AHLA

VOLUME 7 ISSUE 1 August 2018

Fraud & Abuse

A Publication of the American Health Lawyers Association
Fraud and Abuse Practice Group

Table of Contents

A "C Plea" and a Judge
Thomas E. Zeno
Rebecca A. Worthington 1

The Dilemma of Joint Defense Agreements in Internal Investigations After the Yates Memo
Stacy C. Gerber Ward 5

2018 Highlights Some Victories for Defendants in False Claims Act Cases
Danielle E. Holley................................. 9

Resource Corner................................. 11

Fraud and Abuse © 2018 is published by the American Health Lawyers Association. All rights reserved. No part of this publication may be reproduced in any form except by prior written permission from the publisher. Printed in the United States of America."This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought."
—from a declaration of the American Bar Association

A "C Plea" and a Judge

Thomas E. Zeno
Squire Patton Boggs
Washington, DC and Cincinnati, OH

Rebecca A. Worthington
Squire Patton Boggs
Washington, DC

Although counsel and prosecutors negotiate terms of corporate criminal plea bargains, trial courts remain integral to the successful resolution of a criminal guilty plea under Fed. R. Crim. P. 11(c)(1)(C). A recent decision from the U.S. District Court for the District of Massachusetts, *United States v. Aegerion Pharmaceuticals, Inc.*,[1] highlights this point. Judicial review of a "C plea" may be generally limited and rare, but the court in *Aegerion* seriously questioned not only whether judicial review should indeed be so limited, but also whether C pleas are appropriate in the corporate context. As detailed below, the negotiations surrounding the plea agreement in *Aegerion* illustrate the ways in which defense counsel should prepare to address the trial court's concerns, while at the same time addressing those of the client and the prosecutor.

Mechanics of a C Plea

A "C plea" refers to an agreement to plead guilty entered pursuant to Fed. R. Crim. P. 11(c)(1)(C). As distinguished from the much more common plea agreement under Rule 11(c)(1)(A) (in which only charges are negotiated), a C plea allows the prosecutor to "agree that a specific sentence or sentencing range is the appropriate disposition of the case, or that a particular provision of the Sentencing Guidelines, or policy statement, or sentencing factor does or does not apply."[2] A court presented with a C plea agreement may accept it, reject it, or defer a decision until it has reviewed the presentence report.[3] If the court rejects the C plea, the defendant has the option to proceed with the plea knowing that the court "may dispose of the case less favorably toward the defendant than the plea agreement contemplated."[4] Alternatively, the defendant may withdraw the plea and proceed with the case.[5]

Interests of the Organization

In negotiating a plea agreement for a corporate client, the organization relies on outside counsel to obtain the best outcome for the stockholders or owners, employees, and customers or patients of the organization. If a declination of prosecution cannot be achieved, counsel can seek a non-prosecution agreement (NPA) or a deferred prosecution agreement (DPA). These types of agreements avoid the collateral consequences of a criminal conviction. In exchange for an NPA or a DPA, the organization often agrees to separate terms, such as making restitution or taking remedial action (e.g., engaging an independent monitor of its compliance program).

If a guilty plea must be negotiated, the company will prefer a C plea because the specific terms of the sentence are set forth in advance. Such an agreement allows the organization to control some consequences of the guilty plea. Of course, collateral consequences can result from any guilty plea, such as adverse media attention, investor litigation, or government administrative action in the form of debarment or exclusion.[6] However, at least the company can establish terms of the sentence in advance such as amount of restitution, amount of a fine, the type of required remedial action, and the period of supervision.

Although individuals also want to control the consequences of a guilty plea, the government rarely agrees to a C plea with an individual. According to Judge Young in the *Aegerion* opinion, individual defendants "are afforded 'C' pleas only when the government's case is weak and it is trying to lock in the plea or when it is trying to flip an implicated co-defendant and obtain evidence against others. Neither of these concerns apply in most corporate criminal prosecutions."[7] Judge Young explained that "[a] corporation has no Fifth Amendment privilege, and it cannot testify. In my experience, the government never even commences a criminal prosecution against a corporation unless it has a very strong case."[8]

Interests of the Prosecutor

A prosecutor negotiating with counsel for an organization follows the "Principles of Federal Prosecution of Business Organizations" found in the *United States Attorneys' Manual* (USAM) at § 9-28. According to USAM § 9-28.200, an organization "should not be treated leniently because of their artificial nature nor should they be subject to harsher treatment." However, a prosecutor may consider the collateral consequences of a guilty plea upon an organization.[9] Among the collateral consequences recognized by the USAM are the effects of a disposition upon "employees, investors, pensioners, and customers, who may not have been involved in criminal conduct."[10] In addition, the prosecutor may consider other non-penal sanctions available, such as administrative action.[11]

In the end, the prosecutor should resolve the investigation "in a pragmatic and reasoned way that produces a fair outcome."[12] When doing so, a prosecutor may decide that the organization must plead guilty. To obtain that plea, the prosecutor may be willing to negotiate specific terms of the sentence so that the organization can achieve its goal of obtaining a C plea.

Precedent of Deference to Prosecutors

Recent decisions emphatically limit the trial court's supervision of plea bargaining. In 2016, for example, the D.C. Circuit unanimously vacated a district court's conclusion that the prosecution had been "too lenient in agreeing to, and structuring, the DPA."[13] In *United States v. Fokker Services,* the district court had disagreed with size of the fine, lack of a monitor, and the decision not to charge individuals.[14] The appeals court reversed because the Speedy Trial Act "confers no authority in a court" to withhold exclusion of time based on such concerns.[15] The appeals court emphasized that "the fundamental point is that those [charging] determinations are for the Executive—not the courts—to make."[16] Similarly, in *United States v. HSBC Bank USA, N.A.*, the Second Circuit addressed the role of a district court in monitoring the implementation of a DPA, after the district court ordered the government to file a confidential report prepared by an independent monitor regarding the defendant's compliance with the DPA.[17] The government and the defendant appealed the district court's unsealing and redaction orders, "arguing that the district court ran afoul of separation of powers principles by involving itself in the implementation of a DPA."[18] The Second Circuit agreed, holding that the district court "impermissibly encroached on the Executive's constitutional mandate to 'take Care that the Laws be faithfully executed.'"[19] The district court's role "vis-à-vis a DPA is limited to arraigning the defendant, granting a speedy trial waiver if the DPA does not represent an improper attempt to circumvent the speedy trial clock, and adjudicating motions or disputes as they arise."[20]

Interests of the Court

Based on such precedent, an organization might presume that a trial court will accept the terms of a C plea agreement. However, in his November 2017 decision in *Aegerion*, U.S. District Judge William Young indicated his displeasure with Aegerion's C plea agreement right from the beginning.[21] The judge recounted that the company charged more than $300,000 per year for a treatment regimen with its medicine Juxtapid.[22] Aegerion then "engaged in a series of unfair and deceptive acts, including outright fraud, which pervaded corporate management, all designed to increase the use of Juxtapid in circumstances where such treatment was not medically indicated."[23]

Judge Young recognized the limitations that C pleas impose upon judicial sentencing discretion and the prohibition on judicial involvement in plea bargaining. Nonetheless, he reiterated his reasoning from a 2013 decision that "the 'C' plea has no place, save in the rarest circumstances, in the context of corporate criminal pleas."[24] He opined that the Aegerion agreement exemplified "the shocking disparity between the treatment of corporations and individuals in our criminal justice system . . . Corporations routinely get 'C' pleas after closed door negotiations with the executive branch while individual offenders but rarely are afforded the advantages of a 'C' plea. Instead, they plead guilty and face a truly independent judge."[25] He considered C pleas a "cozy model" in which corporations can gain "effective damage control."[26]

With respect to the particulars of the agreement before him, Judge Young found "much to commend the proffered plea."[27] However, he also felt the parties had not explained "why the government does not simply let Aegerion collapse in disgrace."[28] His detailed list of concerns included: (1) the lack of a presentence report; (2) the possibility that the Sentencing Guidelines were not properly calculated, specifically the enhancements for vulnerable victims and sophisticated means; (3) a fine below the recommended fine range; (4) no restitution to the actual victims; (5) an obligation on behalf of the government not to undertake further prosecution of the defendant; (6) a "palid" cooperation agreement; (7) a failure to include a provision for any sort of external compliance review; (8) a prohibition on the court from setting any special conditions aside from a period of probation; and (9) potential that the plea was "premature" because other criminal investigations may require the company's cooperation.[29]

Judge Young also rejected the argument that a C plea is an organization's only option to protect innocent people such as employees and shareholders. The judge interpreted that argument as equivalent to saying "district judges simply are not competent to sentence corporate criminals."[30] Similarly, he rejected as "silly" the argument this C plea should be accepted because many other C pleas had been accepted by other judges.[31]

Judge Young emphasized repeatedly that the parties' representations failed to address his concerns. Although acknowledging he could perhaps accept a C plea if the parties provided sufficient information, he considered that "every corporate 'C' plea diminishes the legitimacy of our independent judiciary."[32] Concluding the instant C plea was not in the public interest, he ordered the case to trial because "trials matter" and the "verdict of an American jury has a moral force incomparably greater than any plea."[33]

Subsequent Deference to the Court

Although either side in *Aegerion* could have appealed Judge Young's rejection of the C plea, such appeals (even if successful) are time-consuming and expensive. Instead, the company requested an expedited pre-plea presentence report and an expedited plea and sentencing hearing. As justification, Aegerion pleaded the need to resolve its dire financial situation.

This time, the government and the company submitted their agreed terms pursuant to Rule 11(c)(1)(B). Under a "B Plea," the government will "recommend, or agree not to oppose" a particular sentence.[34] However, as the Rule specifies, "such a recommendation or request does not bind the court."[35]

Despite the concerns he expressed about C pleas in the corporate context, Judge Young generally abided the agreement formulated as a B plea supplemented with a presentence report. At the sentencing hearing on January 30, 2018, he adjusted the sentencing guidelines range upward by two levels to reflect his conclusion that victims of the offense were vulnerable.[36] In addition, he exercised his expanded authority under a B plea to modify the recommended sentence in two ways. First, he ordered a damages administrator to compensate victims, if damages could be proven, before the remainder would be forfeited to the government.[37] Second, the court required the existing independent auditor to provide copies of future audit reports to the court.[38] Judge Young explicitly sought to limit costs to the company related to producing the reports, but any such additional costs would have to be paid by the company.

Conclusion

Although precedent seems to limit judicial review of a C plea, Judge Young's approach proves that practice can differ from precedent. Counsel should be prepared to explain why potentially relevant provisions of the Sentencing Guidelines do or do not apply. It may be necessary to provide a detailed financial picture to the court as well as justification for not engaging an independent compliance evaluation. Even with agreements over which the government has greater discretion, such as an NPA or a DPA, counsel is well advised to recognize that courts may influence the result. Counsel should anticipate a skeptical bench and be ready to provide satisfactory explanations.

1 280 F. Supp. 3d 217 (D. Mass. 2017).
2 Fed. R. Crim. P. 11(c)(1)(C).
3 Fed. R. Crim. P. 11(c)(3)(A).
4 Fed. R. Crim. P. 11(c)(5)(C).
5 Fed. R. Crim. P. 11(c)(5)(B).
6 *See, e.g.*, *United States ex rel. Barajas v. United States*, 258 F.3d 1004, 1007 (9th Cir. 2001) (noting that a guilty plea did not prohibit the relevant government agency from considering suspension or debarment of the company).
7 280 F. Supp. 3d at 226.
8 *Id.*
9 USAM § 9-28.1100.
10 *Id.*
11 *Id.*
12 *Id.*
13 *United States v. Fokker Servs. B.V.*, 818 F.3d 733, 737-38 (D.C. Cir. 2016).
14 *Id.* at 741.
15 *Id.* at 738.
16 *Id.*
17 *United States v. HSBC Bank USA, N.A.*, 863 F.3d 125, 128-29 (2d. Cir. 2017).
18 *Id.* at 129.
19 *Id.* (citing U.S. Const. art II, § 3).
20 *Id.* at 129.
21 280 F. Supp. 3d at 218. Indeed, Judge Young begins his opinion with the apparently flippant remark, "Let's see if I've got this straight."
22 *Id.*
23 *Id.*
24 *Id.*
25 *Id.* at 224-25.
26 *Id.* at 225-26.
27 *Id.* at 219.
28 *Id.*
29 *Id.* at 219-21.
30 *Id.* at 223.
31 *Id.* at 224.
32 *Id.* at 227.
33 *Id.*
34 Fed. R. Crim. P. 11(c)(1)(B).
35 *Id.*
36 Case No. 1:17-cr-10288 (D. Mass.), Dkt. 38 at 7.
37 Case No. 1:17-cr-10288 (D. Mass.), Dkt. 38-1 at 2-3.
38 *Id.* at 3.

The Dilemma of Joint Defense Agreements in Internal Investigations After the Yates Memo

Stacy C. Gerber Ward
von Briesen & Roper sc
Milwaukee, WI

The Department of Justice's (DOJ's) release in September 2015 of the "Memorandum on Individual Accountability for Corporate Wrongdoing"—the so-called Yates Memo[1]—caused much alarm about the prospect of DOJ's pursuit of individuals for corporate misconduct. More than two years later, the public can start to assess the real effect of that policy. In fact, significant fines have been levied against senior corporate officials. The Chief Executive Officer (CEO) of Tuomey Healthcare System paid $1 million to resolve his role in the allegations pursued by the DOJ that Tuomey violated the Stark Law through its financial relationship with a group of specialists.[2] In reaching the agreement, the CEO also agreed to waive any right to indemnification from the company, ensuring that the settlement was paid out of personal funds.[3] Indeed, in fiscal year 2017, the DOJ touted for the first time that it "obtained more than $60 million in settlements and judgments with individuals under the False Claims Act that did not involve joint and several liability with the corporate entity."[4] Taking individual liability one step further, the DOJ also seems to be willing to consider the liability of lower-level employees. In the recent eClinicalWorks settlement, not only were senior executives jointly responsible for the $155 million settlement, but a software developer and three project managers also entered into settlements with DOJ for $50,000 and $15,000 each, respectively.[5]

In addition to heightening the risk for individual executives, employees, and health care providers, the Yates Memo also creates practical and ethical challenges to attorneys representing health care entities in internal investigations. Joint defense agreements (JDAs) have been common tools for companies, including health care entities, to facilitate these internal investigations. Under the theory of the common interest privilege, JDAs enable counsel for entities and counsel for potentially liable individuals to work collaboratively in the investigation without waiving the attorney-client privilege. However, to receive cooperation credit under the federal prosecutorial guidelines, the Yates Memo requires that companies disclose any wrongdoing by individual employees discovered during the course of an internal investigation. As a result, a collateral consequence of the Yates Memo is that it undermines JDAs because a company seeking cooperation credit will be required to disclose information about a potentially responsible employee that it received through a JDA under the cloak of privilege.

The Role of Cooperation in Federal Prosecutions

Prosecutors have considerable discretion in deciding whether and how to charge a party with criminal or civil violations and in negotiating any resolution. However, this discretion is guided by the "Federal Principles of Prosecution of Business Organizations" (FPP) found in the *United States Attorneys' Manual*.[6] The FPP discusses the factors that prosecutors should consider when deciding whether and how to criminally prosecute a corporation and/or its officials.[7] Those factors include a corporation's cooperation in an investigation of corporate wrongdoing. Specifically, the FPP states: "Cooperation is a mitigating factor, by which a corporation—just like any other subject of a criminal investigation—can gain credit in a case that otherwise is appropriate for indictment and prosecution."[8]

The DOJ's policy on cooperation by corporations is driven to a large extent by the practical challenges of investigating corporate misconduct. The commentary to the policy on cooperation by corporations acknowledges that investigating corporate wrongdoing can present several obstacles, including that lines of authority and responsibility within a corporation may be shared among various divisions or departments so that it is difficult to determine who the decision makers are.[9] In addition, records and personnel may span across many departments and/or broad geography, making the collection of evidence difficult. As a result, "a corporation's cooperation may be critical in identifying potentially relevant actors and locating relevant evidence, among other things, and in doing so expeditiously."[10]

While the impact of cooperation has been somewhat difficult to gauge, in November 2017, the DOJ issued a new enforcement policy that addressed a corporation's cooperation in a different context that may give some insight into how the agency views the benefit of a corporation's cooperation. Regarding violations of the Foreign Corrupt Practices Act (FCPA), if a company cooperates, the DOJ will apply a presumption of declination of prosecution of the company.[11] In a speech given recently to the American Bar Association White Collar Conference, the acting head of the DOJ Criminal Division announced that the November 2017 FCPA enforcement policy will be used as nonbinding guidance in other criminal cases, as well.[12]

The FPP directly applies to criminal prosecutions but the standards arguably also have application to affirmative civil enforcement cases under the False Claims Act (FCA). Even while the tangible benefits of cooperation in a criminal investigation have not been perfectly clear, it is even more difficult to evaluate the tangible benefits of cooperating in a civil investigation. However, not long after the issuance of the Yates Memo, the then-Principal Deputy Associate Attorney General William Baer (who oversaw the DOJ Civil Division) gave a speech at the American Bar Association Conference on False Claims Act enforcement that included comments about cooperating in the context of civil FCA cases.[13] Specifically, Baer stated that, when a company meets

the DOJ's requirements for cooperation, "the department will use its significant enforcement discretion in FCA matters to recognize that cooperation."[14] While analogizing cooperation credit in the civil FCA context to a downward departure in the criminal context, Baer also acknowledged that the analysis is complicated by the remedial and deterrent goals of the statute.[15] Despite those analytical challenges, he concluded that "we are committed to taking into account the disclosures and other cooperation provided by defendants and to resolve a matter for less than [it] would otherwise have settled for based on the applicable law and facts."[16] The DOJ's enforcement discretion when a company cooperates in an FCA investigation can include exercising flexibility in the time period included in the settlement's covered conduct as a limitation on damages and adjusting the multiplier applied to the loss calculation. A similar benefit can be conferred under the self-disclosure protocol for the Department of Health and Human Services Office of Inspector General, which allows for a minimum multiplier of 1.5 times the loss amount, rather than the treble damages mandated by the FCA.[17]

Cooperation and the Yates Memo

While the Yates Memo is most noted for its direction to prosecutors to evaluate individual liability fully when investigating and charging corporate wrongdoing, its directive related to assessing a corporation's cooperation has had a similarly significant impact. The Yates Memo states that for a corporation to receive *any* credit for cooperating, the company must "identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the Department all facts related to that misconduct."[18] A corporation seeking to receive credit for cooperation must be prepared to divulge to the government any information gathered during its internal investigation regarding the misconduct of individual officers or employees. The DOJ has incorporated this requirement into the FPP.[19]

JDAs and the Challenges of Cooperation

Early in an investigation, a company may assert that it is "cooperating" with a government investigation when it is merely producing documents responsive to a government subpoena. However, meeting the government's definition of cooperation involves much more than simply producing documents and has become more challenging under the Yates Memo. Under the Yates Memo, cooperation now requires disclosing individual misconduct to the government, which enhances the potential and actual conflicts of interest between the company that conducts an investigation and the officers and employees who provide information in that investigation. These conflicts of interest can preclude the use of JDAs.

To conduct an effective internal investigation, company investigators often seek direct access to the individuals implicated in the potential misconduct. JDAs are a common tool to facilitate the company's access to those individuals by giving them assurance that any statements made in the context of the investigation will not be shared with law enforcement. As discussed below, JDAs protect information obtained in the course of the investigation (potentially including admissions of wrongdoing) against disclosure, thereby encouraging an individual to share information freely. But now, those companies that seek to obtain cooperation credit from the DOJ must decide at the outset of an investigation whether to offer a JDA to those individuals potentially implicated in the wrongdoing while knowing that not offering a JDA will likely limit or cut off access to those individuals.

The legal basis for JDAs is the "common interest privilege," which allows parties to share communications without waiving the attorney-client privilege as long as those communications are in the furtherance of a common litigation interest shared by the parties. The "common interest privilege" (also referred to as the "joint defense" doctrine) protects "the confidentiality of communications passing from one party to the attorney for another party where a joint defense effort or strategy has been decided upon and undertaken by the parties and their respective counsel."[20] Importantly, once a protected communication has been made pursuant to a JDA, the privilege can only be waived by the consent of all the parties to the agreement.[21] Most written

JDAs expressly incorporate the concept that all parties to the agreement must consent to the release of any privileged information obtained pursuant to the JDA. Moreover, information furnished pursuant to a JDA remains privileged even if the JDA is terminated.[22]

In this context, a company conducting an investigation under the auspices of a JDA likely will be prevented from disclosing information needed to obtain cooperation credit. Without a JDA, however, the company's ability to obtain information may be significantly limited. As such, a company embarking on an investigation must deal with the predicament of not being able to cooperate without obtaining information, but not being able to obtain information if it wants to cooperate. Compounding the problem is that, at the outset of an investigation, it can be difficult to assess whether it is in a company's best interest to seek cooperation credit from the government or whether it should enter into a JDA with any potentially implicated individuals.

Is there a middle ground? The DOJ instructed that "[c]orporations may wish to address this situation by crafting and participating in joint defense agreements, to the extent they choose to enter them, and provide such flexibility as they deem appropriate."[23] Unfortunately, the DOJ has not provided any further guidance on what this flexibility looks like.

Arguably, a company may consider crafting a JDA that permits the company to disclose facts it receives from the employee through a joint defense communication, as opposed to legal opinions or attorney work product. Indeed, many JDAs allow a party to disclose facts discovered independently from the protected communications, so disclosing facts obtained from participants to the agreement would be an extension of that principle. Many individuals may choose to not enter a JDA with such a provision, however. Additionally, the company may consider making future employment contingent on cooperation during an investigation, thereby forcing the employee into entering a JDA under which the company can dictate the terms of the agreement. Both of these options are potentially problematic in that they may erode the trust between its participants and restrain the individual from fully cooperating during an interview, effectively defeating the benefits of a JDA.

Unfortunately, objective data useful in gauging the impact of the Yates Memo on JDAs is not available. The measure of the impact of the memo on corporate investigations could potentially be borne out by tracking the number of resolutions in which corporations received credit for cooperating and those in which the company chose not to seek that credit. However, the DOJ does not track that information. What is known is that the Yates Memo appears to be increasing both the number of recoveries obtained from individuals and the amounts of those individual recoveries in civil FCA cases.[24] Those increasing recoveries suggest that companies will continue to face a difficult choice between entering into JDAs with individuals potentially implicated in a government investigation and seeking cooperation credit from government prosecutors.

Conclusion

While the Deputy Attorney General suggested in October 2017 that changes to the Yates Memo may be on the way,[25] prosecutions of individual corporate employees and officers seem to be continuing at a brisk pace. As a result, companies must carefully weigh the benefits of cooperating with a government investigation against conducting an internal investigation with the cooperation of key employees under the cloak of privilege, because in the current post-Yates Memo environment, it is challenging to do both.

---

1 U.S. Dep't of Justice, Office of Deputy Attorney General, *Individual Accountability for Corporate Wrongdoing*, *available at* https://www.justice.gov/archives/dag/file/769036/download (last visited May 11, 2018).

2 U.S. Dep't of Justice, News Release, *Former Chief Executive of South Carolina Hospital Pays $1 Million*, *available at* https://www.justice.gov/opa/pr/former-chief-executive-south-carolina-hospital-pays-1-million-and-agrees-exclusion-settle (last visited May 11, 2018).

3 Donna S. Clark and Banee Pachuca, *Former Tuomey CEO Settles with DOJ for $1 Million*, Baker Hostetler Health Law Update, Nov. 14, 2016, *available at* (https://www.healthlawupdate.com/2016/11/former-tuomey-ceo-settles-with-doj-for-1-million/) (last visited May 11, 2018).

4 U.S. Dep't of Justice, News Release, *Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017*, *available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017 (last visited May 11, 2018).

5 U.S. Dep't of Justice, News Release, *Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations*, *available at* https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-155-million-settle-false-claims-act-allegations (last visited May 11, 2018).

6 U.S. Dep't of Justice, U.S. Attorneys' Manual § 9-28.700, The Value of Cooperation, *available at* https://www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations#9-28.700 (last visited May 11, 2018).

7 *Id.*

8 *Id.*

9 *Id.*

10 *Id.*

11 U.S. Dep't of Justice, U.S. Attorneys' Manual § 9-47.120–FCPA Corporate Enforcement Policy, *available at* https://www.justice.gov/criminal-fraud/file/838416/download (last visited May 11, 2018).

12 *DOJ Criminal Division Announces FCPA Corporate Enforcement Policy Provides Nonbinding Guidance for All Criminal Cases*, JDSUPRA, Mar. 9, 2018, *available at* https://www.jdsupra.com/legalnews/doj-criminal-division-announces-fcpa-43249/ (last visited May 11, 2018).

13 U.S. Dep't of Justice, Office of Public Affairs, *Acting Associate Attorney General Bill Baer Delivers Remarks on Individual Accountability at American Bar Association's 11th National Institute on Civil False Claims Act and Qui Tam Enforcement*, *available at* https://www.justice.gov/opa/speech/acting-associate-attorney-general-bill-baer-delivers-remarks-individual-accountability (last visited May 11, 2018).

14 *Id.*

15 *Id.*

16 *Id.*

17 U.S. Dep't of Health and Human Services Office of the Inspector Gen., *OIG's Provider Self-Disclosure Protocol—Updated,* Section IV(E), *available at* https://oig.hhs.gov/compliance/self-disclosure-info/files/provider-self-disclosure-protocol.pdf (last visited May 11, 2018).

18 Individual Accountability for Corporate Wrongdoing, *supra* note 1.

19 U.S. Attorneys' Manual § 9-28.700, *supra* note 6.

20 *United States v. Schwimmer*, 892 F.2d 237, 243 (2d Cir. 1989).

21 *In re Grand Jury Subpoenas,* 902 F.2d 244, 248 (4th Cir. 1990).

22 Jonathan N. Rosen, Joint Defense and Confidentiality Agreement (CA), Practical Law Standard Document w-000-0682.

23 U.S. Dept. of Justice, U.S. Attorneys' Manual § 9-28.730.

24 *Compare* U.S. Dept. of Justice, News Release, *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016*, Dec. 14, 2016, *available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016, *with* U.S. Dept. of Justice, News Release, *Justice Department Recovers Over $3.7 Billion From False Claims Act Cases In Fiscal Year 2017*, Dec. 17, 2017, *available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017 (last visited May 11, 2018).

25 Program on Corporate Compliance and Enforcement, New York University School of Law, *Deputy Attorney General Rod Rosenstein Keynote Address on Corporate Enforcement Policy*, Oct. 6, 2017, *available at* https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/ (last visited May 11, 2018).

2018 Highlights Some Victories for Defendants in False Claims Act Cases

Danielle E. Holley
O'Connell and Aronowitz
Albany, NY

For many years, the health law community has seen an overall increase in civil False Claims Act (FCA) cases brought—and a corresponding increase in recoveries from—the Department of Justice (DOJ). In fiscal year (FY) 2016, DOJ recovered more than $4.7 billion in civil cases related to false claims and fraud,[1] followed by $3.7 billion in FCA recoveries in FY 2017, with $2.4 billion of those recoveries attributable to the health care industry.[2] Approximately $425 million in FY 2017 was attributable to those qui tam settlements and judgments in which the United States declined to intervene.[3] Although recoveries did decrease in 2017, the $3.7 billion in recoveries still represents a significant overall increase over the past decade.

Despite these numbers, however, the FCA defense bar has continued to find some success, as highlighted by the cases discussed herein. Indeed, in just the second week of 2018, the Third Circuit handed down an opinion that significantly reins in the extent to which DOJ and/or qui tam relators can obtain recoveries under the FCA that stem from alleged violations of the Anti-Kickback Statute (AKS). Moreover, through the first half of the year, lower courts have continued the general trend of siding with defendants in cases that rest on the Supreme Court's interpretation of the FCA's "materiality" standard, as articulated in its June 2016 decision in *Escobar*.[4] As detailed below, the lower courts' adoption of the "rigorous" materiality standard outlined in *Escobar* has even led to the overturning of major FCA judgments.

On January 9, 2018, in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, the Third Circuit granted summary judgment in favor of the defendants in a qui tam action.[5] In *Greenfield*, the relator, previously a vice president of defendant Accredo Health Group (Accredo), brought a suit alleging that Accredo and affiliates violated the FCA by falsely certifying compliance with the AKS when Accredo made donations to two charities in exchange for the charities making recommendations to its members and inducing referrals to Accredo.[6] The district court granted summary judgment in favor of Accredo, finding the relator failed to demonstrate that, as a result of the alleged AKS violation, Accredo received payment from the federal government linked to Accredo's donations.[7] Specifically, the court held that the relator must show the link that "federally insured patients were referred to Accredo *as a result* of its donation" to the charities.[8] While the district court issued a sweeping decision that significantly increased the burden on relators, the extent of that decision was tempered by the Third Circuit.

On appeal, the Third Circuit addressed what "'link' is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between."[9] Analyzing the statute and finding expansive legislative intent to strengthen qui tam lawsuits and recover all fraudulent attempts to cause sums of money to be paid out by the government, the Third Circuit held that "a 'link' is required" and a relator must demonstrate that "at least one of Accredo's claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute."[10] While not nearly as high of a burden as the district court found, the Third Circuit still did not agree with the relator that a mere temporal link was sufficient.[11] The appeals court found that simply hypothesizing was insufficient and the relator must "point to at least one claim" in support of his allegations.[12] This decision reiterates prior holdings of other courts that there has to be more than temporal proximity and at least a link that identifies basic elements of the "who, what, when, where and how" involved in the alleged AKS violation.[13]

Perhaps even more notable for defendants in FCA cases is the decision by U.S. District Court Judge Steven D. Merryday in *United States ex rel. Ruckh v. Salus Rehabilitation, LLC.*[14] In *Ruckh*, a qui tam relator filed suit alleging that operators and owners of 53 specialized nursing facilities violated the state and federal FCAs by submitting claims for reimbursement for services that were never provided, had paperwork defects such as unsigned or undated records, or had not maintained a comprehensive plan of care.[15] After a more than four-week-long trial, the jury ultimately found the defendants liable, and Judge Merryday entered judgment in the amount of $347,864,285.[16] The defendants filed a motion for judgment as a matter of law and for a new trial. The court overturned the verdict for approximately $347 million in favor of the relator and granted defendants' motion. In deciding the motion, the court addressed the strict enforcement of materiality under *Escobar* and the evidence of the link between the allegations of false claims and payment.[17]

With respect to materiality, the court found that:

> Not only did the relator fail to prove that the governments regarded the disputed practices as material and would have refused to pay, but the relator failed to prove that the defendants submitted claims for payment despite the defendants' knowing that the governments would refuse to pay the claims if either or both governments had known about the disputed practices.[18]

Addressing the materiality standard under *Escobar*, the court held that the relator must prove two elements: (1) non-compliance was material to the government's decision, and (2) the defendant knew that non-compliance was material when the defendant sought payment.[19] The court noted that the materiality and scienter requirements are "rigorous" and that the Supreme Court, in deciding *Escobar*, rejected the "system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely—multiplied by three—because of some immaterial contractual or regulatory non-compliance."[20] In a scathing rebuke of

the relator, the court found that "at most, the relator is able to raise from the fatally deficient record only a faint and formless specter of the necessary materiality" and this judgment is exactly the type of judgment the Supreme Court rejected in *Escobar*.[21] Ultimately, the court found the proof of materiality markedly absent despite ample opportunity to present such proof in a month-long trial.[22]

Notably, the court also struck down the causation theory relator presented. The relator alleged that the management companies exerted corporate pressure upon the facilities to maximize corporate profits, and that this pressure caused the facilities to submit false claims. The court found the relator must show some relevant link to demonstrate that a person (or persons) with corporate knowledge actually gave a directive to maximize profits, and that, in turn, such pressure led to the submission of a false claim to the government.[23] Similar to the Third Circuit's decision in *Greenfield*, the court in *Ruckh* found that more than a temporal link or hypothesis is required.

Several other 2018 decisions also have discussed the heightened standard of materiality articulated in *Escobar*. In one notable case out of the Western District of New York, DOJ alleged that the defendants knowingly falsely certified and represented that they qualified as a service-disabled veteran owned small business (SDVOSB) to gain access to government contracts.[24] Judge Frank P. Geraci, Jr. granted the defendants' motions to dismiss (though he allowed for an amended complaint) upon finding that the government failed to adequately allege that the defendants' online SDVOSB certifications were material to the government's decision to pay.[25] The court also found the complaint lacked any allegations to demonstrate the *Escobar* factor that "the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."[26] Most notably, the court addressed the question of whether the materiality standard from *Escobar* "applies to all FCA claims brought under § 3729(a)(1)(A), only a subset of claims (i.e. it applies to theories of legal falsity but not factual falsity), or only those claims relying on an implied certification theory."[27] Finding that the Second Circuit had not explicitly addressed the issue, the court analyzed the decision in *Bishop II*[28] and found that *Escobar's* materiality standard applied "regardless of whether those claims were brought under a theory of implied false certification, express false certification, or fraudulent inducement."[29]

In analyzing the materiality requirements and the causal links required in pleadings, the court decisions in 2018 appear so far to have increased the relator's burden of demonstrating whether the government would pay, and continue to pay, claims after learning of alleged fraud.[30] As aptly noted in these cases, while the FCA is broad, the allegations cannot be based on minor ministerial mistakes or inconsequential record keeping; rather, a defendant's alleged misconduct must rise to such a level that the government would not have paid a claim. While size and scale matter and materiality remains important, courts also are analyzing the causal link between the alleged conduct and the actual claims submitted for reimbursement.

These cases highlight the increased burden on relators and the potential defenses for defendants. Practitioners will have to wait and see whether these tougher standards turn the tide of increased FCA litigation.

---

1 U.S. Dep't of Justice, News Release, *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016*, *available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.
2 U.S. Dep't of Justice, News Release, *Justice Department Recovers Over $3.7 Billion From False Claims Act Cases in Fiscal Year 2017, available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.
3 Fraud Statistics Overview (Dec. 21, 2017), *available at* https://www.justice.gov/opa/press-release/file/1020126/download.
4 *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016).
5 *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3d Cir. 2018).
6 *Id.*
7 *Id.* at 92.
8 *Id.* (emphasis added).
9 *Id.* at 94.
10 *Id.* at 97.
11 *Id.* at 98.
12 *Id.* at 99.
13 *See also United States ex rel. Barko v. Halliburton Co.,* 241 F. Supp. 3d 37 (D.D.C. 2017), *aff'd United States ex. Rel. Harry Barko v. Haliburton Co.,* 709 Fed. Appx. 23 (D.C. Cir. Dec. 27, 2017); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772 (S.D.N.Y. March 31, 2017); *United States ex rel Colquitt v. Abbott Labs*, 858 F. 3d 365 (5th Cir. 2017).
14 2018 U.S. Dist. LEXIS 5148 (M.D. Fla. Jan. 11, 2018).
15 *United States ex rel. Ruckh v. Salus Rehabilitation, LLC,* No. 8:11-cv-1303-T-23TBM.
16 *United States ex rel. Ruckh v. Salus Rehabilitation, LLC,* No. 811-cv-1303-T-23TMB, Order ECF. DK. 431 (Mar. 1, 2017).
17 *United States ex rel. Ruckh v. Salus Rehabilitation, LLC,* 2018 U.S. Dist. LEXIS 5148 (M.D. Fla. Jan. 11, 2018).
18 *Id.* at *3.
19 *Id.* at *8.
20 *Id.* at *11.
21 *Id.* at *19.
22 *Id.* at *28.
23 *Id.* at *30.
24 *United States v. Strock*, No. 15-CV-0887-FPG, 2018 WL 647471 (W.D.N.Y. Jan. 31, 2018).
25 *Id.*
26 *Id.* at *9.
27 *Id.* at *11.
28 *Bishop v. Wells Fargo & Co.,* 870 F.3d 104 (2d Cir. 2017).
29 *United States v. Strock*, No. 15-CV-0887-FPG, at *12.
30 *United States ex rel. Ruckh v. Salus Rehabilitation, LLC,* 2018 U.S. Dist. LEXIS 5148, at *31 (M.D. Fla. Jan. 11, 2018) (citing *United States ex rel. Harman v. Trinity Indus.*, 872 F.3d 645 (5th Cir. 2017).

Resource Corner

Have You Seen This New Resource?

Stark Law Toolkit

The Stark Law Toolkit aggregates all the significant rulemaking from 1992 to the present, including questions and CMS commentary, in one searchable portfolio. The Toolkit also includes an index covering every Stark Law exception. For example, an attorney researching the rental of office space exception at §411.357(a) can turn to the index to find citations to every substantive discussion of the exception across all applicable Federal Register issuances. In addition, each citation directly links to the corresponding page in the Toolkit portfolio. If the attorney is researching a topic that is not covered in the index, e.g., the definition of "interoperable," she can perform a word search of the entire portfolio to find every instance of the search term.

Access this toolkit at https://www.healthlawyers.org/Members/PracticeGroups/FA/Toolkits/Pages/StarkLawToolkit.aspx.

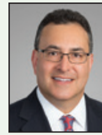
Catch this On-Demand Webinar

OIG Medicare Compliance Audits--What You Need to Know and Best Practices for Responding

The Office of Inspector General regularly conducts Medicare Compliance Reviews of hospitals and health systems, and has recently begun conducting similar reviews of home health agencies and hospices. In this webinar, Kristen Schwendinger, former OIG attorney and panelist, discussed the Medicare Compliance Review process, tips on working through the audit, and strategies for response to adverse audit findings.

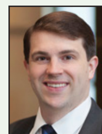
For more information or to register, please go to www.healthlawyers.org/webinars.

FRAUD AND ABUSE PRACTICE GROUP LEADERSHIP



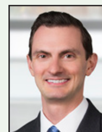
Gary W. Herschman,
Chair
Epstein Becker & Green PC
Newark, NJ
(973) 639-5237
gherschman@ebglaw.com

Jacqueline C. Baratian,
Vice Chair—Research & Website
Alston & Bird LLP
Washington, DC
(202) 239-3484
jacqueline.baratian@alston.com

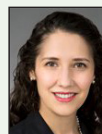


Jacob Harper,
Social Media Coordinator
Morgan Lewis & Bockius LLP
Washington, DC
(202) 739-5260
jacob.harper@morganlewis.com

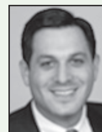
Joseph M. Kahn,
Vice Chair—Publications
Hall Render Killian Heath & Lyman PC
Morrisville, NC
(919) 447-4966
jkahn@hallrender.com



Tony R. Maida,
Vice Chair—Membership
McDermott Will & Emery LLP
New York, NY
(212) 547-5492
tmaida@mwe.com



Caitlin Suzanne McCormick-Brault,
Vice Chair—Educational Programs
Harvard University Law School
617-390-2684
cmccormickbrault@law.harvard.edu



Kevin E. Raphael,
Vice Chair—Strategic Planning and Special Projects
Pietragallo Gordon Alfano Bosick & Raspanti LLP
Philadelphia, PA
(215) 988-1442
ker@pietragallo.com

PUBLISHING STAFF

Cynthia Conner
Vice President of Publishing
(202) 833-0755
cconner@healthlawyers.org

Bianca Bishop
Senior Managing Editor
(202) 833-0757
bbishop@healthlawyers.org

Lisa Salerno
Senior Legal Editor
(703) 489-8426
lsalerno@healthlawyers.org

Matt Ausloos
Publishing Administrator
(202) 833-6952
mausloos@healthlawyers.org

DESIGN STAFF

Mary Boutsikaris
Creative Director
(202) 833-0764
mboutsik@healthlawyers.org

Jen Smith
Graphic Designer/Administrator
(202) 833-0781
jsmith@healthlawyers.org

AHLA

LEARN. NETWORK. ENGAGE.

September 26-28, 2018

Fraud and Compliance Forum

Renaissance Harborplace Hotel | *Baltimore, MD*

Register Now! www.healthlawyers.org/programs

Fraud & Abuse

AHLA

American Health Lawyers Association
1620 Eye Street, NW, 6th Floor • Washington, DC 20006-4010
(202) 833-1100 • Fax (202) 833-1105 • www.healthlawyers.org