False Claims Act & the Health Care Industry: *Counseling & Litigation*

Third Edition

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Chapter 7:02 The Benefits and Risks Associated with Voluntary Disclosures

The OIG refuses to provide assurances in advance regarding the manner in which it will resolve any voluntary disclosure.[1] Thus, any disclosure is fraught with risk. If the provider submits the voluntary disclosure it will, necessarily be handing over documentation to the federal government that indicates that it may have violated federal rules and regulations governing the health care program and then, given the lack of assurances, it must trust the government to settle the matter on fair, even-handed terms.

However, although the submission of a voluntary disclosure is not a risk-free endeavor, it has historically offered a number of benefits to providers who have submitted one. But, even aside from these benefits, there is often no viable alternative to submitting a disclosure once blatant misconduct has been discovered. For example, if company executives learn of blatant misconduct and fail to report that information to the government, they may be subsequently accused of committing a criminal offense.[2] Further, if the government learns that the company knew of the information previously—either because it has been tipped off by a whistleblower or through information obtained in civil discovery—and failed to notify the government, the government will be substantially more aggressive in its settlement discussions with the company.

Following is a discussion of some of the benefits a company can expect to obtain and risks it can expect to incur when it submits any disclosure. Also discussed are the steps the company can undertake to reduce or manage the risks while obtaining the benefits associated with submitting a voluntary disclosure to the government.

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[1] *See, e.g.*, 63 Fed. Reg. 58399, 58400 (Oct. 30, 1998). Specifically, the OIG noted:

> Because a provider's disclosure can involve anything from a simple error to outright fraud, the OIG cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will enure to the disclosing entity. In our experience, however, opening lines of communication with, and making full disclosure to, the investigative agency at an early stage generally benefits the individual or company. In short, the Protocol can help a healthcare provider initiate with the OIG a dialogue directed at resolving its potential liabilities.

[2] According to one press account, D. McCarty Thornton, a former Special Counsel to the HHS Inspector General, pointed out that 42 U.S.C. § 1320a-7b(a)(3), a criminal statute, requires that Medicare money wrongfully gained must be repaid and noted that "[i]f providers acquire knowledge that they are not entitled to keep a [Medicare] payment, for them not to disclose it and repay it is fraudulent and potentially a criminal act" *See Health Care Attorney Disagrees with "Biblical Statements" from Law Enforcement*, 2 HEALTH CARE FRAUD REP. 167, 168 (Mar. 11, 1998).

A. The Incentive to Disclose

The government's enforcement history of the Act's voluntary disclosure provision demonstrates that the disclosing entity substantially minimizes its criminal, civil, and administrative liability and obtains other less tangible benefits.

- *Criminal Exposure.* As noted above, from an historical perspective, it is highly unlikely that the government will institute any criminal proceeding against the company as a result of the disclosure.[3] However, even if criminal action is instituted, the Sentencing Guidelines for Organizations provide relief from substantial fines to those who submit a voluntary disclosure.[4] Under the Guidelines, a mitigating factor to be weighed at sentencing is the corporation's establishment of a compliance program that is directed toward developing, implementing, and enforcing ethical standards and detecting illegal conduct.[5] Thus, even in the unlikely event that the company confronts criminal charges, its liability will be limited as a result of the disclosure.

- *Civil Exposure.* DOJ's enforcement history of the voluntary disclosure provisions of the statute is additional proof that health care providers will be rewarded as a result of the submission of a disclosure. The FCA empowers the court to reduce a party's liability to double, rather than treble, damages when the party submits a valid disclosure.[6] Under its 2013 SDP the OIG has noted that its general practice in SDP matters is to require a minimum multiplier of 1.5 times the single damages, although it may determine that a higher

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[3] *See* Pendergast, *Surviving Self-Governance* at 201–03. In its 2013 SDP, the OIG noted that it "encourages disclosing parties to disclose potential criminal conduct though [sic] the SDP process. OIG's Office of Investigations investigates criminal matters, and any disclosure of criminal conduct through the SDP will be referred to DOJ for resolution. As in civil cases referred to DOJ, OIG will advocate that the disclosing parties receive a benefit from disclosure under the SDP." 2013 SDP at 13.

[4] *See* United States Federal Sentencing Guidelines Manual, Ch. 8.

[5] *Id.*

[6] *See* 31 U.S.C. § 3729(a); *see also* 132 Cong. Rec. 28581 (1986) (the False Claims Act provides a procedure "for corporations to come forward when they discover fraud within their midst. When corporations follow these procedures in cooperating with the Government, the court may impose not only the lesser level of damages, but also a lesser level of penalty") (statement of Senator Grassley).

multiplier is appropriate in individual cases.[7]

- *Administrative Exposure.* As noted above, from an historical per-

[7] *See* 2013 SDP at 2. Further, even in those instances in which the party does not submit a formal voluntary disclosure because it believes that it has clearly complied with the government's rules and regulations but believes that the government may disagree with its position, it is advantageous for the company to disclose its interpretation to the government and receive its assurance that its practices are proper. Under these circumstances, a court will be less inclined to find that a disclosing entity intended to commit fraud in the first instance. *Cf.* United States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321, 328 (9th Cir. 1995) (where contractor had discussed the nonconforming tests with the Army and the Army had approved the tests, the contractor could not have "knowingly" submitted false statements to the government under the Act); Covington v. Sisters of the Third Order of St. Dominic, No. 93-15194, 1995 U.S. App. Lexis 20370 (9th Cir. July 13, 1995) (where hospital had contacted its intermediary to verify that the amount of payments it had received was proper it did not "knowingly" receive an inflated amount even though it was later determined that it had in fact been paid an inflated amount because the intermediary had applied an incorrect geographical factor); United States ex rel. Kreindler & Kreindler v. United Tech. Corp., 985 F.2d 1148, 1157 (2d Cir. 1993) ("The fact that a contractor fully disclosed all information to the government may show that the contractor has not 'knowingly' submitted a false claim, that is, that it did not act with 'deliberate ignorance' or 'reckless disregard for the truth'") (dictum) (internal quotation and citation omitted); United States ex rel. Hefner v. Hackensack Univ. Medical Ctr., No. 01-CV-4078, 2005 U.S. Dist. LEXIS 36427, at *28–*29 (D.N.J. Dec. 23, 2005) (dismissing relator's action because "[w]hile it is clear that Defendants were negligent in monitoring of their billing practices, the hiring of [consultant] to monitor billing compliance and the return of reimbursed monies to Medicare upon discovery of their erroneous acceptance is more evidence of mistake than knowing submission of false claims"), *aff'd*, 495 F.3d 103, 109 (3d Cir. 2007); X Corp. v. Doe, 816 F. Supp. 1086, 1093–94 (E.D. Va. 1993) (contractor's voluntary disclosure of possibly false claims "militates persuasively against finding that the documents clearly establish fraud, for there is no knowing representation of a false claim where, as here, [the company] advised the government about the true nature of the [transaction]") (dictum), *aff'd without op.*, 19 F.3d 1430 (4th Cir. 1994). *But cf.* United States ex rel. Cantekin v. University of Pittsburgh, 192 F.3d 402 (3d Cir. 1999). In *Cantekin*, the relator sued (among others) a researcher, claiming that the researcher had failed to disclose that he received industry funding when he applied for grants from the National Institute of Health (NIH). Before filing the lawsuit, the relator had informed the NIH about defendant's receipt of industry funding, and, only then, did the defendant write to the program administrator listing his industry funding. *Id.* at 414. As a result of this disclosure, the district court dismissed the relator's lawsuit. The Third Circuit held that the district court's basis for dismissal was mistaken. First, the court pointed out that the FCA "has a specific provision dealing with someone who comes forward and discloses his or her false claims" and that "this provision merely reduces the defendant's liability from treble to double damages; it does not exonerate a defendant of a violation." *Id.* at 415. Second, the court pointed out that defendant's disclosure did not comply, in any event, with the FCA's voluntary disclosure provision, because the defendant did not make the disclosure within thirty days of becoming aware of the violation and made the disclosure only after he learned that he was under investigation. *Id.*

spective, it is highly unlikely that the government will undertake any adverse administrative action against the company as a result of the submission of a voluntary disclosure.[8] However, even in the unlikely event that the government undertakes such action, the submission of the disclosure will likely result in the government's limiting the duration of the exclusion because of the company's demonstrated willingness to institute corrective action and exercise self-governance.[9]

Additionally, besides reducing the company's criminal, civil, and administrative exposure, at least two other benefits result from the submission of a disclosure. First, the issuance of a disclosure to the government permits the company to control the timing and scope of the government's investigation. In a government-initiated investigation, the government will typically issue subpoenas and interview company employees. During this process, the company has little or no knowledge of the full scope of the government's investigation. Conversely, under the voluntary disclosure program, the government, as a general matter, does not issue subpoenas, and the company is afforded the luxury of interviewing its own employees and reviewing its claims. The company's ability to conduct its own investigation prior to being subjected to governmental oversight minimizes the risk of its being blindsided by a secret governmental investigation and better enables it to defend (or explain) its conduct.

Second, a timely disclosure may serve to preempt an employee from initiating a *qui tam* action or, if an action is filed, may provide the company with a defense to the action. Employees who witness their company submit a voluntary disclosure are less likely to file a *qui tam* action because the government is already aware of the allegations.[10] Indeed, under these

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[8] *See* Pendergast, *Surviving Self-Governance* at 201–03; *see also* Rockelli, *HHS VDP Program Continues* at 745 (In all cases in which companies had been accepted into the OIG Program, "the IG waived its exclusion sanctions in view of the self-disclosure"). In non-binding guidelines regarding the circumstances under which the OIG will exercise its discretion to impose a permissive exclusion on a provider, one factor the OIG considers is whether the entity brought "the activity in question to the attention of the appropriate Government officials prior to any Government action, e.g., was there any voluntary disclosure regarding the alleged wrongful conduct?" 62 Fed. Reg. 67392, 67393 (Dec. 24, 1997).

[9] Additionally, the OIG states that its usual practice is to not require that the disclosing entity enter into an integrity agreement. *See* 2013 SDP at 2 ("Since 2008, we have resolved 235 SDP cases through settlements. In all but one of these cases, we have released the disclosing parties from permissive exclusion without requiring any integrity measures").

[10] Of the 129 voluntary disclosure cases that have been closed under *DOD*'s voluntary

circumstances, the government may actually oppose the relator's participation in the action, because if the relator is permitted to proceed, the government must share, at a minimum, 15% of its recovery with a whistleblower who, because the government is already aware of the allegations, did nothing to contribute to the action.[11] Additionally, the company can create a jurisdictional defense to a *qui tam* action if either the submission of the report qualifies as a public disclosure or if the information underlying the document is subsequently publicly disclosed. As has been discussed in detail in Part 3, *qui tam* actions are jurisdictionally barred, in most cases, when the allegations or transactions underlying the action have been publicly disclosed.[12]

B. The Risks Underlying the Disclosure

Although there are immediate and important benefits to disclosures, the company's candor is not unaccompanied by risks. Set forth below are the likely risks and suggested methods to minimize the risk.

Employee's action. There is risk that a disciplined or discharged employee may challenge his or her employer's actions.[13] The more serious the wrongdoing, the more likely the disciplinary action will result in termination rather than some lesser penalty, such as a reprimand or suspension without pay. Inevitably, some employees will challenge the disciplinary actions by filing lawsuits for wrongful termination, slander, defamation, or invasion of privacy. To reduce the likelihood of an adverse judgment arising from an employee action challenging the company's disciplinary action, the provider should have a comprehensive compliance program that includes employee training and fraud awareness programs and specific provisions relating to disciplinary action that will be initiated against those who breach the

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disclosure program, only 4 have involved *qui tam* actions. *See Use and Administration of DOD's Voluntary Disclosure Program* at 2.

[11] *Cf.* United States ex rel. Fine v. Sandia Corp., 70 F.3d 568, 572 (10th Cir. 1995) ("Congress instituted the *qui tam* provisions of the FCA to encourage private citizens to expose fraud that the government itself cannot easily uncover. That purpose is not served by allowing *qui tam* plaintiffs to recover where, as here, the government has already identified the problem and has an easily identifiable group of probable offenders.")

[12] *See* 31 U.S.C. § 3730(e)(4). An exception to this general rule applies when the whistleblower is the "original source" of the public disclosure. *Id.* § 3730(e)(4)(B).

[13] Once a corporation discovers that its employees have engaged in wrongdoing, it will often initiate specific disciplinary measures against those who participated in the misconduct. Indeed, as part of its report to the government, the company must "[d]escribe any disciplinary action taken against corporate officials, employees and agents as a result of the disclosed matter." *See* 63 Fed. Reg. at 58402.

provisions of the compliance program. By providing employees clear guidance regarding the integrity demands of the employer's program, employees are less likely to seize upon ambiguities in order to press their claims. If the employee is discharged and the company executes a release with the employee, the company should consider ensuring that the release is broad enough to cover any subsequent *qui tam* action that the employee may file. Several courts have ruled that a release will bar the relator from filing a subsequent *qui tam* action when the government is aware of the alleged fraud and had an opportunity to investigate prior to the time in which the release is executed.[14] However, several courts have ruled that where the government is not aware of the allegations or has not had an adequate opportunity to investigate the allegations, the relator's release does not bar the relator's *qui tam* action.[15]

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[14] **If the government is aware of the alleged misconduct, a court may enforce an employee's release not to file a *qui tam* against the company.** *See, e.g.*, United States ex rel. Hall v. Teledyne Wah Chang Albany, 104 F.3d 230 (9th Cir. 1997) (release will be enforced when government has full knowledge of the relator's charges and had investigated them before the relator and the defendant had executed their release); United States ex rel. Chandler v. Swords to Ploughshares, No. C-96-0578, 1999 U.S. Dist. LEXIS 3007 at *8–*9 (N.D.Ca. Mar. 11, 1999) (because the government was aware of the relator's allegations prior to the time in which the relator signed a release related to a state court proceeding, "the public policy . . . of encouraging individuals to report fraud to the government does not require the court to deny effect to an otherwise binding settlement" and thus relator's "claim is barred by his earlier settlement . . . ."). *See also* United States ex rel. Gebert v. Transport Admin. Servs., 260 F.3d 909, 916 (8th Cir. 2001) (holding that pre-filing release the relators had executed prior to filing the *qui tam* action with the bankruptcy trustee and the defendants barred the relators' subsequent *qui tam* action when facts underlying cause of action was known to the relators at the time the release was executed. The court reasoned that the "right of parties to contract is fundamental . . . , and the agreement therefore carries with it a strong presumption of enforceability. In addition, the posture of this agreement as a small part of a larger bankruptcy proceeding implicates concerns that are unique to bankruptcy: creditors and other interested parties want debtors to be forthcoming about all of their assets, and enforcing the settlement agreement and release would serve as an incentive for debtors to be candid about their assets during bankruptcy proceedings. The harm to the public interest is further limited in that the settlement agreement and release only runs to parties to the agreement, not to other relators or the government") (citation omitted).

[15] **When the government is not aware of the allegations or has not had an adequate opportunity to investigate the allegations, courts have ruled that the relator's release does not bar the relator's *qui tam* action.** *See, e.g.*, United States v. Northrop, 59 F.3d 953 (9th Cir. 1995) (prefiling release of *qui tam* claim could not be enforced to bar subsequent *qui tam* action); United States ex rel. Powell v. Am. Intercontinental Univ., Inc., No. 1:08-CV-2277, 2012 U.S. Dist. LEXIS 97587 at *34 (N.D. Ga. July 12, 2012) (finding employment release did not bar the relator's *qui tam* action when "there is no evidence that the Government was aware of this conduct prior to this lawsuit's filing"); United States ex rel.

Decisions like *George Washington Univ.*—holding that relator's release, which became effective after the relator filed her qui tam action, would not be enforced—are poorly reasoned. Once the *qui tam* action is filed, the relator's release should be enforced because at that point the government is aware of the underlying allegations and may effectively enforce its rights. The government should not, at that time, be required to share any portion of its recovery with a relator that had bargained away her rights. Society's interest is advanced by both the government receiving 100% of the recovery and the relator's bargain being enforced.[16]

El-Amin v. George Washington Univ., No. 95-2000, 2007 U.S. Dist. LEXIS 32166 at *25–*26 (D.D.C. May 2, 2007) (refusing to enforce release where it was signed before but did not become effective until relator had filed her *qui tam* action because otherwise the relator would possess, in essence, the ability to dismiss the action notwithstanding statutory command that action can only be dismissed with the consent of the United States and noting "that enforcement of a release entered into during the government's statutorily prescribed 60-day evaluation period. . . without the government knowledge or consent. . . is outweighed by the more pressing policy considerations and is therefore unenforceable") (citations omitted); United States ex rel. DeCarlo v. Kiewit, 937 F. Supp. 1039 (S.D.N.Y. 1996) (same); United States v. Am. Healthcorp, Inc., Medicare & Medicaid Guide (CCH) ¶ 43,681 (M.D. Tenn. Sept. 14, 1995) (same), *reh'g granted and order vacated on other grounds*, 914 F. Supp. 1507 (M.D. Tenn. 1996). *See also* United States ex rel. Longhi v. Lithium Power Tech. Inc., 575 F.3d 458, 474 (5th Cir. 2009) (finding that the "district court correctly found that [the relator] signed the release eleven days after he filed the qui *tam* complaint and was therefore unable to personally dismiss the case" because once an action is filed it may only be dismissed if the court and Attorney General give written consent to the dismissal); *cf.* United States ex rel. Leveski v. ITT Educ. Servs., 2009 U.S. Dist. LEXIS 88197 at *6 (S.D. Ind. Sept. 23, 2009) (finding that employment release did not bar subsequent *qui tam* action because relator's "claims in this suit are not based upon and do not relate to her employment; her claims are derivative in nature, based on an obligation owed to the Government").

[16] *See, e.g.*, United States ex rel. Radcliffe v. Purdue Pharma, 600 F.3d 319, 333 (4th Cir. 2010) (applying a "government knowledge" standard and finding that when "the government was aware, prior to the filing of the qui tam action, of the fraudulent conduct represented by the relator's allegations, the public interest has been served and the Release should be enforced"); United States ex rel. Ritchie v. Lockheed Martin Corp., 558 F.3d 1161, 1170 n. 8, and 1171 (10th Cir. 2009) (ruling that where the company had voluntarily disclosed the alleged misconduct before the former employee filed the qui tam action, the former employee's release was enforceable because the federal interest in receiving the disclosure and encouraging settlements outweighed its interest in supplementing federal enforcement that it would have received if the relator could proceed with the qui tam action and noting that notwithstanding the relator's release of claims the "government owns the FCA action" and thus would be "still free to bring its own suit after a would be relator settles his or her own claim"); United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 336-38 (D. Mass. 2011) (noting that there "is an emerging agreement within the Courts of Appeals that pre-filing releases bar subsequent qui tam claims if (1) the release can be fairly interpreted to

One district court has also ruled that where the government did not know of the allegation at the time the relator signed the release, the release did not bar the *qui tam* action.[17]

An employee filing qui tam action stemming from the disclosure. Employees, even those that participated in the company's internal investigation, may file a *qui tam* action in the hope of profiting from corporate wrongdoing.[18]

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encompass *qui tam* claims and (2) public policy does not otherwise outweigh enforcement of the release" and finding that relator's claims were barred by virtue of the relator's pre-filing release because the Food and Drug Administration was aware of the allegations before relator signed the release and filed his action and thus "the public interest in bringing fraud against the government to light is greatly diminished and, ultimately, outweighed by the public interest in encouraging private settlement of claims").

[17] *See* United States ex rel. McNulty v. Reddy Ice Holdings, Inc. No. 08-cv-12728, 2011 U.S. Dist. LEXIS 140316 at *53 (E.D. Mich. Dec. 7, 2011). The court reasoned that drawing the line there furthered public policy because companies would have an incentive to tender prompt self-disclosures because, if furnished before an employee executed a release, the release would be enforced and the relator dismissed from the lawsuit. *Id.* at *51–*53. Presumably, under the court's logic, after the release is executed, the company would have no interest to self-disclose because it would assume that the relator would not file a qui tam in light of the release. The court's reasoning is flawed. As the courts that have enforced relators' releases have pointed out, the purpose of the qui tam provisions is to provide the government with knowledge of the alleged fraud so that the government can undertake effective action to protect its interest. After the government has obtained such knowledge of fraud—from any source—no qui tam action is necessary to protect the government's interest because politically accountable officials in the Department of Justice are well positioned to undertake that function. Thus, if the government has knowledge, it frustrates, not furthers, the public interest to permit relators to advance their action and thereby compel the government to share a substantial portion of the government's recovery with someone who filed an action without furnishing any new information to the government. Under these circumstances, the relator is not breaking a conspiracy of silence but only repeating what the government already knows. Thus, under these circumstances—regardless of whether the government learns the information before the relator signs the release or after the relator signs the release (but before the relator files the lawsuit)—public policy would be advanced by enforcing the parties' release and dismissing the relator from the lawsuit. Accordingly, rather than drawing the line at whether the government knew before or after the release, courts should, instead, draw the line at whether the government knew before or after the relator filed the lawsuit.

[18] ***Qui Tam* actions based upon a company's voluntary disclosure to the government may be subject to dismissal under the public disclosure bar:** *See* United States ex rel. Cherry v. Rush-Presbyterian/St. Luke's Med. Ctr., No. 99 C 06313, 2000 U.S. Dist. LEXIS 21010 (N.D. Ill. Jan. 16, 2001); *cf.* United States ex rel. Brennan v. Devereux Found., No. 01-4540, 2003 U.S. Dist. LEXIS 2783 (E.D. Pa. Feb. 25, 2003). *But see* United States ex rel. Rost v. Pfizer Inc., No. 06-2627, 2007 U.S. App. LEXIS 26486 at *23 (1st Cir. Nov. 15, 2007) (rejecting notion that voluntary disclosure to the government can constitute a public disclosure and noting that the "effect of [defendant's] argument would be to reinstate exactly what Congress eliminated—the 'government knowledge' bar. It is an insufficient response to

There are at least two measures a provider may undertake to reduce the likelihood that a whistleblower will misappropriate the fruits of its voluntary disclosure investigation in order to file a *qui tam* action. The employer should use only highly trusted employees to assist in its internal investigation and should ensure that the voice of each, to the extent possible, is incorporated into the final product. *Qui tam* actions in this context *frequently* result from an employee's belief that the employer has intentionally downplayed the results of the investigation. Thus, the employer, upon submitting its report, should inquire of each participant whether that person believes that the report fully and accurately describes the misconduct that is being reported. If there is disagreement, steps should be taken to minimize the basis and scope of the dispute.

Governmental action. The government itself, a friendly adversary at the start of the voluntary disclosure proceeding, may turn hostile and either threaten to file an action based upon the conduct underlying the disclosure or accuse the party of submitting a false disclosure statement because the party did not fully disclose the entire scope of the misconduct.[19] To reduce

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argue, as [defendant] does, that the government knowledge bar created by its reading is a very limited one and applies only where the government official receiving the disclosure is the appropriate investigatory official. Only one court has adopted such a reading. . . . We find no support in either the language or the history of the statute for such a reading"). Some *qui tam* actions brought as a result of a voluntary disclosure have resulted in a substantial recovery. For example, in *United States ex rel. Keeth v. United Tech. Corp.*, the company had disclosed to the government, pursuant to DOD's voluntary disclosure program, that it had received an overpayment of $75 million. *See* NEW YORK TIMES, April 1, 1994 at D1 (describing case). It repaid the overpayment and promised to investigate the transactions fully and to disclose any additional wrongdoing to the government. *Id.* The relator, who was a corporate vice president and a member of the internal investigative team, believed that the company's disclosure statement was a whitewash, intended as much to conceal as to disclose since it downplayed or omitted discussion of facts unfavorable to its position. He filed a lawsuit under the *qui tam* provisions of the statute. *Id.* As a result of the *qui tam* complaint the company paid the government an additional $150 million, of which the relator received more than $22 million. With this case as a precedent, other corporate insiders are likely to appropriate internal corporate investigatory material in order to obtain a private profit.

[19] Indeed, such a result occurred in *In re Parker Hannifin Corp.* After the company had reported the disclosure, a person, who did not file a *qui tam* action, anonymously reported to the government that the company omitted crucial details from its report. *See* DEFENSE CONT. LITIG. REP. 72 n.7 (Oct. 27, 1994). As a result of the person's report, the government deposed a number of corporate insiders to determine whether the contractor intentionally misled the government. *Id.* at 68, 70. As a result of the investigation, the government concluded that the contractor's voluntary disclosure report contained false statements and the contractor paid a substantial fine. *Id.* In this regard, the OIG in its Guidelines point out that "the intentional submission of false or otherwise untruthful information, as well as the intentional omission

the likelihood that the government will prosecute the company on the basis of the disclosure, the company should ensure that its disclosure report does in fact disclose, not conceal, the misconduct. While the government conducts a verification audit, the company should not minimize the importance of disclosing all the facts underlying its internal investigation. If witnesses or documents reveal that the company withheld facts that the government believes it needs to ascertain the scope of the misconduct, the government will become more aggressive in its negotiations with the company to resolve the matter.

Moreover, under its 2013 SDP, the risk of an adverse governmental action is more pronounced. The OIG, in its SDP, announced that in "making a disclosure, a disclosing party must acknowledge that the conduct is a potential violation" of federal criminal, civil, or administrative laws for which civil monetary penalties are authorized.[20] Additionally, the OIG noted that it questioned whether disclosures where the disclosing party stated that "the Government may think there is a violation, but we disagree" raise questions about whether the matter is appropriate for the SDP.[21]

If the OIG requires the disclosing entity to admit that it believes that there is a potential violation of law without any qualification, the price of admission into the OIG program may be too high. This is true for a couple reasons. First, there are many occasions of regulatory ambiguity where the disclosing party believes that its interpretation is correct and the government's is wrong. Indeed, in many such instances, courts in FCA actions have agreed with the defendant and disagreed with the government either at trial or at summary judgment.[22] Under these circumstances, if the defendant preferred to file a disclosure and to resolve the ambiguity under the SDP protocol and pay the amount the OIG requires rather than confront the prospect of a future FCA action filed either by the government or a relator, the disclosing party would be required to certify to a falsehood—that it believes that there is a potential violation of law when it does not—to gain

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of relevant information, will be referred to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in the Federal health care programs." 63 Fed. Reg. at 58403.

[20] *See* 2013 SDP at 3.

[21] *Id.* at 4.

[22] *See, e.g.*, United States ex rel. Lawson v. Aegis Therapies, Inc., No. 210-072, 2015 U.S. Dist. LEXIS 45221 (S.D. Ga., Mar. 31, 2015); United States ex rel. Jamison v. McKesson Corp., 900 F. Supp. 2d 683 (N.D. Miss. 2012); United States v. Prabhu, 442 F. Supp. 2d 1008 (D. Nev. 2006); United States v. Medica-Rents Co., 285 F. Supp. 2d 742 (N.D. Tex. 2003), *aff'd in relevant part*, 2008 U.S. App. LEXIS 17946 (5th Cir. Aug. 19, 2008).

admission. Second, by making a false admission, a disclosing party may incur tangible harm. In describing why no FCA violation occurred, a defendant would like to explain to a court that it did not knowingly submit false claims because it did not, and could not, have reasonably believed that its claims were false or fraudulent. If the defendant is required to state, contrary to fact, that it believes the claims were potentially in violation of law, there is no doubt that in subsequent litigation, the government, or a relator, would seek to use that statement against the disclosing party.

If the OIG persists in demanding an admission, then prudent health care entities may be better advised, in appropriate cases, to simply make a disclosure to CMS or the Medicare Administrative Contractor. Those entities can refer the matter to the OIG in appropriate cases. Moreover, by making the disclosure, the defendant still preserves future defenses in any subsequent FCA action that it did not knowingly submit false claims.

Waiver of the attorney client privilege. There is an additional element of risk in that all material arising from the company's internal investigation and governmental disclosure may be found to be nonprivileged because the material was released to a third party, namely the government. Regarding the issue of confidentiality, the OIG, in its Guidelines, provides:

> In the normal course of verification, the OIG will not request production of written communications subject to the attorney-client privilege. There may be documents or other materials, however, that may be covered by the work product doctrine, but which the OIG believes are critical to resolving the disclosure. The OIG is prepared to discuss with provider's counsel ways to gain access to the underlying information without the need to waive the protections provided by an appropriately asserted claim of privilege.[23]

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[23] 63 Fed. Reg. at 58403. Some of the work product material the OIG requests access to is summaries of interviews that are conducted pursuant to the internal investigation. Specifically, it requests:

> [a] list of all individuals interviewed, including each individual's business address and telephone number, and their positions and titles in the relevant entities during both the relevant period and at the time the disclosure is being made. For all individuals interviewed, provide the dates of those interviews and the subject matter of each interview, as well as summaries of the interview. The health care provider will be responsible for advising the individual to be interviewed that the information the individual provides may, in turn, be provided to the OIG. Additionally, include a list of those individuals who refused to be interviewed and provide the reasons cited.

Id.

Notwithstanding the OIG's assurances, some courts have ruled that companies cannot "selectively assert" the attorney-client privilege or application of the work product doctrine by waiving the privilege in its disclosures to the federal government while asserting the privilege in other litigation involving the same or similar facts.[24] Thus, until the attorney-

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[24] **Courts have ruled that companies cannot selectively waive the privilege:** *See, e.g.*, In Re: Columbia/HCA Healthcare Corp. Billing Practices Litigation, 192 F.R.D. 575 (M.D. Tenn. 2000), *aff'd*, 293 F.3d 289 (6th Cir. 2002). In *Columbia/HCA*, the company, in response to the government's investigation, turned over documents. Prior to releasing the documents, the company entered an agreement with the government that the production of documents did not constitute a waiver of attorney-client privilege or protection of the work product doctrine. *Id.* at 577. The company claimed that, because of this agreement, the documents remained privileged when non-governmental plaintiffs sought the documents in other litigation. The court disagreed and granted the plaintiffs' motion to compel the production of these documents. The court ruled: "Clients who wish to selectively disclose privileged documents and the entity to whom they wish to disclose the documents cannot negate a waiver simply by agreeing to do so. . . . Accordingly, the Court holds that even in the context of a government investigation, voluntary disclosure of privileged materials to the government constitutes a waiver of the attorney-client privilege to all other adversaries." *Id.* at 579. The Sixth Circuit affirmed the district court, ruling that neither the attorney-client privilege nor the work product doctrine applied to documents that the company produced to the government under a confidentiality agreement. *See id.* 293 F.3d at 303, 306–07. *See also*, Westinghouse Elec. Corp. v. The Republic of the Philippines, 951 F.2d 1414 (3d Cir. 1991) (Westinghouse had waived attorney client privilege and work product privilege by its disclosures to the SEC and DOJ and thus Philippine government could obtain this material in action against the company); In re Martin Marietta Corp., 856 F.2d 619 (4th Cir. 1988) (company waived attorney-client privilege and work product doctrine with respect to its position paper, internal audit report and interview memoranda when it disclosed the material to the government during its investigation when former employee subpoenaed the material for use in his criminal trial); In re Subpoena Duces Tecum (Tosero), 738 F.2d 1367, 1370 (D.C. Cir. 1984) (company willingly sacrificed its attorney-client confidentiality by voluntarily disclosing material in an effort to convince the SEC that an enforcement action was unwarranted because "a client cannot waive that privilege in circumstances where disclosure might be beneficial while maintaining it in other circumstances where nondisclosure would be beneficial"); *see generally* United States ex rel. Falsetti v. S. Bell Tel., 915 F. Supp. 308 (N.D. Fla. 1996). In *Southern Bell*, the court refused to apply the "self-critical analysis" privilege in a *qui tam* action where the defendant invoked the privilege to protect from disclosure a retrospective internal investigation it had conducted. The court stated that before recognizing a new rule of privilege, it must inquire into whether Congress has had the opportunity to consider whether a privilege should apply. *Id.* at 310–11. In reviewing the FCA, the court concluded that although Congress had applied some protection regarding the disclosure of information provided to the government in the context of a submission of a voluntary disclosure (*see* § 3729(d)), providing that information voluntarily disclosed to the government was exempt from disclosure under the Freedom of Information Act), it created no other privilege regarding FCA actions in general. Accordingly, the court denied the

client privilege and work product protection issues are resolved, prudent counsel must tailor the disclosure so that it is detailed enough to obtain credit under the Sentencing Guidelines and be acceptable to the OIG under its voluntary disclosure program, yet general enough so as not to waive applicable privileges. One recommended method is to limit the report to the facts that were uncovered during the internal investigation, but to withhold, in the initial disclosure, the underlying communications and material from which the facts were gleaned.[25] Because of the government's need to verify the facts underlying the report, and thus its likely demand that the provider disclose its source material, this strategy may only achieve limited success. Consequently, extra care should be taken to ensure that the internal investigation, and the record underlying the investigation, be as thorough and accurate as is possible so that if the material is deemed to be nonprivileged in subsequent litigation, the underlying record will not be misinterpreted.[26]

Thus, when company officials learn of possible misconduct, the issue is not **should** we disclose but **how** to disclose. The "how to disclose" question is answered only by careful study of the pertinent risks—the risks of employee actions, *qui tam* actions, or a governmental enforcement action—and analysis of how each of these risks can be minimized. If these risks are successfully managed, then the benefits flowing from the disclosure—

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defendant's request that it recognize the self-critical analysis privilege in the context of a *qui tam* action. *See also* United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., No. 01-4078, 2003 U.S. Dist. LEXIS 15225 at *9 (D.N.J. Aug. 14, 2003) (refusing to apply the self-critical analysis privilege because defendant's "speculative contention that disclosure would deter it from aggressively self-criticizing itself is unsubstantiated and insufficient to veto the strong public interest in access to the information").

[25] *See* Alan W.H. Gourley, *Protecting Corporate Information*, BNA/ACCA Compliance Manual ch. 6. The foundation for this recommendation is that courts are less inclined to find waiver of the attorney-client privilege and work product protection if only facts, and not communications, are disclosed. *Id.*

[26] Even outside of the voluntary disclosure context, whenever a party engages the government in discussions regarding its potential liability under the FCA, the party should enter into a confidentiality agreement with DOJ. A primary risk is that any information delivered to DOJ may subsequently be delivered to a *qui tam* relator if such an action, unbeknownst to the company, is pending, which is possible because the case remains under seal for a prolonged period, or may be provided to a relator in a subsequently filed *qui tam* action. For a more detailed account of the various benefits and risks associated with submitting a voluntary disclosure, *see* Robert Salcido, *HHS' Voluntary Disclosure Program: How to Obtain Benefits under the Program while Minimizing Risk*, (Vol. 8, No. 4) at 1 HEALTH LAW (1995).

reduced civil fines and governmental declination of criminal prosecution and administrative action—will substantially outweigh the risks inherent in submitting the disclosure.