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Critical Legal Issues: WORKING PAPER SERIES

How Exclusion and Debarment Empower Prosecutors to Vastly Expand False Claims Act Liability

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HOW EXCLUSION AND DEBARMENT EMPOWER PROSECUTORS TO VASTLY EXPAND FALSE CLAIMS ACT LIABILITY

INTRODUCTION

This WORKING PAPER explores how the Department of Health and Human Services' (HHS) exclusion powers and the Federal Acquisition Regulations' (FAR) debarment regime have empowered federal prosecutors to define the scope of the civil False Claims Act (FCA) and punish healthcare companies and other government contractors, as well as those companies' executives, for conduct that falls far short of traditional notions of fraud. The specter of the "corporate death sentence" of exclusion or debarment, along with uncertainty about what constitutes compliance with the FCA under expansive new theories of liability, gives prosecutors immense leverage in FCA settlement negotiations. In all but rare cases, companies choose to settle the case at hand rather than risk litigation and the prospect of being barred from doing any future business with the federal government. As a result, prosecutors are able to enforce expansive theories of FCA liability that become the *de facto* law whether or not statutory or judicial precedent supports them. In other words, it is now often prosecutors—not Congress or the courts—who effectively define the contours of the FCA.

Both the courts and Congress could implement changes to diminish prosecutors' outsized role in interpreting the FCA and ensure that only defendants that engage in truly fraudulent conduct face the threats of exclusion and debarment. Specifically, judges could provide more certainty to FCA defendants by strictly enforcing the FCA's materiality

requirement under the US Supreme Court's recent decision in *Universal Health Services, Inc. v. US ex rel. Escobar*, 136 S. Ct. 1989 (2016). Moreover, Congress could limit exclusion and debarment to traditional cases of fraud by adding an intent requirement, thereby limiting these severe penalties to cases of serious, intentional misconduct.

I. FALSE CLAIMS ACT

The FCA is the primary tool for combatting fraud against the federal government. In 2015, the Department of Justice (DOJ) recovered over $3.5 billion under the statute. The FCA prohibits a wide range of false and fraudulent representations that lead to improper receipt or retention of federal money. The elements of an FCA cause of action are: (i) a claim for payment; (ii) that is false or fraudulent; (iii) that is made or carried out with the requisite scienter, *i.e.*, knowledge of the falsehood; and (iv) that is material.[1] Generally speaking, courts have interpreted the FCA very broadly to cover conduct that far exceeds traditional notions of fraud.

A. Elements of an FCA Claim

1. *Claim*

The FCA defines "claim" to mean "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property" that is either (1) "presented to an officer, employee, or agent of the United States"; or (2) "made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government ... provides or has provided any

[1] *See* 31 U.S.C. § 3729 *et seq.*

portion of the money or property requested or demanded."[2] Congress and the courts have developed a broad meaning of "claim," which now encompasses a variety of submissions, both directly to the government and indirectly through third parties, which are intended to cause government payment.

2. *Falsity*

Federal courts, including the Supreme Court, have also developed an expansive definition of "falsity" under the FCA. The FCA has always prohibited claims for payment that are expressly false—*i.e.*, those that contain factually false misrepresentations of the goods or services provided to the government or those that contain express false certification of compliance with regulatory or contractual provisions. But just recently, the Court held that the FCA also covers claims that are impliedly false, *i.e.*, those that impliedly indicate compliance with a material contractual or regulatory provision regardless of whether the claim includes an express false statement.[3] As the Supreme Court recently explained:

> By punishing defendants who submit 'false or fraudulent claims,' the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. When ... a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided.[4]

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[2] 31 U.S.C. § 3729(a)(2)(A).

[3] *See Escobar*, 136 S. Ct. at 1999-00 (holding that the FCA reaches not just "express falsehoods" but also "misrepresentations by omission" where the defendant "makes specific representations about the goods or services provided" and "fails to disclose noncompliance with material statutory, regulatory, or contractual requirements").

[4] *Id.* at 1999.

3. *Scienter*

The FCA's scienter element is likewise broad. The FCA "require[s] no proof of specific intent to defraud," and thus encompasses mental states that don't rise to level of scienter required in common law fraud claims.[5] Beyond punishing defendants with "actual knowledge" that a claim is false, the FCA's scienter requirement also applies to false claims made with (1) "deliberate ignorance of the truth or falsity of the information" or (2) "reckless disregard of the truth or falsity of the information."[6]

3. *Materiality*

The FCA's "materiality" element relates to the nexus between the false information and the government's decision to make payment. Not all false representations connected to government payment create FCA liability; rather, the false statement must be material to the government's payment decision. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[7]

Recently, however, the Supreme Court expanded the definition of "material" and strengthened FCA defenses on the issue of materiality, particularly in cases where the government had some knowledge of the false information before making payment.[8] In *Escobar*, the Court called the materiality element a "demanding" one that that cannot be met when "noncompliance is minor or insubstantial" and held that a false claim is not material merely because "the Government would have the option to decline to pay if it knew of the

[5] 31 U.S.C. § 3729(b)(1)(B).

[6] *Id*. at § 3729(b)(1)(A).

[7] *Id.* at § 3729(b)(4).

[8] *See Escobar*, 136 S. Ct. at 1989.

defendant's noncompliance."[9] Significantly, the Court also stated that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."[10]

B. Damages and Penalties

Even putting aside exclusion and debarment, the FCA imposes substantial financial penalties, providing for treble damages plus a penalty of up to $21,563 for each false claim. Courts have generally taken a broad view of the government's "loss" in FCA cases, creating the potential for staggering financial liability that can bear little relation to the extent of the alleged fraud or the government's actual loss. For example, in cases where the government receives primarily intangible benefits under a contract benefiting third parties—such as grant programs—the government can receive as damages triple the *entire contract amount*.[11] In addition to damages, a defendant can be liable for a civil penalty of between $10,781.40 and $21,562.80 for *each* invoice under the contract, of which there can be thousands or even tens of thousands, particularly in the healthcare field.[12]

II. EXCLUSION AND DEBARMENT

On top of FCA damages and penalties, healthcare providers and other government contractors face a potential corporate death sentence if they are found to have violated the FCA. The Social Security Act (SSA) permits HHS to exclude companies or individuals from

[9] *Id.* at 2003-04.

[10] *Id.* at 2003.

[11] *See, e.g.*, *US v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1277-79 (D.C. Cir. 2010) (explaining scenarios in which federal appellate courts have permitted trebling the entire contract value based on the theory that the government received no direct, tangible benefit).

[12] *See, e.g.*, *US ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364, 384, 389 (4th Cir. 2015) (upholding award of damages and penalties topping $239 million, including a civil penalty of more than $119 million predicated on 21,730 false claims).

participation in federal healthcare programs based on a broad range of violations, including some that overlap with FCA liability. Likewise, FAR permits contracting agencies to debar government contractors from receiving government contracts based on violations of the FCA or failure to affirmatively disclose "credible evidence" of such violations. Because these draconian penalties are tied directly to FCA liability, they provide prosecutors with the ultimate cudgel to extract FCA settlements favorable to the government.

A. Exclusion

Exclusion is the mechanism by which HHS, acting through its Office of Inspector General (OIG), prohibits individuals and entities from participating in Medicare, Medicaid, and other federal healthcare programs. Excluded individuals and entities are barred from receiving payment under a federal healthcare program during the duration of their exclusion, which can be permanent.

The SSA sets out two types of exclusion: mandatory and permissive. Mandatory exclusions are imposed automatically when an individual or entity is convicted of one of four categories of criminal offenses, including felony convictions for healthcare fraud.[13] Mandatory exclusions last at least five years.[14]

Permissive exclusions can be imposed on any of sixteen separate grounds.[15] The grounds for permissive exclusion relate to a broad range of conduct, including conduct that overlaps with FCA liability. For example, an entity can be excluded for violations of the Civil Monetary Penalties Law (CMPL) or the Anti-Kickback Statute (AKS), violations which can also

[13] 42 U.S.C. § 1320a–7(a).

[14] *Id*. at § 1320a–7(c)(3)(B).

[15] *Id*. at § 1320a–7(b).

result in FCA liability.[16] The minimum period of a permissive exclusion differs depending on the violation (some violations have no minimum period), and in some cases the period can be shortened based on mitigating circumstances.[17] The SSA also provides a mechanism for permissive exclusion from providing services reimbursable under federal healthcare programs.[18]

Before 1998, permissive exclusion only applied to direct providers like doctors and hospitals. But that year, HHS broadened the permissive exclusion to apply to indirect providers and suppliers of items reimbursable under healthcare programs, such as pharmaceutical and biotechnology companies.[19] An excluded party now violates the SSA (and may be subject to a civil monetary penalty of $10,000 for each violation) if it furnishes to federal program beneficiaries items or services for which federal reimbursement is sought.[20] This expansion has dramatically increased the number of cases in which prosecutors can threaten exclusion. It also goes hand-in-hand with expansions of the FCA that have increased potential liability for indirect recipients of federal funds.

Exclusion can be levied against individuals as well as companies, and it generally amounts to the end of an individual's career in the healthcare industry. The SSA provides

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[16] *Ibid*.; *see also id.* at § 1320a–7a(8) (providing liability under the CMPL for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program," conduct which also violates the FCA under an effectively identical provision); *Cooper v. Pottstown Hosp. Co. LLC*, 651 Fed. App'x. 114, 115 (3d Cir. 2016) (AKS violations constitute false claims under the FCA).

[17] 42 U.S.C. § 1320a-7(c)(3)(D) - (G).

[18] 42 U.S.C. § 1320c-5.

[19] *See* 42 C.F.R. § 1000.10 ("Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.").

[20] 42 C.F.R. §§ 1001.1901(b)(3) and 1003.102(a)(2)-(3).

that companies that employ excluded individuals as officers, directors, agents, or managing employees may be excluded on a company level from participation in federal health care programs.[21] The excluded individual or entity also may be subject to treble damages for the amount claimed for each item or service rendered.[22] Thus, to avoid penalties, any entity that receives federal healthcare funding may employ an excluded individual only if the entity is both able to pay the individual exclusively with non-federal funding sources and the excluded individual's services relate solely to non-federal program patients. Exclusion thus effectively precludes employment of an excluded individual in any capacity by a healthcare entity that receives reimbursement, indirectly or directly, from any federal healthcare program.

HHS OIG has immense discretion in determining when to invoke permissive exclusion, as well as its scope, and recent guidance from the agency demonstrates that HHS OIG intends to pursue the exclusion remedy aggressively. In April 2016, HHS OIG published a memorandum explaining that it evaluates each case of potential exclusion on a "risk spectrum" by considering numerous factors in four categories: (1) "nature and circumstances of the conduct;" (2) "conduct during investigation;" (3) "significant ameliorative factors;" and (4) "history of compliance."[23] The memorandum further explains that HHS OIG "*presumes* that some period of exclusion should be imposed against a person who has defrauded Medicare or any other Federal health care program" in violation of the FCA but that this

[21] 42 U.S.C. § 1320a-7(b)(15).

[22] 42 C.F.R. § 1001.3002.

[23] *See* Office of Inspector General, United States Department of Health and Human Services, *Criteria for implementing section 1128(b)(7) Exclusion Authority* at 4-7 (Apr. 18, 2016), *available at* https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf (emphasis added).

presumption "is rebuttable in certain situations."[24] The memorandum also highlights the strong incentives for companies to settle FCA allegations when exclusion is at play, noting that "OIG often concludes that exclusion is not necessary to protect the Federal health care programs if the person agrees to appropriate integrity obligations. In these cases, OIG will require integrity obligations in exchange for a release of OIG's 1128(b)(7) exclusion authority."[25]

HHS OIG's aggressive use of exclusion is particularly evident in the context of the so-called responsible corporate officer (RCO) doctrine. Under that doctrine, a corporate manager can be criminally liable for a company's regulatory violations of the Food, Drug, and Cosmetic Act on a strict-liability basis—*i.e.*, with no evidence of intent, knowledge, or even negligence. This criminal liability can then become the basis for permissive exclusion.[26]

B. Debarment

The power of agencies to debar government contractors from receiving government contracts is another form of corporate death sentence that prosecutors use to extract large settlements from companies accused of FCA violations. FAR Subpart 9.4 prescribes the procedures and grounds for debarring contractors from receiving government contracts, two of which can be triggered by FCA violations. First, a contractor can be debarred following a civil judgment "of fraud," including FCA violations, in connection with a government

[24] *See id*. at 4 (emphasis added).

[25] *See id.* at 2.

[26] In 2012, the United States Court of Appeals for the District of Columbia upheld HHS's exclusion of Purdue Pharma executives based on their RCO pleas related to misbranding Oxycontin despite no evidence or admission of their knowledge of or personal involvement in the fraudulent acts of Purdue Pharma employees. *Friedman v. Sebelius*, 686 F.3d 813, 824 (D.C. Cir. 2012). [Ed. Note: WLF filed *amicus* briefs in the district and appellate court cases in support of Friedman. *See* http://www.wlf.org/litigating/case_detail.asp?id=614.]

contract.[27] Second, under the mandatory disclosure rule, a contractor can also be debarred for "[k]nowing failure by a principal ... to timely disclose to the Government ... credible evidence of" a violation of the FCA.[28] As with exclusion, individuals as well as companies can be debarred. FAR Subpart 9.4 defines a "contractor" eligible for debarment as "any individual or entity" who conducts business with the government, submits offers for or is awarded a government contract, or "reasonably may be expected" to do so.[29] While debarment is always discretionary and never mandatory, agencies have wide latitude to debar a contractor it deems not a "responsible contractor[]."[30] Pending its investigation, an agency may temporarily suspend a contractor on the same grounds as for debarment, except that the agency needs only "adequate evidence" rather than a conviction or civil judgment.[31]

C. Scienter in Exclusion and Debarment

The exclusion statutes and FAR generally impose no scienter requirement for exclusion or debarment beyond the knowledge element (if any) of the underlying violation.

The only specific scienter requirement in the exclusion statutes applies to owners of a sanctioned entity, who can be excluded on a personal basis only if they knew or should have known of the underlying violation.[32] This additional requirement does not apply, however, to officers or managing employees of sanctioned entities, meaning that HHS OIG "has the authority to exclude every officer and managing employee of a sanctioned entity" "based

[27] FAR § 9.406-2(a)(1).

[28] *Id*. at § 9.406-2(b)(1)(vi).

[29] FAR § 9.403.

[30] FAR § 9.406-2(a).

[31] FAR § 9.407-1(b).

[32] 42 U.S.C. § 1320a-7(b)(15).

solely on their position within the entity" regardless of their level of knowledge about or involvement in the violation.[33] Indeed, HHS OIG has indicated that it "will operate with a presumption in favor of exclusion" "when there is evidence that an officer or a managing employee knew or should have known of the conduct," indicating that a mere negligence standard is sufficient for HHS OIG to pursue exclusion.[34]

FAR also generally imposes no scienter requirement. As relevant to the FCA, a contractor can be debarred for (1) incurring a civil judgment for an FCA violation; or (2) "[k]nowing failure by a principal" to disclose to the government "credible evidence" of an FCA violation. With respect to an FCA judgment, as explained above, there need not be any intent to defraud. And while "knowing" might appear to be a high standard with respect to the duty to disclose, the "credible evidence" standard is murky and often creates uncertainty about whether internal reports of potential FCA violations require disclosure—particularly under expansive and vague theories of liability like implied certification. "Credible evidence" is also a lower standard than the threshold of proof in court, as commentators have stated that it "is a subjective standard that may lie somewhere between reasonable grounds to believe ... and a preponderance of evidence[]."[35] A contractor thus can be debarred for failing to disclose alleged FCA violations that purportedly meet the "credible evidence" standard even if they might have been dismissed in court.

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[33] *See* Office of Inspector General, United States Department of Health and Human Services, *Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act* at 1-2, *available at* https://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (last visited Nov. 14, 2016).

[34] *Id*. at 2.

[35] Robert K. Huffman, Frederic M. Levy, *Guide to the Mandatory Disclosure Rule*, 2010 A.B.A. Sec. Pub. Cont. L. at 64.

III. THE EFFECT OF EXCLUSION AND DEBARMENT ON FCA SETTLEMENT NEGOTIATIONS

A. Expansion of the FCA and Uncertainty Regarding Its Scope

For the past 30 years, the FCA has expanded substantially in almost every respect. A substantial degree of uncertainty regarding the contours of FCA liability has accompanied that expansion.

The expansion of the statute began with the 1986 amendments. Those amendments defined "knowledge" to include "deliberate ignorance" or "reckless disregard" of the truth or falsity of the claim or statement.[36] In other words, the statute no longer required an intent to defraud, and thus became far more expansive than common-law fraud. The 1986 amendments also increased the damages multiplier from double to triple.[37] Thus, at the same time Congress expanded the scope of conduct covered by the statute, it substantially increased the potential damages for a violation.

More recently, Congress expanded the FCA to include indirect claims for payment. Traditionally, FCA liability had been limited primarily to companies that directly submitted claims to the government or made false statements in connection with direct payments. The Fraud Enforcement and Recovery Act of 2009 expanded FCA liability to downstream recipients of federal money.[38] Courts have also taken an expansive view of what constitutes a "claim" under the FCA, reasoning that it was intended to reach not just direct claims, but

[36] False Claims Amendments Act, Pub. L. No. 99-562, 100 Stat. 3153 (1986).

[37] *Ibid*.

[38] *See* 31 U.S.C. § 3729(b)(2)(A)(ii).

also a wide manner of indirect reimbursement requests that call on the federal fisc.[39]

The notion of falsity has expanded too, particularly after the Supreme Court's July 2016 decision in *Escobar*. There, the Court found that a claim can be "false or fraudulent" even if it is not expressly or literally false. That is, the Court held that FCA liability can attach "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[40]

Even the range of FCA penalties increased recently, nearly doubling from $5,500 - $11,000 per false claim, to $10,781.40 - $21,562.80.[41] This increase will have a substantial impact on FCA cases involving a high volume of claims, particularly in the healthcare industry.

Along with this expansion in scope has come a greater degree of uncertainty regarding the contours of FCA liability. The uncertainty has been particularly acute after *Escobar*. Indeed, *Escobar* raises substantial questions about what contractual or regulatory violations will create FCA exposure, not to mention disclosure requirements. The Court did apply a heightened materiality standard and instructed lower courts to strictly apply the materiality and scienter requirements to cabin potentially limitless exposure for such violations. However, how that instruction will be applied in practice remains unclear. The focus on materiality and scienter also increases the difficulty of getting a case dismissed at

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[39] *See Escobar*, 136 S. Ct. at 1996 (explaining the broad scope of "claims" that implicate the FCA).

[40] *Id*. at 2001.

[41] 81 Fed. Reg. 42491; 20 C.F.R. § 356.3.

the outset prior to discovery, as questions concerning the effect of a falsehood on the government's payment decision and the defendant's state of mind generally require discovery and raise factual issues.

Not surprisingly, this confluence of events has resulted in an uptick in FCA actions. The FCA has become the primary vehicle for government healthcare fraud enforcement, as courts have expanded theories of liability and Food and Drug Administration enforcement actions have lagged. Companies that manufacture and sell drugs and other medical products have been particularly targeted in recent years.[42] At the same time, defense-industry government contractors have remained a frequent focus of FCA investigations and suits. While the annual total of FCA actions in the defense space has declined the past few years, the dollar value of recoveries remains high—2013 was the biggest year for FCA recoveries in which the Department of Defense was the primary client agency.[43] Moreover, expanded theories of liability, particularly after *Escobar*, have created exposure for new industries and types of alleged misconduct, as contractors face FCA cases for allegedly misrepresenting their qualifications or status, inflating costs, evading customs duties, providing false certifications of compliance, and producing defective products.

B. Yates Memorandum

Increasing the stakes of FCA litigation even more has been DOJ's recent decision to

[42] *See, e.g.*, Press Release, United States Department of Justice, Office of Public Affairs, *Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014* (Nov. 20, 2014) ("The pharmaceutical industry accounted for a substantial part of the $2.3 billion in health care fraud recoveries in fiscal year 2014."); Press Release, United States Department of Justice, Office of Public Affairs, *Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013* (Dec. 20, 2013) ("Some of the largest recoveries [in FY 2013] involved allegations of fraud and false claims in the pharmaceutical and medical device industries.").

[43] *See* United States Department of Justice, Civil Division, *Fraud Statistics – Overview, October 1, 1987 – September 30, 2015*, at 6 (Nov. 23, 2015), *available at* https://www.justice.gov/opa/file/796866/download.

prioritize pursuing individual liability against corporate executives. This policy was announced in a September 2015 memorandum by Deputy Attorney General Sally Quillian Yates, now known as the Yates Memo. Per the memorandum, DOJ will "focus on individuals from the inception of" both civil and criminal investigations.[44] It will also condition corporate credit for cooperation on the company's providing all relevant information about executive misconduct and will not, "absent extraordinary circumstances," permit corporate resolutions to protect individuals from civil or criminal liability.[45] The substantially increased threat of individual liability only adds to the pressure on healthcare providers and government contractors to settle FCA claims.

C. Exclusion and Debarment in FCA Settlement Negotiations

The vast majority of the government's immensely growing FCA recoveries in recent years come from settlements rather than judgments.[46] This is no surprise; the new and expansive theories of FCA liability coupled with DOJ focus on corporate executives provide the government with massive settlement leverage. The murkiness surrounding these expansive theories of liability in turn creates uncertainty about compliance and litigation risk. Did the company comply with its regulatory requirements? If perhaps it did not, were those

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[44] *See* United States Department of Justice, Office of the Deputy Attorney General, *Individual Accountability for Corporate Wrongdoing*, at 2 (Sept. 9, 2015), *available at* https://www.justice.gov/dag/file/769036/download.

[45] *Ibid.*

[46] DOJ's public statistics on FCA recoveries combine settlement and judgment recoveries. However, a review of DOJ's public statements about major FCA cases from any recent year shows how settlements dominate overall recoveries. For example, DOJ's press release for FCA recoveries in fiscal year 2015, which touted total recoveries topping $3.5 billion, singled out twenty-five cases and investigations that led to major recoveries. *Every one* of these recoveries was reached through a settlement. *See* Press Release, United States Department of Justice, Office of Public Affairs, *Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015* (Dec. 3, 2015), *available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.

requirements material to payment such that it could be subject to FCA liability? Answering these questions with reasonable certainty is often impossible, which means that companies can rarely be confident about their chances in court. In addition, the government's authority, via Civil Investigative Demands, to conduct one-way discovery against FCA targets and witnesses permits DOJ to support its liability theories while producing no evidence of its own that might, for instance, disprove materiality.

Adding to this already-lopsided playing field, the threat of exclusion or debarment often makes the risk of FCA litigation intolerable. For many healthcare companies and other government contractors, exclusion or debarment for even a few years is a death sentence. The power to threaten exclusion of executives of medical products companies and other government contractors—to effectively end their careers in the industry—only increases prosecutors' leverage in settlement negotiations. A company in this situation has only two options: (1) fight to win the case to avoid exclusion or debarment; or (2) pay to settle the case and agree to a compliance initiative in exchange for removing the risk of exclusion or debarment. Unsurprisingly, most companies choose the second option.

IV. PROBLEMS RESULTING FROM THE SIGNIFICANT FCA SETTLEMENT LEVERAGE CREATED BY EXCLUSION AND DEBARMENT

The current state of FCA law, combined with exclusion and debarment, provides strong incentives for healthcare companies and other government contractors to settle FCA cases regardless of whether prosecutors can establish actual fraud or even clear liability. This problem, which commentators have observed with increasing urgency in recent years,[47]

[47] *See, e.g.,* Joseph W. Golinkin II, note, *Fishing with Landmines: Healthcare Fraud and the Civil False Claims Act—Where We Are, How We Got Here, and the Case for More Trials*, 40 AM. J. CRIM. L. 301 (2013)

results in at least four significant problems:

First, it is manifestly unjust and fundamentally unfair that companies and individuals can be subject to exclusion or debarment and effectively expelled from industry for conduct that does not even amount to common-law fraud. Even if the likelihood of exclusion or debarment is slim in the absence of intent or where a defendant violates a contractual or regulatory requirement, the threat during any settlement negotiations with DOJ amounts to negotiating with a gun to the defendant's head, and can result in large and unjust settlements.

Second, the glaring absence of court decisions as a result of so many cases settling magnifies the considerable uncertainty already inherent in current FCA law regarding what constitutes unlawful behavior.

Third, the threat of exclusion and debarment allows prosecutors to force FCA settlements—and thus effectively impose FCA liability—based on broad and untested theories of FCA liability.

Fourth, while settlements may avert a corporate death sentence, they can impose huge costs that compromise a company's ability to do business, create jobs, and serve the public efficiently. Such costs have other profound effects on the healthcare and government contracting industries.

(discussing how the FCA and exclusion combine to "preclude even innocent parties from fighting an FCA accusation").

V. SOME SUGGESTIONS FOR CONGRESS AND THE COURTS TO LEVEL THE FCA PLAYING FIELD

Exclusion and debarment are arguably necessary and important regulatory tools for punishment of intentional, egregious government-contract fraud. But defendants finding themselves on the fringe of FCA liability should not face the threat of such draconian penalties.

Courts could help to eliminate this problem by following *Escobar*'s instruction to more closely scrutinize materiality and scienter in FCA cases. *Escobar* did create substantial uncertainty regarding the scope of implied-certification liability. But by calling for "strict enforcement of the Act's materiality and scienter requirements,"[48] *Escobar* also implicitly encouraged federal judges to limit FCA liability to conduct that more closely approximates actual fraud. These principles, if followed, would help provide more defined contours regarding the scope of the FCA, thereby permitting defendants to better evaluate the merits of their cases in the context of settlement negotiations with DOJ.

Congress could also help to alleviate the negative effects of DOJ's lopsided FCA settlement leverage by adding a scienter requirement to the exclusion and debarment statutes. Such a requirement would eliminate the possibility of a disproportionate punishment for conduct that does not amount to common-law fraud. And in doing so, it would reduce the pressure on healthcare and government-contractor defendants to settle cases involving questionable liability, thereby increasing the likelihood that such cases would be litigated and subject to judicial interpretation.

[48] *Escobar*, 136 S. Ct. at 2002 (citation omitted).

CONCLUSION

With so many cases settling, prosecutors—and not the courts or Congress—effectively define the contours of the federal government's most important fraud statute unchecked by legal precedent or an adversarial process on a level playing field. This creates clear separation of powers problems. It could not have been Congress's intent that DOJ would effectively become the judge, jury, and executioner of FCA claims.

