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2019 Year-end White Collar Updates

Introduction

In 2019, the US Department of Justice (DOJ) and other federal regulators continued to emphasize the importance of effective compliance programs, self-disclosure of violations of the law and cooperation with regulators during investigations.

This alert sheds light on some of the updated guidance from various government agencies released last year, landmark state and federal court cases changing the enforcement landscape, as well as what they mean for companies dealing with them.

Below is a list of topics discussed in this alert. (You may click on a topic to jump there.)

DOJ Updates: Emphasis on Prevention, Cooperation and Voluntary Self-Disclosure

In 2019, the DOJ further memorialized its commitment to rewarding companies for effective compliance programs, self-disclosure of violations of the law, and cooperation with regulators during investigations.

In 2018, the DOJ announced that the Foreign Corrupt Practices Act (FCPA) Corporate Enforcement Policy, which provides incentives – including declination to prosecute – for companies that voluntarily report wrongdoing to the DOJ, would be applied by the Criminal Division beyond the FCPA cases.[1] Additionally, the DOJ issued a memorandum providing guidance on the usage of monitors resulting from corporate criminal resolutions, announcing several factors prosecutors should consider in determining whether to require a corporate monitor as part of a settlement in the first place, including the adequacy of the compliance program and how the corporation has invested in and improved its program and committed to remediation.[2]

In continuation of this trend, throughout 2019, a number of divisions of the DOJ announced, memorialized or renewed their commitments to rewarding proactive and cooperative behavior by targets of civil and criminal investigations.

False Claims Act (FCA) Guidance: DOJ Released Guidelines on Cooperation Credit in FCA Cases

In May, the Civil Division of the DOJ published new guidelines on the cooperation credit available in FCA cases.[3] The guidelines emphasize voluntary disclosure, but also highlight other ways companies can earn cooperation credit in FCA actions.

Briefly, the FCA creates civil liability for persons that knowingly present, or cause to be presented, false or fraudulent claims to the US government. The updated guidelines reflect the DOJ's efforts to incentivize the voluntary disclosure of misconduct and full cooperation from targets of the FCA investigations.

1 DOJ Office of Public Affairs, *Deputy Attorney General Rosenstein Delivers Remarks at the 32nd Annual ABA National Institute on White Collar Crime* (Mar. 2, 2018), https://www.justice.gov/opa/speech/deputy-attorney-general-rosenstein-delivers-remarks-32nd-annual-aba-national-institute.

2 DOJ Criminal Division, *Selection of Monitors in Criminal Division Matters* (Oct. 11, 2018), https://www.justice.gov/opa/speech/file/1100531/download.

3 Justice Manual, § 4-4.112.

Under the guidelines, the maximum credit that a party may earn "may not exceed an amount that would result in the government receiving less than full compensation for the losses caused by the defendant's misconduct (including the government's damages, lost interest, costs of investigation, and relator [whistleblower] share)." In essence, the credit will reflect a reduction of the penalties and treble damages available under the FCA.

The new guidelines provide a non-comprehensive, non-mandatory list of activities that the DOJ might consider when evaluating whether a party deserves FCA cooperation credit. For example, a party should make a "proactive, timely, and voluntary self-disclosure" about the misconduct, identify the individuals involved in the misconduct, admit liability or accept responsibility for the wrongdoing, and assist in the determination or recovery of the losses caused by the organization's misconduct, among other proactive measures.

When evaluating whether such actions warrant credit, the DOJ will consider four factors:

1. Whether the party's assistance was timely and voluntary
2. Whether the testimony or information provided is truthful and complete
3. The "nature and extent" of the party's assistance
4. The "significance and usefulness of the cooperation to the government"

The DOJ will also consider a party's remedial actions, including any root-cause analysis, the implementation of an effective compliance program, and the disciplinary actions taken.

Even if an entity or individual does not qualify for maximum credit, they may receive "partial credit" if they have "meaningfully assisted the government's investigation by engaging in conduct qualifying for cooperation credit." Meaningful assistance is not defined, but the guidelines do refer to the general guidelines for civil DOJ compromises, which warn that the "mere submission of legally required information, by itself, generally does not constitute meaningful assistance."[4] Most often, this type of partial credit will include reduced penalties or damages sought by the DOJ.

The guidelines clearly state that the DOJ has discretion beyond the factors listed, and may consider other issues, such as the seriousness of the violation, the extent of the damages, any history of recidivism, or the ability of the wrongdoer to satisfy an eventual judgment. According to the guidelines, such issues may reduce the available credit, or even preclude credit eligibility altogether.

Updated Guidance on Evaluating the Effectiveness of a Company's Corporate Compliance Program

Also in May 2019, the DOJ's Criminal Division updated its 2017 guidance on evaluating the effectiveness of a company's corporate compliance program.[5] The updated guidance evaluates compliance programs through three fundamental questions:

1. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith?
3. Does the corporation's compliance program work in practice?

Is the Corporation's Compliance Program Well Designed?

The updated guidance instructs prosecutors to examine the comprehensiveness of a company's program's design, and how well ethics and compliance are integrated into the company's operations and workforce. Companies should identify, assess and define their risk profiles and design their compliance programs to detect the types of misconduct most likely to occur. Prosecutors will consider whether the compliance program is being effectively disseminated to, and understood by, employees through policies, training and communications. Prosecutors will also evaluate the quality of the confidential reporting structure, and whether the company has effective means of evaluating and managing third-party partners and acquisition targets.

Is the Program Being Applied Earnestly and in Good Faith?

Under the second question, prosecutors will consider whether a compliance program is simply a "paper program," or one that is "implemented, reviewed and revised." Such considerations include whether there is clear commitment by senior and middle management, whether the program has sufficient resources and autonomy, and how the company incentivizes ethical behavior and disciplines unethical behavior.

Does the Corporation's Compliance Program Work?

Finally, the updated guidance provides that prosecutors will consider whether the program is effective in practice. The mere fact that misconduct has occurred does not necessarily mean that the program was ineffective. As such, prosecutors will consider how the misconduct was detected, what investigative resources were in place, and the nature and thoroughness of any root-cause analysis and resulting remediation.

4 Justice Manual, § 4-3.100(3).

5 DOJ Criminal Division, *Evaluation of Corporate Compliance Programs* (April 2019), https://www.justice.gov/criminal-fraud/page/file/937501/download.

The updated guidance, though intended as a tool for prosecutors, provides valuable insight to companies. Now that the DOJ has revealed the considerations it uses to determine whether to bring charges, implement a monitor and what penalties to impose, companies should consider whether a robust review of their policies and procedures is necessary. The DOJ has expressed commitment to incentivize and reward companies that implement effective compliance programs. Thus, doing the work to bring a company in line with the DOJ's guidelines provides an opportunity to avoid government scrutiny.

Cooperation in FCPA Cases

In November, the DOJ's Criminal Division made slight but meaningful changes to its FCPA corporate enforcement policy as well.[6] The policy offers companies the presumption of a declination of prosecution if they (1) self-report foreign bribery, (2) cooperate with a subsequent government probe, and (3) fully remediate compliance failures. The updated policy seeks to clarify what the DOJ expects from companies wishing to receive cooperation credit in FCPA matters.

To qualify for credit under the policy, companies are expected to disclose "all relevant facts known to it at the time of the disclosure, including as to any individuals substantially involved" in the misconduct. A footnote explaining the change adds that the DOJ "recognizes that a company may not be in a position to know all relevant facts at the time of a voluntary self-disclosure, especially where only preliminary investigative efforts have been possible." A company "should make clear" when its disclosure is based on a preliminary investigation, but "should nonetheless provide a fulsome disclosure" of what it knows at the time.

Another change in the policy relates to proactive cooperation, where companies provide information even when not specifically asked. Previously, companies were required to inform prosecutors of opportunities for the DOJ to obtain relevant evidence not in the company's possession and not otherwise known to the DOJ. The updated policy provides more clarity regarding this mandate, stating that companies must let the DOJ know "where the company is aware of relevant evidence not in the company's possession."

These revisions follow additional changes made to the policy earlier in 2019. In March, prosecutors relaxed the policy by requiring that companies disclose information about "all individuals substantially involved" in the wrongdoing, rather than on all employees tied to the misconduct. The change dovetailed with 2018 reforms to the Yates Memo that softened cooperation requirements on businesses.

Antitrust Division

The DOJ's Antitrust Division also announced updates to policies relating to positive credit companies can earn in antitrust matters. In July, the Antitrust Division promised to "(1) change its approach to crediting compliance at the charging stage; (2) clarify its approach to evaluating the effectiveness of compliance programs at the sentencing stage; and (3) for the first time, make public a guidance document for the evaluation of compliance programs in criminal antitrust investigations."[7]

In order to effectuate its new approach, the Antitrust Division updated the Justice Manual by deleting language that credit should not be given at the charging stage for a compliance program, and publishing a guide for evaluating compliance programs.

At the charging stage, the Antitrust Division will consider the three fundamental questions identified above, as well as the effectiveness of the company's antitrust compliance program. Considerations include (1) the design and comprehensiveness of the program; (2) the culture of compliance within the company; (3) responsibility for, and the resources dedicated to, antitrust compliance; (4) antitrust risk assessment techniques; (5) compliance training and communication to employees; (6) monitoring and auditing techniques, including continued review, evaluation and revision of the antitrust compliance program; (7) reporting mechanisms; (8) compliance incentives and discipline; and (9) remediation methods.

During the sentencing phase, the Antitrust Division's approach to compliance considerations will be in accordance with the US Sentencing Guidelines and 18 U.S.C. § 3572. The guidance not only discusses reductions in sentencing for an "effective" compliance program, but also provides directions for case-specific assessments. Other sections include guidance on the Antitrust Division's approach to recommending probation, periodic compliance reports as a condition of probation, or an external monitor to ensure the implementation of an effective compliance program.

The Antitrust Division's action demonstrates the importance of a company's antitrust program in reducing potential liability. However, it should not be misconstrued as an automatic pass for corporate misconduct that slips through an effective program. It remains to be seen how much weight prosecutors will give a compliance program, particularly where aggravating factors exist. Yet the Antitrust Division's new consideration of a company's compliance program in the charging and sentencing stages of a criminal antitrust investigation provides an incentive for companies to implement and invest in robust compliance programs.

6 Justice Manual, § 9-47.000, https://www.justice.gov/jm/jm-9-47000-foreign-corrupt-practices-act-1977#rfn1.

7 DOJ Office of Public Affairs, *Assistant Attorney General Makan Delrahim Delivers Remarks at the New York University School of Law Program on Corporate Compliance and Enforcement* (July 11, 2019), https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-new-york-university-school-l-0.

National Security Division (NSD)

In December, the DOJ's NSD revised its 2016 policy on the cooperation credit available to companies that voluntarily self-disclose willful violations of export control and sanctions laws. The 2019 NSD guidance provides additional transparency concerning the benefits of self-reporting to the NSD, and the potential consequences of failing to do so.[8]

The guidance continues to require that a company (1) voluntarily self-disclose violations of export controls or sanctions laws to the NSD; (2) fully cooperate with the ensuing investigation; and (3) timely and appropriately remediate. However, the revised policy departs from its 2016 predecessor in three critical ways.

Benefits of the Voluntary Self-Disclosure Program

Under the 2016 guidance, a company could be eligible for the possibility of a non-prosecution agreement, a reduced period of supervised compliance, a reduced fine and forfeiture, and no requirement for a monitor. However, under the revised guidance, it is presumed that the company will receive a non-prosecution agreement, will not pay a fine and will not require the appointment of a monitor.

Impact of Aggravating Circumstances

Previously, where aggravating factors were present, "a more stringent resolution" was required. Aggravating factors may include the export of items controlled for nuclear non-proliferation or missile technology reasons to a proliferator country, the export of items known to be used in the construction of weapons of mass destruction, the export of items to a terrorist organization or hostile foreign power, repeated violations or knowing involvement of upper management in the criminal conduct.

Under the 2019 NSD guidance, where such aggravating factors are present, the DOJ will accord or recommend a fine that is at least 50% less than the amount otherwise available by law, and the NSD will not require the appointment of a monitor.

Inclusion of Financial Institutions (FIs)

In a footnote, the 2016 guidance expressly excluded FIs from the policy because of their "unique reporting requirements under their applicable statutory and regulatory regimes." However, the 2019 guidance removes this carve-out, specifying that "all business organizations, including FIs, can take advantage of the Policy."[9]

Although the 2019 NSD guidance provides for enhanced incentives for those companies that can meet the disclosure, cooperation and remediation requirements set forth in the guidance, additional considerations and ambiguities still remain for companies, and particularly FIs, considering whether to voluntarily self-disclose to the NSD. Often, a potential issue appears to be only a minor regulatory concern, until internal analysis later reveals that there are criminal implications, or that the actions were taken "willfully." As such, the providing of voluntary self-disclosure will continue to be a deeply factual question evaluated on a case-by-case basis.

DOJ Guidance on Inability to Pay Claims

In October, the Criminal Division of the DOJ released a memorandum providing guidance for prosecutors responding to corporations' claims that they are unable to pay a criminal fine or monetary penalty. An "inability to pay" claim is typically raised by corporate defendants when a potential fine, though allowable by law, would be destructive to the company. Previously, the Criminal Division followed the "inability to pay" process for resolving civil claims under the FCA. The new guidance, however, arms criminal prosecutors with their own detailed framework to evaluate a corporation's inability to pay.

Under the framework, the DOJ and the defendant company must first reach an agreement as to both the form of a corporate criminal resolution and the appropriate monetary penalty based on the law and facts. At that point, the business organization must provide a complete and timely response to the Inability-to-Pay Questionnaire (appended to the guidance). The questionnaire seeks information regarding a company's inability to pay, including its current assets, liabilities, liens and claims, and requests supporting documentation. It also includes questions relating to capital budgets and projections, proposed changes to the corporate structure, and any restructuring plans.

Where, based on the provided information, legitimate questions exist regarding an organization's inability to pay the agreed upon fine, the guidance requires prosecutors to consider the following, non-exhaustive list of factors: (1) background on the current financial condition; (2) alternative sources of capital; (3) collateral consequences; and (4) victim restitution considerations.

If, after this complex, fact-based analysis, the Criminal Division lawyers find that an organization is unable to pay, the guidance instructs prosecutors to adjust the monetary penalty amount. However, such an adjustment should only be made "to the extent necessary to avoid (1) threatening the continued viability of the organization and/or (2) impairing the organization's ability to make restitution to victims."

The guidance demonstrates the first instance that the DOJ formally recognized its dedication to considering a range of factors, including collateral consequences in sentencing and settlement. Like the other guidance provided by the DOJ in 2019, this memorandum should provide additional transparency to those companies at risk of "significant adverse collateral consequence[s]" as a result of paying hefty penalties.

8 DOJ National Security Division, *Export Control And Sanctions Enforcement Policy For Business Organizations* (Dec. 13, 2019), https://www.justice.gov/nsd/ces_vsd_policy_2019/download.

9 DOJ Office of Public Affairs, *Department of Justice Revises and Re-Issues Export Control and Sanctions Enforcement Policy for Business Organizations* (Dec. 3, 2019), https://www.justice.gov/opa/pr/department-justice-revises-and-re-issues-export-control-and-sanctions-enforcement-policy.

Regulatory Updates: Other Regulators Following DOJ's Guidance/Lead

Office of Foreign Assets Control (OFAC)

In 2019, other federal regulators also emphasized the proactive actions companies can take to reduce penalties for violations of the law. Most notably, the Department of the Treasury's OFAC finally published long-awaited guidance for national and international organizations subject to its regulation (the Framework).

The inaugural "Framework for OFAC Compliance Commitments" provides guidance on the essential components of a sanctions compliance program and describes how OFAC may evaluate these components in resolving investigations and determining the amount of any penalties. The Framework is organized around five "essential" elements of a risk-based compliance program: (1) management commitment; (2) risk assessment; (3) internal controls; (4) testing and auditing; and (5) training.

OFAC also provided a non-exhaustive list of root causes associated with apparent violations of the regulations administrated by OFAC. The list, generated from numerous enforcement actions where deficiencies or weaknesses were identified in a sanctions compliance program, helpfully provides OFAC's summary of particular deficiencies in sanctions compliance programs that contributed to OFAC's enforcement decisions in the past.

The OFAC Framework does not necessarily offer novel insights into the constitution of strong versus weak compliance programs. However, it does serve as further evidence of a trend among US enforcement agencies and DOJ divisions to emphasize transparency and cooperation with regulated entities.

Securities and Exchange Commission (SEC)

In 2019, the SEC penalized a public company for violating US economic sanctions, putting companies on notice that the DOJ and OFAC are not the only sanctions enforcers in Washington DC.

The SEC cited the "books and records" and "internal controls" provisions of the Securities Exchange Act of 1934 (Exchange Act), which require public companies to keep accurate books and records, and maintain internal controls sufficient to ensure that transactions are executed in accordance with management directives and accurately recorded for reporting in the company's financial statements. The SEC often cites public companies for violations of these provisions in cases involving allegations of foreign bribery under the FCPA. However, the SEC's 2019 action against Quad/Graphics broke new ground, finding that a public company violated these provisions not only through a foreign bribery scheme, but also through a scheme to evade longstanding US sanctions against Cuba.

The order marks a rare foray by the SEC into the enforcement of US sanctions. It remains to be seen whether this expansion of SEC authority will be limited to sanctions, or may extend to other areas of financial crime, such as money laundering. What is clear from the Quad Order is that the SEC is exploring new avenues to police issuers and other parties under its supervision. If the SEC will exercise authority over sanctions violations, it is entirely possible that it will investigate other financial compliance failures by issuers, broker-dealers and investment advisers. For example, the SEC may consider whether an inadequate anti-money laundering compliance program could give rise to an internal controls violation or a violation of the SEC's investor disclosure requirements.

Healthcare Fraud

DOJ Priority on Healthcare Fraud Enforcement Under the FCA Continue

Over the years, the DOJ has increased its enforcement activity in the healthcare space, changing the landscape and nature of not only criminal charges facing industry actors, but also civil recoveries. During the fiscal year ending September 30, 2019, the DOJ recovered more than US$3 billion from civil cases involving fraud and false claims against the government.[10] More than US$2.6 billion of those recoveries resulted from settlements and judgments relating to the healthcare industry, including from matters involving drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians.

DOJ recoveries from FCA matters over the past decade peaked in 2014 and 2016, with recoveries of US$6 billion and US$4.7 billion, respectively.[11] Although the most recent figures are not as high, they do follow the overall trend of fiscal year recoveries totaling approximately US$3 billion, with healthcare-related matters comprising two-thirds of those totals.[12] As in prior years, the DOJ has continued to emphasize the high priority placed on FCA enforcement and the successful recoveries obtained from such matters.

10 DOJ Office of Public Affairs, *Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019* (January 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

11 DOJ Civil Division, *Fraud Statistics – Overview*, Oct. 1, 1986 – Sept. 30, 2019, https://www.justice.gov/opa/press-release/file/1233201/download. The 2014 recoveries were bolstered by settlements from banks exceeding approximately US$4.65 billion related to the housing and mortgage crisis. The 2016 recoveries were similarly augmented by settlements related to mortgage fraud, with approximately US$1.3 billion obtained from banks.

12 DOJ Civil Division, *Fraud Statistics – Overview*, Oct. 1, 1986 – Sept. 30, 2019, https://www.justice.gov/opa/press-release/file/1233201/download. Approximate recoveries from 2010 – 2019 are as follows: 2010 – US$3 billion (US$2.5 billion from healthcare); 2011 – US$3 billion (US$2.4 billion from healthcare); 2012 – US$5 billion (US$3.1 billion from healthcare); 2013 – US$3 billion (US$2.7 billion from healthcare); 2014 – US$6 billion (US$2.4 billion from healthcare); 2015 – US$3 billion (US$2.1 billion from healthcare); 2016 – US$4.7 billion (US$2.7 billion from healthcare); 2017 – US$3.7 billion (US$2.1 billion from healthcare); 2018 – US$2.8 billion (US$2.5 billion from healthcare); 2019 – US$3 billion (US$2.6 billion from healthcare).

Whistleblower Protections in Healthcare Fraud

A large number of FCA cases brought or investigated by the DOJ are initiated as a result of whistleblower involvement. For the fiscal year 2019, the DOJ recovered more than US$2.1 billion under the *qui tam* (or whistleblower) provisions of the FCA and paid out US$265 million to the individuals who filed these actions.[13]

Healthcare-related violations of the FCA vary from failure to document patient care, off-label promotion and unnecessary medical services, to excessive billing charges and other claims. Generally, such violations implicate the following provisions: (1) knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;[14] (2) knowingly making, using or causing to be made a false record or statement in order to get a false claim paid or approved;[15] (3) conspiring to commit a violation of the FCA;[16] or (4) knowingly concealing, or knowingly and improperly avoiding or decreasing an obligation to pay (known as the "reverse false claim").[17]

The FCA is a powerful tool, largely due to the significant damages provisions. Violations of the FCA can result in treble damages, as well as a mandatory penalty of US$11,181 to US$22,363 per false claim.[18] Whether the FCA suit is initiated by the government or by the *qui tam* relator (i.e., whistleblower), the liability, damages and penalties provisions remain the same. Defendants are also liable for lawyers' fees and litigation costs.

Relators are incentivized to bring *qui tam* actions because they are awarded a share of any recovery that is made against a defendant. If the government intervenes, the relator is entitled to receive between 15% and 25% of the amount recovered by the government. If the government declines to intervene and the suit still proceeds, the relator's share increases to between 25% and 30%.[19] There are also robust protections under the FCA, designed to protect whistleblowers from retaliation, harassment or discrimination based on their conduct.[20]

Recent Cases Under the Granston Memo

A 2018 memorandum issued by DOJ senior officials (dubbed "the Granston Memo)" signaled an important shift in FCA enforcement strategy by encouraging prosecutors to dismiss weak FCA cases to advance the government's interests, preserve limited resources and avoid potentially adverse precedent.[21] On March 12, 2019, Deputy Associate Attorney General Stephen Cox stated the DOJ's use of its dismissal authority is largely used to "reign in overreach in whistleblower litigation."[22]

The Granston Memo suggests seven non-exhaustive factors government lawyers should consider in deciding whether to seek dismissal of a *qui tam* filing: (1) curbing meritless *quit tams*; (2) preventing parasitic or opportunistic *qui tam* actions; (3) preventing interference with agency policies and programs; (4) controlling litigation brought on behalf of the US; (5) safeguarding classified information and national security interests; (6) preserving government resources; and (7) addressing egregious procedural errors.[23]

Using these factors, the DOJ recently dismissed several *qui tam* actions. As a result, there is a circuit split regarding whether the government's dismissal right is reviewable where a relator can show that the dismissal was fraudulent, arbitrary and capricious, or illegal,[24] or whether the government has an "unfettered right to dismiss" FCA actions.[25] Resolving the split may clarify the extent to which the DOJ's more aggressive approach in dismissing, or declining to pursue *qui tam* claims, can stand, but, based on the amount of money the government can recoup from healthcare industry violations, expect increased prosecutions based on *qui tam* claims the DOJ views as worthy.

13 DOJ Office of Public Affairs, *Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019* (January 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

14 31 U.S.C. § 3729(a)(1)(A).

15 31 U.S.C. § 3729(a)(1)(B).

16 31 U.S.C. § 3729(a)(1)(C).

17 31 U.S.C. § 3729(a)(1)(G). The Affordable Care Act of 2010 established the deadline for reporting and returning an overpayment is the later of either 60 days after an overpayment has been identified or the date of a corresponding cost report. However, the CMS Overpayment Rule was vacated in 2018 (see Sec. II.2).

18 In January 2018, the DOJ increased FCA penalties to US$11,181 to US$22,363.

19 § 3730(d).

20 31 U.S.C. § 3730(h)(1).

21 DOJ Civil Division, *Memorandum: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)* (Jan. 10, 2018), https://www.fcadefenselawblog.com/wp-content/uploads/sites/561/2018/01/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.

22 DOJ Office of Public Affairs, *Deputy Associate Attorney General Stephen Cox Gives Remarks to the Cleveland, Tennessee, Rotary Club* (Mar. 12, 2019), https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-gives-remarks-cleveland-tennessee-rotary.

23 *Id.*

24 The *Sequoia* standard, set forth in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998), is followed by: *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 936, 940 (10th Cir. 2005), *United States v. EMD Serono, Inc.*, 370 F. Supp. 3d 483 (E.D. Pa. 2019), and United States ex rel. CIMZNHCA, LLC v. UCB, Inc., No. 17-CV-765-SMY-MAB, 2019 WL 1598109 (S.D. Ill. Apr. 15, 2019).

25 *Swift v. United States*, 318 F.2d 250, 252-53 (D.C. Cir. 2003) (rejecting the *Sequoia* standard and finding that government dismissals are unreviewable except in cases of fraud). The *Swift* standard is recognized by: *United States ex. rel. Davis v. Hennepin County*, No. 18-CV-01551(ECT/HB), 2019 WL 608848 (D. Minn. Feb. 13, 2019), *United States ex rel. Sibley v. Delta Reg'l Med. Ctr.*, No. 17-CV-000053-GHDRP, 2019 WL 1305069 (N.D. Miss. Mar. 21, 2019), and *United States ex rel. De Sessa v. Dallas Cty. Hosp. Dist.*, No. 3:17-CV-1782-K, 2019 WL 2225072 (N.D. Tex. May 23, 2019).

Evolution of Caremark

In 2019, the corporate officer and director "duty of care" saw a significant shift that may result in more, and more successful, claims brought by shareholders for violations of that duty.

The Duty of Directors and Officers

Generally, the law imposes on company directors and officers a duty to act with the level of care of a reasonable person in similar circumstances and to put the corporation's interests ahead of their own.[26] A director or officer may be liable for breaching his or her fiduciary duty if a plaintiff can demonstrate that he or she knew, or should have known, about the violations of law, that they took no steps in a good faith effort to prevent or remedy the situation, and that such failure proximately resulted in shareholder loss.[27]

The landmark case announcing this rule is *In re Caremark International*. There, shareholders filed a derivative suit against healthcare provider directors to recover losses resulting from the company's violations of various laws and regulations. Although the provider had implemented measures to assure compliance with anti-kickback provisions of Medicare, two officers and two other employees were indicted for violations of those laws. The derivative suit alleged that the directors breached their duty of care by failing to monitor the corporation's activities and allowing those officers to violate the law on their watch. In approving a proposed settlement, the *Caremark* court held that "a director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards."[28]

Years later, the case of *Stone v. Ritter* confirmed the duty of oversight standard announced in *Caremark*, and added that directors must exercise "good faith" in dealing with potential violations of the law.[29] The court held that "[w]here directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities, they … fail[] to discharge that fiduciary obligation in good faith."[30] Recognizing the high standard, the Delaware Supreme Court acknowledged that "a claim that directors are subject to personal liability for employee failures is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."[31]

Shift in *Caremark* Standard

On June 18, 2019, the Delaware Supreme Court reversed the dismissal of derivative claims based on an alleged breach of the duties of loyalty under *Caremark*, following a listeria outbreak at ice cream manufacturer Blue Bell Creameries USA, Inc. that resulted in not only the deaths of three people, but also a recall of all of its products, shut down of its plants and lay-offs of over a third of its workforce. In *Marchand v. Barnhill*,[32] the plaintiffs claimed Blue Bell's directors failed to institute a system of controls and reporting regarding food safety. In reversing the lower court's dismissal, the Delaware Supreme Court focused not on the effectiveness of a board-level compliance and reporting system, but rather on "whether the complaint pleads facts supporting a reasonable inference that the board did not undertake good faith efforts to put a board-level system of monitoring and reporting in place."[33] The court acknowledged that "[a]lthough *Caremark* is a tough standard for plaintiffs to meet," here, management only reported to the board on operational issues, not compliance with food safety.[34] Accordingly, the court concluded that the plaintiff was entitled to prove the claims set forth in the complaint, as he had pled "facts supporting a fair inference that no reasonable compliance system and protocols were established as to the obviously most central consumer safety and legal compliance issue facing the company, the board's lack of efforts resulted in it not receiving official notices of food safety deficiencies for several years, and that, as a failure to take remedial action, the company exposed consumers to listeria-infected ice cream, resulting in the death and injury of company customers."[35]

Looking to the *Marchand* decision, on October 1, 2019, a Delaware Court of Chancery found that the plaintiff shareholders in that case have "well-pled a *Caremark* claim" by alleging the defendant biopharmaceutical company's board ignored multiple warning signs related to a drug that was "intrinsically critical to the company's business operation" and that management was inaccurately reporting a drug's efficacy.[36] The *Marchand* decision and subsequent cases have shown that the Delaware courts are looking to board-level efforts to oversee compliance with governing law, particularly in situations where the compliance issues are critical to the company's business.

26 *In re Caremark Int'l*, 698 A.2d 959 (Del. Ch. 1996).

27 *Id.* at 971.

28 *Id.* at 970.

29 *Stone v. Ritter*, 911 A.2d 362, 369 (Del. Nov. 6, 2006).

30 *Id.* at 369-70.

31 *Id.* at 372 (internal quotation marks omitted).

32 *Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019)

33 *Id.* at 821.

34 *Id.* at 822.

35 *Id.* at 824.

36 *In re Clovis Oncology, Inc. Derivative Litigation*, No. 2017-0222-JRS, 2019 Del. Ch. LEXIS 1293 (Del. Ch. Oct. 1, 2019).

Lessons Learned

Although, in the past, *Caremark* claims rested upon what was described as "the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment,"[37] the standard has shifted in favor of plaintiffs in 2019. Plaintiffs may now prevail at the pleading stage by alleging the board failed to implement any reasonable oversight system over central compliance risks. While *Caremark* claims will still be difficult to plead successfully, the *Caremark* standard is evolving and Delaware courts have laid the groundwork for viable claims focused on the existence of reasonable board-level oversight. This oversight not only extends to ensuring a system is in place to obtain key compliance information, but also the board's obligation to actively monitor whether the company is compliant rather than passively rely on management representations with respect to critical regulatory issues.

DOJ Tackles the Opioid Crisis

Since 2016, the DOJ has committed to combating the opioid epidemic in the US.[38] This effort has included investigating and prosecuting high-impact cases, enhancing regulatory enforcement, encouraging information sharing and funding enforcement-related research. In 2019, the DOJ ramped up its efforts to combat the opioid crisis by pursuing not only civil, but also criminal actions against wrongful entities and individuals.

Civil Enforcement

At the beginning of the year, the DOJ filed the first action of its kind to stop Tennessee pharmacies from unlawfully dispensing opioids. The action was part of a coordinated effort by the DOJ's Prescription Interdiction and Litigation Task Force, which was formed in 2018 to temper the number of opioid overdoses in the US. The DOJ alleged that Oakley Pharmacy, Dale Hollow Pharmacy and Xpress Pharmacy were dispensing and billing Medicare for prescriptions in violation of the Controlled Substances Act and the FCA.[39] Allegedly, the defendants dispensed controlled substances while ignoring numerous "red flags" of diversion and abuse, in violation of their duty to ensure that prescriptions were written for a legitimate business purpose. According to the civil complaint, the defendants' unlawful distribution of opioids was tied to the deaths of at least two people and the serious overdoses of numerous others. D. Christopher Evans, Special Agent in Charge of DEA's Louisville Field Division, said, "the action should serve as a warning to those in the pharmacy industry who choose to put profit over customer safety." Furthermore, Evans said, "given the national public health emergency resulting from the opioid crisis in our nation, the US Attorney's Office will use every resource at our disposal to stop pharmacies and pharmacists from continuing to abuse their dispensing authority to fuel this epidemic."[40]

In furtherance of their mission to fight the opioid crisis, in May 2019, the DOJ's Civil Division and the US Attorney's Office for the Northern District of Texas filed an action to stop two Texas doctors from unlawfully prescribing opioids linked to diversion and abuse.[41] The complaint alleged that the doctors prescribed numerous prescriptions without a legitimate medical purpose and outside the usual course of professional practice. The DOJ vowed to continue to investigate doctors who conduct this kind of practice in an effort to combat the opioid crisis.

Criminal Enforcement

In addition to civil enforcements, the DOJ pursued criminal prosecutions against individuals involved in the prescription of opioids. In October 2018, the DOJ formed the Criminal Divisions' Appalachian Regional Prescription Opioid (ARPO) Strike Force in an effort to eradicate the unlawful distribution of opioids in an area heavily plagued by opioid use.[42] In 2019, the ARPO Strike Force coordinated two notable law enforcement actions, charging 60 individuals across 11 federal districts in the first, and 13 individuals across five federal districts in the second.[43] Those criminally charged included doctors, nurse practitioners and other licensed medical professionals. The alleged offenses related to the unlawful distribution of opioids and other narcotics through "pill mill" clinics. The DOJ considers the ARPO Strike Force an enduring commitment to stamp out opioid trafficking.

Conclusion

The DOJ is aggressively working to combat the opioid crisis, and both companies and individual actors are subject to civil and criminal enforcement actions by the DOJ. With the intense focus and the expansive reach, there will most likely be an uptick in enforcement actions against wrongdoers in the coming year.

Fallout From the *Hoskins* Decision

The *Hoskins* Decision

The 2018 rationale of the Second Circuit in *United States v. Hoskins* underwent the crucible of a trial last year. Lawrence Hoskins, a UK national and former executive of the UK subsidiary of Alstom SA., was charged with conspiracy to violate the FCPA for his role in bribery schemes involving a US subsidiary. Hoskins was not employed by the US subsidiary and was not physically in the US during the alleged bribery scheme.

37 *Stone v. Ritter*, 911 A.2d at 372 (quoting *In re Caremark*, 698 A.2d at 967).

38 DOJ, *Department of Justice Strategy to Combat Opioid Epidemic* (Sept. 21, 2016), https://www.justice.gov/opioidawareness/file/896776/download.

39 DOJ Office of Public Affairs, *Justice Department Files First of its Kind Action to Stop Tennessee Pharmacies' Unlawful Dispensing of Opioids* (Feb. 8, 2019), https://www.justice.gov/opa/pr/justice-department-files-first-its-kind-action-stop-tennessee-pharmacies-unlawful-dispensing.

40 *Id.*

41 DOJ Office of Public Affairs, *Justice Department Files Action to Enjoin Texas Doctors from Illegally Prescribing Highly Addictive Opioids and Other Controlled Substances* (May 10, 2019), https://www.justice.gov/opa/pr/justice-department-files-action-enjoin-texas-doctors-illegally-prescribing-highly-addictive.

42 DOJ Office of Public Affairs, *Second Appalachian Region Prescription Opioid Strikeforce Takedown Results in Charges Against 13 Individuals, Including 11 Physicians* (Sept. 24, 2019), https://www.justice.gov/opa/pr/second-appalachian-region-prescription-opioid-strikeforce-takedown-results-charges-against-13.

43 *Id*; DOJ Office of Public Affairs, *Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals* (April 17, 2019), https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against.

In *Hoskins*, the Second Circuit rejected the government's conspiracy theory of violating the FCPA by holding that the "government may not expand the extraterritorial reach of the FCPA by recourse to the conspiracy and complicity statutes." The court explained its decision by relying on three main factors: (i) the presumption against extraterritorial application of US statutes; (ii) the plain language of the FCPA limiting potential defendants to defined categories; and (iii) the legislative history of the FCPA, which demonstrated clearly Congress' intent to limit the statute's extraterritorial reach.

In the Trial Court

The Second Circuit remanded the case so that the government could try to prove that Hoskins took part in a bribery scheme while acting as an agent of a domestic concern. The verdict came in November 2019. After hearing the evidence and arguments of counsel, the jury convicted Hoskins under the agency theory.

Fallout

This is not the last to be heard about the *Hoskins* decision, however, and it will have lasting implications in FCPA investigations and prosecutions. First, in order to convict *Hoskins*, the government was forced to shift its focus at trial from the broad and seemingly shapeless concept of conspiracy and instead prove that an agency relationship had been established. The government will need to maintain this shift in focus when collecting evidence during similar investigations in the future. Second, the definition of agency was hotly debated during the trial, and it will likely be a question for the Second Circuit to consider on appeal. Additionally, the government could continue to pursue its conspiracy theory outside the boundaries of the Second Circuit in the hopes of generating a Circuit split, which would enhance the odds of Supreme Court review. Finally, the rationale of *Hoskins* is likely to be applied to US sanctions law. Although the concurrence in *Hoskins* emphasized that the opinion applies to a narrow group of statutes, sanctions statutes, such as the International Emergency Economic Powers Act (IEEPA), seem to fall within that group. The applicability of *Hoskins* to sanctions depends, in part, upon the particular sanctions regime. The nuances among Iranian, North Korean, Venezuelan and the numerous other sanctions regimes must be approached with care.

Cross-border Cooperation

Criminal schemes have become increasingly transnational in recent years. In acknowledging this new reality, the DOJ has initiated policies for working with foreign law enforcement agencies that address the unique issues of fighting crime on this scale.

Obtaining Evidence Abroad

To facilitate the collection of evidence located abroad and avoid the challenges of requiring companies to comply with inconsistent laws, the DOJ will usually invoke the assistance of the foreign sovereign through a Mutual Legal Assistance Treaty (MLAT). The Office of International Affairs will advise prosecutors in selecting the appropriate method for requesting assistance from the foreign sovereign.

In a speech at the American Bar Association's Global White Collar Crime Institute Conference this summer, Deputy Assistant Attorney General Matt Miner recognized that global companies are frequently subject to competing, and sometimes conflicting, legal and regulatory requirements. For example, the European Union's General Data Protection Regulation (GDPR) can place companies intending to cooperate with US law enforcement authorities in the unnavigable position of serving competing masters. The FCPA Corporate Enforcement Policy, which guides corporate enforcement cases across the Criminal Division, is sensitive to this issue. A company that can establish that such a disclosure would cause it to violate foreign laws with no available alternatives will not be required to provide such information.

Balancing Corporate Resolutions When Multiple Law Enforcement Agencies Are Involved

The DOJ's Policy on Coordination of Corporate Resolution Penalties is also sensitive to the challenges of multiple enforcement agencies imposing corporate resolutions on global companies. It "instruct[s] Department components to appropriately coordinate with one another and with other enforcement agencies in imposing multiple penalties on a company in relation to investigations of the same conduct." The goal of this policy is to eliminate duplicative punishments for the same conduct, which can be unfair and deprive a company of the finality ordinarily available with just one prosecuting agency.

Examples of International Cooperation

Over the last several years, the US and Brazil have had an uncommonly successful relationship in investigating and prosecuting corruption. For example, this summer, the DOJ collaborated with Brazilian prosecutors in an investigation of TechnipFMC plc (Technip) related to two separate foreign bribery charges of influencing government officials in Brazil and Iraq. In accordance with the Policy on Coordination of Corporate Resolution Penalties, the DOJ credited Technip the approximately US$214 million it agreed to pay Brazilian authorities as part of its settlement agreement for the same conduct.

In another example of international law enforcement cooperation, the largest Russian telecommunications company, Mobile Telesystems PJSC (MTS), paid a combined US$850 million to the DOJ and the SEC to resolve charges of bribing government officials in Uzbekistan. Key to the success of the investigation was the assistance US law enforcement received from the governments of Austria, Belgium, Cyprus, France, Ireland, Isle of Man, Latvia, Luxembourg, Norway, the Netherlands, Switzerland, Sweden and the UK.

Conclusion

To respond to the cross-border nature of corporate law enforcement, the DOJ has increasingly relied on the cooperation of its foreign counterparties. There are inherent challenges to having multiple law enforcement agencies investigating and punishing the same conduct, and the DOJ will seek to harmonize these competing interests. We expect to see these trends continue in the future.

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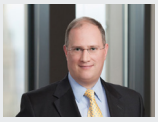

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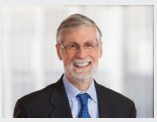

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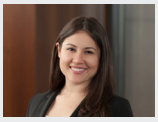

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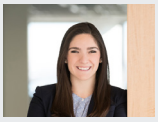

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