants alleging that they violated the FCA because they knowingly created and operated a supply company in violation of Medicare Supplier Standards. The district court granted defendants' FCA summary judgment motion regarding the Supplier Standards allegations, finding that the government's prior administrative proceedings demonstrated that the defendant supply company was entitled to payment. *See United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664 (N.D. Miss. 2011).

Mr. Salcido has authored a number of books and chapters in leading publications (including the American Health Lawyers Association, BNA Books, and Bloomberg BNA) regarding the application of the FCA, including:

- False Claims Act & the Health care Industry: Counseling & Litigation (2d ed. American Health Lawyers Ass'n 2008) (3d edition forthcoming in 2016)
- 2014 Supplement to False Claims Act and the Health care Industry: Counseling and Litigation (American Health Lawyers Ass'n 2014)
- "The False Claims Act in Health Care Prosecutions: Application of the Substantive, Qui Tam and Voluntary Disclosure Provisions," in *Health Care Fraud and Abuse: Practical Perspectives*, Ch. 3 (3d ed. BNA Books 2013) (with annual supplements)
- "False Claims Act: Health Care Applications and Defenses" in Bloomberg BNA Health Law and Bus. Series No. 2650 (2012) (with annual supplements).

Because of his work successfully defending a number of FCA lawsuits, he has been recognized in:

- The National Law Journal in its 2014 Litigation Trailblazers & Pioneers as one of 50 "people who have made a difference in the fight for justice" for his outstanding work in defending FCA lawsuits
- Chambers USA: America's Leading Lawyers for Business (2006-2015), in the 2011-2015 editions of Chambers USA, listed under Health Care: Regulatory and Litigation, Leading Individuals (Nationwide) (Band 1) and as Health Care Leading Individuals (District of Columbia) (Band 1)
- *Law360*, which selected Mr. Salcido as one of the four Health Care MVPs for 2012 based upon a successful trial verdict obtained in the Golden Living FCA/Anti-Kickback Act lawsuit
- Before entering private practice, Mr. Salcido served as trial counsel for the U.S. Department of Justice Civil Fraud Section, which has nationwide jurisdiction over the FCA, where he led several successful prosecutions of the FCA on the United States' behalf.



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