Vinson&Elkins

GOVERNMENT INVESTIGATIONS & WHITE COLLAR CRIMINAL DEFENSE REPORT

RECENT ENFORCEMENT TRENDS: HEALTHCARE AND LIFE SCIENCES SECTOR

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INTRODUCTION

Over the past year, there have been several developments in the government enforcement landscape for the Healthcare and Life Sciences Sector. From settlements of bribery charges under the Foreign Corrupt Practices Act ("FCPA") to the Department of Justice's ("DOJ" or the "Department") Healthcare Fraud Strike Force, the Healthcare and Life Sciences Sector faces a shifting environment of government inquiry and enforcement. With this report of recent enforcement trends, we are highlighting the key government enforcement policies and actions that Healthcare and Life Sciences Sector professionals need to know.

Adopted in 2016, the **GDPR** was fully implemented in the European Union on May 25, 2018.

Healthcare and Life Sciences Sector made up **nearly 90%** of the total False Claims Act recovery in 2018.

Diligence in identifying and handling violations is still prudent, particularly for healthcare and life sciences firms doing business abroad. Companies with operations in China should be particularly attentive, as the DOJ has suggested that the region will receive greater scrutiny. But if violations emerge, companies are more likely than in the recent past to obtain friendly resolutions—if the matter is handled correctly. The DOJ has issued new policies that encourage prosecutors to not bring charges against cooperating companies. Reflecting those changes, the DOJ has seemed more inclined to resolve investigations with declinations or deferred prosecution agreements, although those resolutions nevertheless are likely to involve a penalty or disgorgement of profits paid to the Securities and Exchange Commission ("SEC"). Consistent with DOJ guidance, individuals remain a target for DOJ prosecution.

As frequent recipients of government funds, healthcare and life sciences companies are also likely to continue to face scrutiny from the government for possible fraudulent claims, especially with respect to claims involving opioids. While the government's False Claims Act ("FCA") recovery in 2018 was the lowest it has been in a decade, claims involving the Healthcare and Life Sciences Sector made up nearly 90% of the total recovery. On the other hand, companies are likely to find more relief from private FCA lawsuits as the DOJ takes a more proactive approach in moving to dismiss suits, even over relators' objections.

The DOJ also continues to prioritize the Healthcare and Life Sciences sector in its antitrust enforcement. The DOJ's ongoing investigation into generic drug companies and recent settlements with two different hospital groups over civil antitrust charges highlight the need for companies to carefully review their antitrust compliance programs.

We provide updates on these activities and more in this report.

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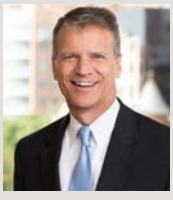

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FOREIGN CORRUPT PRACTICES ACT: GOVERNMENT ENFORCEMENT POLICIES

Speeches and statements by senior DOJ officials regarding the FCPA reflect that the Department is setting a different enforcement tone: While still emphasizing that it seeks to hold wrongdoers accountable, the agency appears more sympathetic to the burdens that investigations place on companies. In light of these policies, the Healthcare and Life Sciences Sector is likely to see more favorable resolutions resulting from voluntary disclosures of FCPA violations and subsequent cooperation with the government.

WHAT YOU NEED TO KNOW

- The policies the DOJ announced this year reflect that cooperation and self-disclosure are likely to result in lenient results for companies.
- The DOJ has tightened the standard for imposing monitors on companies.
- To avoid “piling on” fines and penalties, the DOJ is requiring its attorneys to consider apportionment with other government authorities engaged in parallel investigations.
- Companies doing business in China should be wary of new scrutiny by the DOJ on possible FCPA violations.

EXPANDED USE OF THE FCPA CORPORATE ENFORCEMENT POLICY

BACKGROUND OF THE FCPA CORPORATE ENFORCEMENT POLICY In 2016, the DOJ launched the FCPA Pilot Program, a one-year program under which companies that voluntarily self-disclosed FCPA wrongdoing, cooperated fully with the subsequent investigation, and made full remediation for the wrongdoing that the government did not already know about were eligible for significant reductions in the fines and penalties the DOJ could impose. In November 2017, in apparent recognition of the success of the Pilot Program, Deputy Attorney General Rod Rosenstein announced that the program would be made permanent. Titled the FCPA Corporate Enforcement Policy ("the Policy") and included in the Justice Manual,[1] the Policy added new incentives to encourage companies to self-report and cooperate:

1. A presumption that the DOJ would decline to prosecute the company, if the company a) self-reported, b) fully cooperated, and c) made timely and appropriate remediation;
2. If aggravating factors require that the DOJ bring an enforcement action, a company still would receive a 50% discount off the low-end of the U.S. Sentencing Guidelines range for fines and penalties if it self-reported, fully cooperated, and made timely and appropriate remediation.

EXPECTATIONS UNDER THE POLICY In an October 2018 speech, Principal Deputy Assistant Attorney General John Cronan provided guidance regarding the DOJ's expectations for voluntary disclosure and cooperation under the Policy. For companies intending to self-disclose, "sooner rather than later" is the prevailing philosophy; companies "should not wait until after completing a significant internal investigation before coming forward."

When companies do self-disclose, they should be prepared to provide certain information to the government. Mr. Cronan provided a useful checklist for companies of details they should have ready:

- Identities of the persons overseeing and undertaking the investigation, whether outside counsel, company employees, or other outside advisors like an accounting firm;
- Identity of who the investigative team reports to, whether an audit committee, management, the general counsel, or someone else;
- Whether anyone is walled off from the investigation and whether they are represented by counsel;
- The nature, scope and status of the investigation;
- Plans for the investigation, including the locations and conduct under scrutiny;
- Steps taken to preserve and collect potentially relevant evidence, including electronic documents and devices, and any obstacles with preservation efforts;
- Identities of individuals interviewed;
- Plans for future interviews; and
- Identities of individuals who know about the investigation.

Companies also must be prepared to explain how they intend to move forward, including offering a rational explanation for the company's investigative plan.

Mr. Cronan emphasized that companies should promptly reach out to the government when they uncover key information in their investigation and should apprise the government if there is information the company cannot provide to the government, perhaps arising from privilege, data privacy, blocking statutes or other obstacles.

USE OF THE POLICY OUTSIDE OF TYPICAL FCPA CIRCUMSTANCES FCPA cases in which the Policy likely applies most often involve allegations of a company and possibly its subsidiaries having been involved in bribery in foreign countries or having lax internal controls. In several speeches this year, however, DOJ senior officials announced that the principles articulated in the Policy would serve as guidance beyond the typical FCPA context.

In March, Mr. Cronan, then-Acting Assistant Attorney General, announced that the Policy would be "non-binding guidance" for all cases the DOJ's Criminal Division brings, not just FCPA cases.[2] The DOJ also plans to use the Policy as guidance for wrongdoing discovered before or soon after a merger or acquisition. In July, Deputy Assistant Attorney General Matthew Miner announced that successor companies in mergers or acquisitions will receive leniency under the Policy for disclosing FCPA wrongdoing discovered "in connection with" the transactions and cooperating with any follow-on investigations.

In September 2018, Mr. Miner stated that the Policy would serve as guidance for the DOJ's approach to non-FCPA wrongdoing discovered as part of a merger or acquisition. For companies that discover wrongdoing after a merger or acquisition, Mr. Miner recommended following the steps outlined in the Policy, namely voluntarily disclosing the wrongdoing and fully cooperating with any follow-on investigation.

FCPA OPINION PROCEDURE For companies that unearth wrongdoing during due diligence prior to a merger or acquisition, Mr. Miner suggested using the DOJ's FCPA Opinion Procedure ("Opinion Procedure"), which allows companies to obtain an opinion from the DOJ about whether actions the company intends to take comply with the DOJ's current FCPA enforcement policy.

Under the Opinion Procedure, companies can submit a written request for an opinion from the DOJ about prospective conduct. After receiving all necessary information, the DOJ has 30 days to provide its opinion about whether the proposed activities comply with its FCPA enforcement policy. If the DOJ issues a written opinion that the activities comply with the enforcement policy, the company receives a rebuttable presumption in any subsequent enforcement action of compliance with the FCPA. To encourage use of the Opinion Procedure, Mr. Miner stated that the DOJ is able, "to a degree," to expedite issuance of its analysis in light of acquisition and merger deadlines.

To be able to use the Opinion Procedure, companies should consider tailoring any non-disclosure agreements executed during pre-merger or acquisition due diligence to allow for limited disclosure of information suggesting wrongdoing.

DOJ MOVES AWAY FROM YATES MEMO

BACKGROUND OF THE YATES MEMO In 2015, then-Deputy Attorney General Sally Yates issued a memorandum titled Individual Accountability for Corporate Wrongdoing ("Yates Memo"), which outlined the DOJ's focus on accountability for individuals culpable of wrongdoing. The Yates Memo required companies to disclose "all individuals involved in or responsible for" identified misconduct, regardless of position, status, or seniority. Companies that failed to comply would not receive any cooperation credit.

A NEW STANDARD FOR COOPERATION CREDIT

In November 2018, Deputy Attorney General Rod Rosenstein announced a step back from the all-or-nothing approach of the Yates Memo. Mr. Rosenstein said that individual culpability remains a top priority of the DOJ but explained that the requirement to identify "all" individuals that were involved could lead to delayed resolution of investigations and undue burdens on companies. The DOJ's new policy focuses instead on individuals who were "substantially involved in or responsible for" the wrongdoing.

Notably, the policy differentiates between the standards that companies must meet in the criminal and civil contexts. For any cooperation credit in a criminal setting, the new policy requires companies to identify ***all*** individuals who were "substantially involved in or responsible for" the wrongdoing.

For credit in the civil setting, however, government attorneys have discretion to award full or partial credit depending on the nature of a company's cooperation. To receive any credit, companies must identify all senior officials who meet the new standard of involvement in wrongdoing. To receive maximum credit, a company must identify all employees who meet the new standard of substantial involvement or responsibility.

As a practical matter (and as Mr. Rosenstein suggested in his remarks), this new standard may not mark much of a change from the DOJ's actual implementation of the Yates Memo. According to Mr. Rosenstein, the DOJ was not strictly enforcing the standard set in the Yates Memo in either the civil or criminal context. The policy therefore may be mostly a way to bring the DOJ's policy in line with the practice of its attorneys. The fact that the DOJ has not issued a formal memorandum with the new guidance nor revised relevant sections of the Justice Manual suggests that the DOJ may not see this change as a significant departure from the practices of its attorneys.

To effectively take advantage of the new policy, companies should establish with the government a metric for determining "substantial involvement" and "responsibility," such as whether individuals had to actually partake in the wrongdoing to meet the standard or whether knowledge is sufficient to bring an individual within the scope of the government's interest. An early determination of the standard of involvement may avoid complications or delays later in the investigation.

SEE V&E'S E-LERT ON THE DOJ'S NEW POLICY:

DOJ Announces Revised Policy Reflecting Move Away From Yates Memo

DOJ ISSUES ANTI-PILING-ON POLICY

In a move that should provide some comfort for companies facing investigations by multiple government agencies, in May 2018 the DOJ announced a new policy regarding the treatment of penalties and fines in parallel investigations. The directive, which has come to be known as the "anti-piling-on" policy, recommends coordination with other government entities on penalties and fines when doing so would "allow the interests of justice to be fully vindicated."

The new policy, which appears in Section 1-12.100 of the Justice Manual, requires DOJ attorneys to coordinate internally to avoid duplicative fines and penalties. It also recommends that DOJ attorneys consult with other enforcement agencies, such as state, local, and foreign governments, who are engaged in parallel investigations to consider whether to coordinate the fines and penalties imposed on companies. Interestingly, the policy also advises DOJ attorneys not to use the threat of criminal enforcement as a way to get companies to agree to civil or administrative penalties.

In determining whether and how to coordinate, DOJ attorneys have to consider several factors:

- the seriousness of the misconduct;
- the statutory requirements for fines, penalties, and forfeitures;
- whether there is a risk of delay in reaching a final resolution; and
- the timeliness of a company's disclosure and the nature of its cooperation.

When entering into negotiations with the DOJ or any other government entity, companies should use these factors to come prepared with arguments that the anti-piling-on policy applies.

V&E's team is noted for its "extraordinary service and sophisticated understanding of various industries and government investigations."

– Legal500 United States: Dispute Resolution, Corporate Investigations and White-collar Criminal Defense 2018

DOJ ANNOUNCES NEW POLICY ON CORPORATE MONITORS

In October, Assistant Attorney General Brian Benczkowski announced the DOJ's new policy for government-appointed monitors assigned to companies. The new policy provides a potentially heightened standard for imposing a monitor on a company.

BACKGROUND OF THE DOJ'S CORPORATE MONITOR POLICY In the past, the government has imposed monitors on companies as a condition of non-prosecution agreements, deferred prosecution agreements, or plea agreements. The goal of a monitor is to have an outside individual (or team) that ensures company compliance with the terms of the agreements. Monitors, however, are imposed at the company's expense and can be burdensome to future operations.

Within the last decade, the DOJ has twice issued guidance on the issue of imposing corporate monitors, first in 2008 in what is known as the Morford Memorandum ("Morford Memo"), and again in 2009 in what is known as the Breuer Memorandum ("Breuer Memo").[3] The Morford Memo, which this new DOJ policy supplements, requires federal prosecutors to consider the potential benefits to the corporation and the public from imposing a monitor as well as the costs and impact to the company that result from a monitor.

TOUGHER STANDARD FOR IMPOSING MONITORS Coupled with Mr. Benczkowski's remarks, the new policy makes clear that the DOJ considers the imposition of monitors to be the exception, rather than the rule, a point Mr. Benczkowski made explicitly in his announcement. The policy itself also states that monitors "will not be necessary in many corporate criminal resolutions," especially where a company has demonstrated that its compliance program and internal controls are "effective and appropriately resourced at the time of resolution."

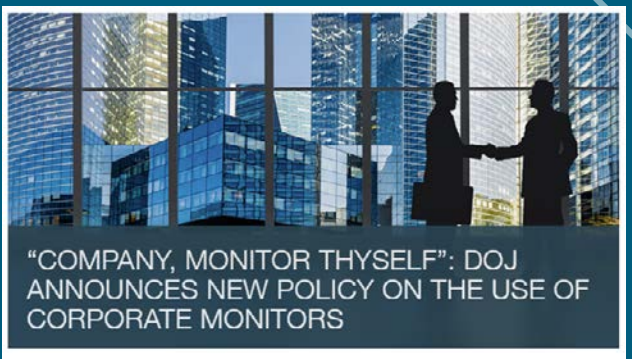
The new DOJ policy expands on what prosecutors must consider when weighing the benefits and costs of a monitor, requiring prosecutors to consider the following factors:

- Whether the wrongdoing involved the manipulation of a company's books and records or exploiting inadequate compliance programs and internal controls;
- Whether the wrongdoing was pervasive within the company, and especially whether senior management was involved;
- Whether companies have invested in and improved their compliance programs and internal controls; and
- If there are improvements to compliance programs and internal controls, whether the effectiveness of those programs and controls has been tested.

To best position themselves in the event of having to disclose wrongdoing, healthcare and life sciences companies should regularly test their compliance programs and internal controls to ensure that they are effective. They should also consider documenting the metrics they use for evaluating a successful compliance and controls program.

NEW TRAINING IN COMPLIANCE FOR DOJ ATTORNEYS In his announcement, Mr. Benczkowski also explained that the DOJ intends to set up training for its

SEE V&E'S E-LERT ON THE DOJ'S NEW POLICY:



"COMPANY, MONITOR THYSELF": DOJ ANNOUNCES NEW POLICY ON THE USE OF CORPORATE MONITORS

V&E FCPA & Global Anti-Corruption Update, October 18, 2018

By Jessica Heim, Amy Riella, Tyler Layton and Eric Hernandez*

New guidance from the Department of Justice ("DOJ" or "the Department")

federal prosecutors in how to assess the effectiveness of a company's compliance efforts. This training represents a move away from the DOJ's previous reliance on a single compliance expert who was tasked with counseling all prosecutors on the adequacy of companies' compliance programs. Assuming the DOJ follows through on the training, healthcare and life sciences companies are likely to find prosecutors who are more fluent in the demands of compliance programs as well as the benefits possible from effective programs.

DOJ'S CHINA INITIATIVE COULD TRIP UP COMPANIES DOING BUSINESS IN CHINA

A new initiative by the DOJ to focus enforcement resources on China may expose companies doing business in China to additional FCPA scrutiny. In November, then-Attorney General Jeff Sessions announced a new focus by the DOJ on trade theft cases by Chinese nationals, on reviewing foreign investment in U.S. infrastructure and telecommunications, and on enforcement of the Foreign Agents Registration Act. Tucked away in the fact sheet for this China Initiative was the goal of "[i]dentify[ing] Foreign Corrupt Practices Act (FCPA) cases involving Chinese companies that compete with American businesses."

Although the language of the initiative is to police Chinese companies that use corruption to unfairly compete with American businesses, the FCPA generally only applies to companies that do business in the United States, trade on U.S. exchanges, or do something in the United States as part of their scheme to bribe a foreign official (like taking a foreign official on a trip in the United States). Companies that may be targets of the DOJ's new initiative are likely to have fairly close ties to the United States. As detailed below, a few healthcare and life sciences sector companies that operate in China have already faced investigations by the SEC and DOJ.

Given that industry players in China are often state-owned (and therefore considered government agents under the FCPA), there is already risk of bribery charges under the FCPA for healthcare and life sciences companies that operate in China. Combined with the DOJ's new spotlight on corporate operations in China, 2019 could see more companies being swept into FCPA investigations.

SEE V&E'S E-LERT ON THE CHINA INITIATIVE:

DOJ's Spotlight on China May Shed Light on More Than Intended

FOREIGN CORRUPT PRACTICES ACT: NOTABLE ENFORCEMENT TRENDS AND ACTIONS

The July 2017 announcement from then-acting Chief of the DOJ's Fraud Section Sandra Moser that the Department's FCPA Unit would be partnering with the Corporate Strike Force of the Health Care Fraud Unit suggested that the DOJ would increase scrutiny of FCPA violations in the Healthcare and Life Sciences Sector. The enforcement of the FCPA over the past two years suggests, however, that the DOJ and the SEC have shifted toward favorable resolutions, especially for companies that voluntarily self-disclose FCPA violations. Notable resolutions in the Healthcare and Life Sciences Sector reflect that the DOJ has engaged with companies in this sector consistent with its overall FCPA enforcement trends.

WHAT YOU NEED TO KNOW

- Voluntary disclosure and cooperation is more likely to lead to a decision not to bring charges by the DOJ, the SEC, or both, even if companies have to pay fines, penalties, or disgorgement.
- Complacency can be problematic, as a failure to voluntarily disclose or to have a robust compliance program and internal controls are more likely to lead to criminal charges, imposition of a corporate monitor, or both.

FCPA ENFORCEMENT TRENDS

In 2017 and 2018, the number of FCPA corporate enforcement actions decreased, with the 11 resolutions in 2017 and 15 resolutions in 2018 below the Obama administration's peak in 2016 of 25 resolutions.[4]

Of the 16 corporate enforcement actions in 2018, the SEC resolved charges against companies in 14 of the cases. The DOJ, in contrast, imposed penalties pursuant to an agreement in only six of the cases. In two additional cases, the DOJ imposed "declinations with disgorgement" (the DOJ declined to prosecute but required the company to disgorge its profits from the misconduct) under the Corporate Enforcement Policy. The DOJ formally declined to bring charges pursuant to that policy in two additional cases. For the remaining six cases, the DOJ did not offer any formal disclosure about its decision.

The 16 corporate enforcement actions in 2018, however, is still the third largest number of resolutions in a particular year over the last ten years, with 2016 (25 resolutions) and 2010 (21 resolutions) the only years to surpass that number. The early enforcement trends of the administration suggest that the FCPA is likely to remain an enforcement priority for the DOJ and the SEC.

The number of formal declinations by the DOJ pursuant to the Corporate Enforcement Policy has likewise remained steady.[5] In 2016, the DOJ formally announced declinations in five cases pursuant to the Pilot Program, the predecessor to the Corporate Enforcement Policy. In 2017, there was a dip with only two formal declinations announced by the DOJ, but that number increased again in 2018 to four declinations. The number of formal declinations is likely to increase as the Corporate Enforcement Policy gains more traction within the Department.

NOTABLE HEALTHCARE AND LIFE SCIENCES FCPA ACTIONS

The Healthcare and Life Sciences Sector saw its share of FCPA enforcement actions in the past year. Two of the 16 enforcement actions in 2018 involved healthcare or life sciences companies, and the sector saw one unannounced declination from the SEC and the DOJ. Because hospitals or healthcare insurers may be state-owned or controlled in some countries, doctors and other employees of these entities may qualify as foreign officials under the FCPA. Compliance programs and internal controls thus remain important tools to avoid running afoul of the FCPA.

Below, we provide details of the enforcement actions against healthcare and life sciences companies.

Corporate FCPA Enforcement Actions

SANOFI SETTLES SEC FCPA BOOKS AND RECORDS CHARGES FOR OVER $25 MILLION In September 2018, French pharmaceutical company Sanofi settled an FCPA charge with the SEC for more than $25 million. That amount consisted of approximately $17.5 million in disgorgement, $2.6 million in prejudgment interest, and $5 million in penalties. The SEC's findings, which Sanofi neither admitted nor denied, described bribery schemes aimed at increasing sales in Kazakhstan and the Middle East.

The purported schemes varied by region, but generally involved alleged bribes that were disguised as discounts, product samples, consulting agreements, clinical studies, and travel and entertainment expenses. According to the SEC's allegations, employees paid these bribes to local healthcare providers at public institutions to increase prescriptions and purchases of Sanofi's products. The SEC alleged that the payments were falsely recorded as legitimate expenses, which reflected insufficient controls over the company's books and records. The SEC claimed that, as a result, Sanofi violated the FCPA's accounting provisions.

In the settlement order, the SEC noted Sanofi's compliance program improvements during the investigation, including increasing the number of compliance officers globally, placing compliance officers in high-risk areas, and improving the operations of local compliance committees. According to the SEC, Sanofi also strengthened its policies about interactions with healthcare professionals and government officers, and its gifts and entertainment policies.

Sanofi announced in March 2018 that the DOJ had closed its investigation and was not bringing an enforcement action against the company.

STRYKER RESOLVES FCPA CHARGE WITH SEC FOR $7.8 MILLION In September 2018, medical device manufacturer Stryker settled an FCPA accounting provision charge by the SEC for $7.8 million. According to the SEC's allegations, which Stryker neither admitted nor denied, Stryker failed to keep adequate records for a variety of transactions in India, China, and Kuwait and had insufficient controls to detect purported improper conduct by its subsidiaries.

The SEC claimed that Stryker's Indian subsidiary did not adequately document a portion of high-risk transactions in India, including consultation payments to healthcare providers, discounts, and marketing expenses. The SEC further alleged that Stryker's Chinese subsidiary worked with sub-distributors that were not vetted pursuant to Stryker's accounting control provisions, with the subsidiary purportedly at times falsifying records to conceal the lack of vetting. And in Kuwait, Stryker allegedly failed to implement controls over a distributer who made improper per-diem payments to healthcare providers for attendance at an all-expenses-paid Stryker event.

In addition to paying a $7.8 million civil penalty, Stryker agreed to retain an independent consultant to conduct reviews and make recommendations respecting Stryker's internal controls, bookkeeping, and procedures with respect to third parties for 18 months. The SEC's requirement that Stryker hire an outside monitor to ensure its compliance with the FCPA likely stemmed from the fact that Stryker previously settled similar FCPA charges with the SEC nearly five years ago.

Stryker made no announcement regarding whether the DOJ had initiated or resolved its own investigation into the FCPA allegations.

Declinations of FCPA Charges

CHINA-BASED SINOVAC BIOTECH ANNOUNCED DECLINATIONS FROM DOJ AND SEC Sinovac Biotech ("Sinovac"), a pharmaceutical company based in China, announced in August 2018 that it had received a declination from the SEC, followed in September by an announcement of a declination by the DOJ. The DOJ and SEC had been investigating allegations that Sinovac employees had bribed an official at China's Food and Drug Administration and officials at China's Center for Disease Control. The allegations regarding China's Food and Drug Administration official arose from a 2016 report by Geoinvesting, a financial research firm, which claimed that a Sinovac executive had bribed the Chinese official to aid with Sinovac's vaccine clinical trials. In the midst of Sinovac's internal investigation into the Geoinvesting report, apparently several of its salespeople were named as part of Chinese court judgments of corruption against officials at China's Center for Disease Control.

After Sinovac disclosed its internal investigation into the Geoinvesting report, in April 2017 the SEC notified the company that it was opening an enforcement inquiry and served the company with a subpoena requesting documents. The DOJ approached Sinovac in September 2017 with a parallel investigation. Sinovac announced publicly that it was fully cooperating with both investigations.

Ongoing FCPA Investigations

UK'S SERIOUS FRAUD OFFICE, DOJ, AND SEC SEEK INFORMATION FROM GLAXOSMITHKLINE REGARDING THIRD-PARTY ADVISORS IN CHINA In February, pharmaceutical company GlaxoSmithKline ("GSK") disclosed that the UK's Serious Fraud Office ("SFO"), which has been investigating GSK's business dealings in China since 2014, requested information about GSK's engagement of third-party advisors. GSK also acknowledged that the DOJ and SEC requested additional information in light of the SFO's request.

This matter previously appeared to be closed as far as U.S. enforcers were concerned when, in 2016, GSK resolved FCPA charges with the SEC through a $20 million settlement and obtained a declination from the DOJ. GSK was also subjected to a $490 million fine by a Chinese court in 2014.

According to the SEC's 2016 allegations, which GSK neither admitted nor denied, GSK engaged in a scheme between 2010 and 2013 to increase sales of its products through bribes of inflated travel expenses and gifts to healthcare providers. GSK's prior settlement pertained to the FCPA's books and records provisions.

Although GSK's disclosure sheds little light on the direction the SFO, DOJ, and SEC may be taking, the ongoing scrutiny of GSK's operations in China reflects the federal government's focus on that region. Healthcare and life sciences companies should regularly test their internal controls for their operations in China, given the government's focus there.

FOREIGN CORRUPT PRACTICES ACT: NOTABLE CASE LAW

As the DOJ and the SEC have pursued more FCPA cases in court against individuals, federal courts have weighed in with their interpretations of the jurisdictional and statute of limitations requirements under the FCPA. Traditionally, because the DOJ and the SEC often resolved FCPA charges through settlements, there was little case law interpreting the FCPA statute and even less case law discussing corporate obligations under the FCPA. These recent cases offer guidance from the courts about the scope of the FCPA's reach.

WHAT YOU NEED TO KNOW

- The SEC is likely to face tighter control by courts over FCPA cases that fall outside of the five-year statute of limitations.
- A conspiracy charge under the FCPA can only reach a foreign citizen who can be held directly liable under the FCPA either: 1) as an agent or employee of an American entity or 2) for engaging in activity in the United States in furtherance of the misconduct.
- The DOJ can pursue alternative theories of FCPA violations to establish that it has jurisdiction over an individual.

SEC CANNOT OVERCOME STATUTE OF LIMITATIONS IN FCPA CASE

A July decision by a district court in the Eastern District of New York in *SEC v. Cohen, et al.*[6] may be the start of a curtailment of the SEC's broad interpretation of its FCPA enforcement powers. Relying on the Supreme Court's 2017 *Kokesh v. SEC* decision,[7] the district court held that the five-year statute of limitations barred the SEC from bringing FCPA and Investment Advisors Act claims.

The SEC filed a lawsuit under the FCPA and the Investment Advisors Act against two former employees of Och-Ziff Capital Management Group ("Och-Ziff") for a bribery scheme to direct African business toward Och-Ziff. In the suit, the SEC sought disgorgement and an injunction against future violations. The defendants moved to dismiss, arguing that the SEC's claims against them were barred by the statute of limitations.

The district court agreed with the defendants that the SEC's claims were barred by the five-year limitation under the *Kokesh* decision. In *Kokesh*, the Court held that the five-year statute of limitations applies to the SEC's disgorgement remedy because the disgorgement remedy serves as a penalty, even if the SEC does not label it as such. Relying on that reasoning, the district court held that the SEC's disgorgement claims against the defendants, which arose out of conduct occurring before the five-year statute of limitations, were time barred.

In a possible further restriction of the SEC's interpretation of its enforcement powers, the district court also held that the SEC's sought-after "obey the law" injunctions (i.e. requiring the defendants to obey all securities laws in the future) were also penalties that were subject to the five-year limitation.

The district court's decision is a departure from pre-*Kokesh* case law in which the SEC routinely pursued cases beyond the five-year statute of limitations on grounds that disgorgements and injunctions were not subject to the statute of limitations (or, indeed, any statute of limitations). The district court also acknowledged that its decision on the nature of the "obey the law" injunctions was in tension with an Eighth Circuit decision, *SEC v. Collyard*,[8] in which the Court of Appeals suggested that an injunction may not be subject to the five-year limitation.

Cohen and *Collyard* reflect the changing landscape for SEC enforcement after *Kokesh*. The next few years could see additional challenges by parties facing SEC enforcement and possibly changes in the types of FCPA cases the SEC decides to bring.

SECOND CIRCUIT DELINEATES THE REACH OF THE FCPA

In August 2018, in *United States v. Hoskins*,[9] the Second Circuit outlined the boundaries of the FCPA's jurisdiction outside the United States against foreign nationals. The Court of Appeals held that a charge of conspiracy to violate the FCPA does not reach a foreign national who is not accused of taking any steps to further the scheme within the United States.

In 2013, the DOJ sought to charge Lawrence Hoskins, a British national and former Alstom UK executive, with conspiring to violate the FCPA for an alleged scheme to bribe Indonesian officials through payments to consultants for a $118 million project to build power stations. In late 2015, the district court dismissed one count of Mr. Hoskins' indictment, finding that he could not be held liable solely for aiding and abetting or conspiring to violate the FCPA. The district court reasoned that the FCPA applied only to three categories of persons: 1) issuers of securities registered on national exchanges; 2) American companies, American persons, and their agents; and 3) foreign persons taking acts to further a corruption scheme in the United States, and that the defendant did not fall into any of the categories.

On appeal, the Second Circuit agreed that Mr. Hoskins had to fall within one of the three categories of direct liability to be liable for conspiracy to violate the FCPA. The Second Circuit held that the structure of the FCPA statute made clear that Congress did not intend to extend accomplice or conspiracy liability to persons that did not fall within the three explicit categories. Because Mr. Hoskins was never a U.S. citizen, national, or resident, and was never accused of committing

acts in furtherance of the alleged bribery scheme in the United States, he could only be charged as an agent of a domestic concern. The Second Circuit reversed the district court, however, to the extent that the district court's ruling did not allow for the DOJ to prove conspiracy on the theory that Mr. Hoskins was an agent of Alstom's U.S. subsidiary.

As the DOJ continues to pursue individual cases under the FCPA, it nevertheless may pursue this theory in other courts to test whether other circuit courts will have a different interpretation of the FCPA. In other words, *Hoskins* may be only the first word in a longer debate about the scope of the FCPA's jurisdiction.

THE DOJ WINS ON TWO THEORIES IN FCPA TRIAL

A district court in the Southern District of New York allowed the DOJ to go to trial against defendant Chi Ping "Patrick" Ho on two distinct but parallel theories of FCPA jurisdiction: 1) that Dr. Ho was an agent of a domestic concern and 2) that he committed prohibited acts while in the United States. The DOJ alleged that at the time of two alleged bribery schemes in Chad and Uganda, Dr. Ho was the head of and acting on behalf of an NGO that was based in part in Virginia, where it was registered as a Section 501(c)(3) organization. The DOJ also alleged that Dr. Ho participated in a conference in New York City, where introductions between eventual participants in the scheme took place.

In a motion to dismiss several of the charges against him, Dr. Ho argued that the structure of the FCPA did not permit him to be charged as both an agent of a domestic concern *and* as a foreign national who committed an act on U.S. soil. Dr. Ho asserted that if he qualified as an agent of a domestic concern, under the statute's language, he could not also be a foreign national committing an act on U.S. soil. The government argued that the FCPA did not preclude "agents" of domestic concerns from also being foreign nationals who committed acts within the United States. The district court agreed with the DOJ and denied Dr. Ho's motion. In December 2018, the jury convicted Dr. Ho under both theories.

Reflecting his intention to appeal the conviction, Dr. Ho asked the district court to enter a judgment of acquittal, which the district court denied.

If Dr. Ho follows through with his intention to appeal the conviction, the Second Circuit will have another opportunity to weigh in on the scope of the FCPA, specifically whether the DOJ can properly bring charges—and get convictions—based on theories that an individual is both an agent of a domestic entity and a foreign national acting on U.S. soil. In the meantime, the DOJ is likely to continue pursuing both theories against individuals to the extent possible.

SEE V&E'S BULLETIN ON DR. HO'S CASE

Jury Convicts on Both Bites at the Apple in FCPA Case

V&E FCPA and Global Anti-Corruption Update, December 14, 2018

FCPA cases infrequently make it to trial. But, on December 5, 2018, a jury convicted Chi Ping "Patrick" Ho on seven counts related to his participation in bribery schemes involving officials of Chad and Uganda. Even more

FALSE CLAIMS ACT: GOVERNMENT ENFORCEMENT POLICIES

The DOJ recently implemented new policies regarding the False Claims Act, and they have already caused reverberations in FCA cases. The FCA creates criminal and civil liability for misrepresentations made to the federal government as part of a "claim" to the government for money. In addition to civil and criminal enforcement by the DOJ, the FCA has a *qui tam* provision that allows private parties (called "relators") to sue on behalf of the government and, if successful, receive a percentage of the government's recovery. As frequent recipients of government funds, the Healthcare and Life Sciences Sector will be particularly impacted by these new policies.

WHAT YOU NEED TO KNOW

- Where warranted, the DOJ will take a more proactive approach to intervening in *qui tam* FCA cases to dismiss cases over the relators' objections.
- DOJ attorneys may use violations of only statutes or regulations as the basis for an FCA case. They cannot rely on noncompliance with sub-regulations or guidance documents.

DOJ POLICY FOR GOVERNMENT DISMISSAL OF *QUI TAM* FCA ACTIONS

In an internal memorandum signed by the Director of the DOJ's Civil Fraud Division Michael D. Granston (the "Granston Memo") that was leaked to the public, the government announced a new policy tasking DOJ attorneys with more proactively evaluating *qui tam* FCA cases to determine whether the DOJ should intervene to dismiss the case. The FCA allows such a procedure, so long as the relators who brought the case have an opportunity to voice their objections. As the Granston Memo notes, however, the DOJ traditionally has used its power "sparingly."

The memorandum suggests a more proactive approach by DOJ attorneys. When *qui tam* cases are filed, the DOJ is notified and must determine whether to intervene to take over the case. The Granston Memo advises DOJ attorneys to simultaneously consider whether to move to dismiss the action. As the memorandum explains, the power to dismiss cases is "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent."

The memorandum's purpose is to "provide a general framework for evaluating when to seek dismissal under section 3730(c)(2)(A) and to ensure a consistent approach to this issue." It outlines seven non-exhaustive factors that DOJ attorneys should consider:

1. **Curbing Meritless *Qui Tam* Actions.** *Qui tam* complaints that include defective legal theories, frivolous factual allegations, or are otherwise meritless on their face are subject to dismissal. In addition, if facts uncovered during the investigation of the complaint's allegations reveal that the case is meritless, dismissal is warranted.
2. **Preventing Parasitic or Opportunistic *Qui Tam* Actions.** Noting that the purpose of the FCA's *qui tam* provision is to incentivize private parties to disclose information unknown to the DOJ, the memorandum encourages intervention where the allegations only duplicate ongoing government investigations.
3. **Preventing Interference with Agency Policies and Programs.** Because of the discovery involved, a *qui tam* action can interfere with a federal agency's internal administration, such as by slowing down time-sensitive government programs or causing economic harm to the government. Those circumstances may warrant a motion to dismiss.
4. **Controlling Litigation Brought on Behalf of the United States.** Threats to the DOJ's other litigation goals, such as settlement negotiations or risks of unfavorable precedent, warrant dismissal.
5. **Safeguarding Classified Information and National Security Interests.** *Qui tam* actions that intrude on classified information, such as cases related to national security, may warrant dismissal.
6. **Preserving Government Resources.** The memorandum recommends dismissal when the costs to the government, such as monitoring the litigation and federal agencies responding to discovery requests, are outweighed by any possible recovery in a *qui tam* action.
7. **Addressing Egregious Procedural Errors.** Cases are candidates for dismissal when the *qui tam* relator has made such serious procedural errors, such as failing to serve the complaint on the DOJ, that the DOJ is unable to conduct a proper investigation.

The Granston Memo acknowledges that the DOJ must apply to the district court in which the *qui tam* action is pending for the case to be dismissed and includes at least one example of a court approving dismissal for each of the seven factors. The circuit courts of appeals currently are split over the standard that district courts must apply when deciding whether to grant the DOJ's motion. In the Ninth Circuit, for example, the DOJ must show a "valid government purpose."[10] In the D.C. Circuit, in contrast, the DOJ has an "unfettered right" to dismiss a *qui tam* action.[11]

The DOJ's more proactive approach to dismissing *qui tam* FCA actions is likely to spur more analyses by the circuit courts on what, if anything, the DOJ must show to use its dismissal power. The DOJ predictably has advocated the D.C. Circuit's "unfettered right" standard as the correct approach.[12]

LIMITS ON USE OF AGENCY GUIDANCE DOCUMENTS IN DOJ'S AFFIRMATIVE CASES

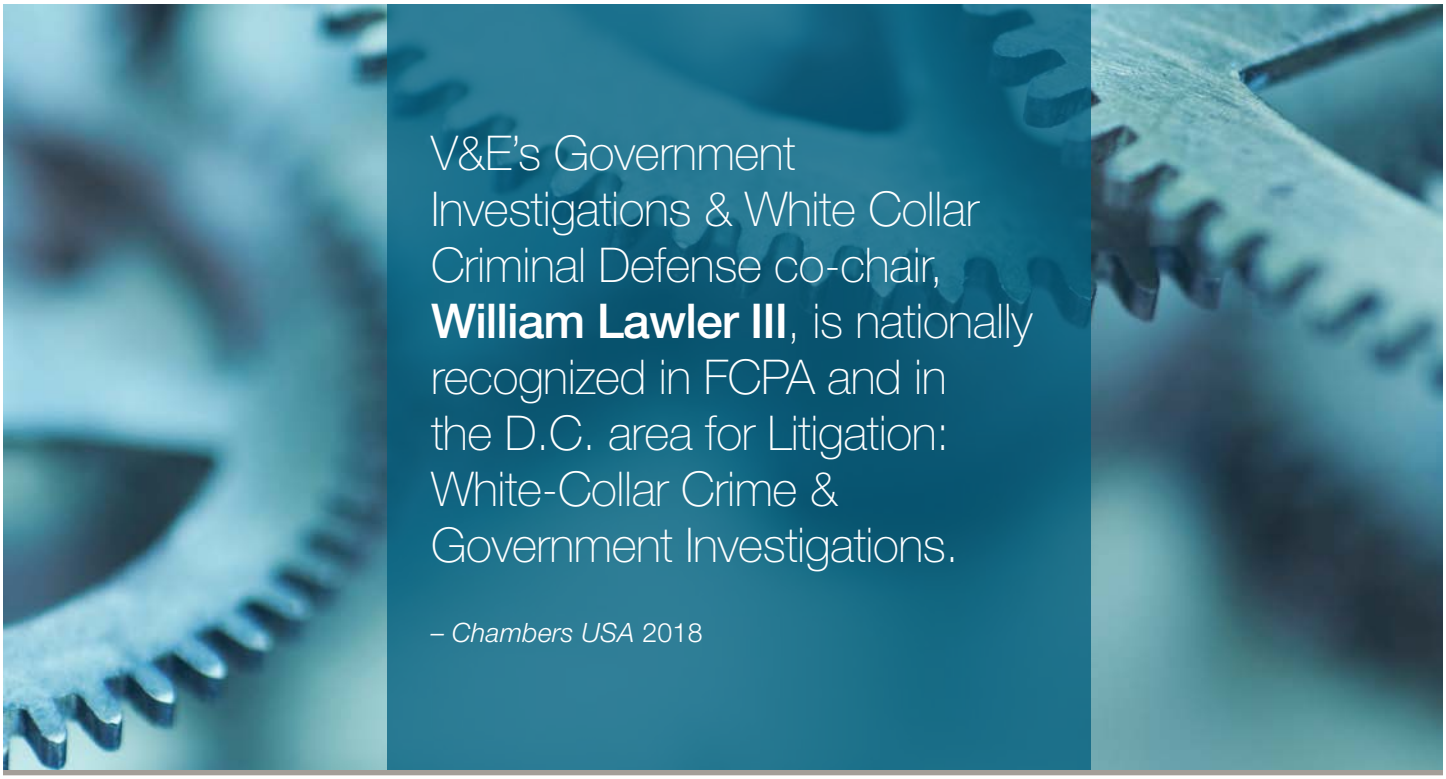
In a two-page memorandum titled "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases," signed by then-Associate Attorney General Rachel Brand (the "Brand Memo"), the DOJ announced a new internal policy limiting the enforceability of federal agencies' guidance documents. Federal agencies like the Food and Drug Administration and the Centers for Medicare and Medicaid Services issue guidance documents interpreting statutes and regulations that affect those agencies.

The Brand Memo states that the DOJ may not "convert agency guidance documents into binding rules" and may not "use noncompliance with guidance documents as a basis for proving violations of applicable law." In a footnote, the memorandum expressly states that the guidance applies to the DOJ's approach in FCA actions. Under the Brand Memo, the DOJ's FCA actions must be based on failing to comply with statutes or regulations, rather than failing to comply with requirements that may be laid out in an agency's guidance documents.

The Brand Memo arrived on the heels of a November 16, 2017 memorandum signed by then-Attorney General Jeff Sessions, which prohibited the DOJ itself from issuing guidance documents that would act as binding rules on the public. In support of his policy, Mr. Sessions noted that regulations generally must go through a process of notice and comment from the public, whereas guidance documents do not. As a result, by making guidance documents obligatory, the DOJ effectively was circumventing the required procedure for rules and regulations.

Together, the policies illustrate the DOJ's move away from allowing agency guidance to dictate compliance standards for, or otherwise bind, any entity outside of the executive branch.

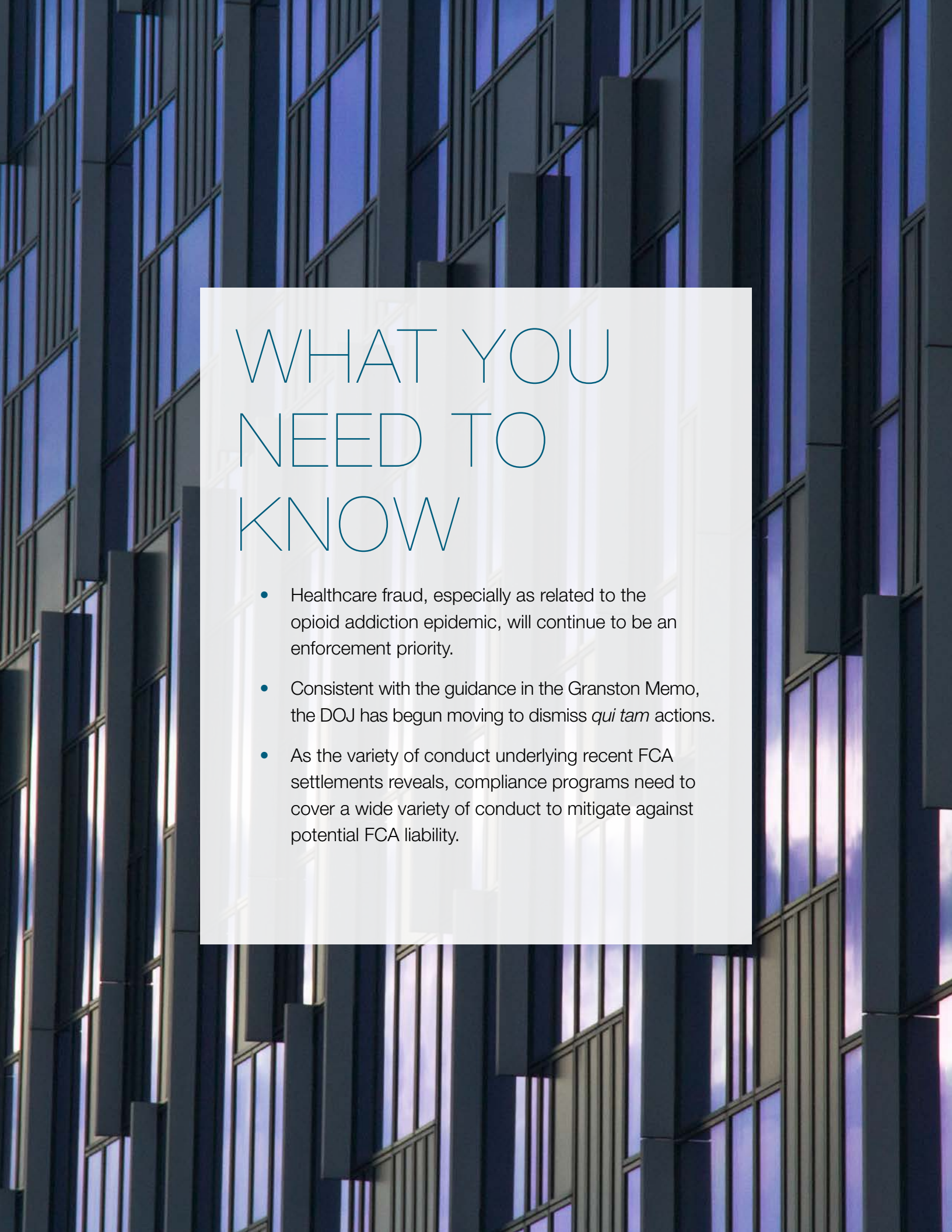
The Brand Memo, however, does recognize certain instances in which agency guidance documents may be relevant. It notes, for example, that when guidance documents explain or paraphrase statutes and regulations, the DOJ may use the fact that a party has read a guidance document to help prove that the party knowingly violated the underlying statute or regulation. Nevertheless, the Brand Memo marks a shift away from using guidance documents to outline legal obligations.



FALSE CLAIMS ACT: NOTABLE ENFORCEMENT TRENDS AND ACTIONS

The Healthcare and Life Sciences Sector has been and is likely to continue to be the focus of the DOJ's FCA enforcement actions. Of the approximately $2.8 billion that the government recovered in FCA actions in its 2018 fiscal year (October 2017 to September 30, 2018), $2.5 billion—or nearly 90%—of that total came from enforcement actions in the Healthcare and Life Sciences Sector.[13] With the DOJ's ongoing focus on the opioid epidemic, healthcare and life sciences companies are likely to see continued scrutiny of their government claims.

The DOJ has begun, however, to implement the Granston Memo's guidance, resulting in numerous DOJ motions to dismiss *qui tam* actions. The DOJ's more proactive approach may result in companies getting relief from the most problematic *qui tam* cases.



WHAT YOU NEED TO KNOW

- Healthcare fraud, especially as related to the opioid addiction epidemic, will continue to be an enforcement priority.
- Consistent with the guidance in the Granston Memo, the DOJ has begun moving to dismiss *qui tam* actions.
- As the variety of conduct underlying recent FCA settlements reveals, compliance programs need to cover a wide variety of conduct to mitigate against potential FCA liability.

FCA ENFORCEMENT TRENDS

As noted above, in the government's 2018 fiscal year, it recovered over $2.8 billion under the FCA. Although a seemingly large amount, that recovery is the lowest since 2009's $2.4 billion recovery and is much lower than the peak in 2014 when the government collected over $6.1 billion. All told, in the past decade, the government has recovered less than $3 billion in only three years: 2008, 2009, and 2018.

The number of new FCA matters was relatively steady as compared to past years. There were 122 non-*qui tam* actions and 645 *qui tam* actions. Since 2008, the number of *qui tam* actions has steadily increased from 379 in 2008 to a peak of 757 in 2013 and stayed in the 600-700 range through 2018. Non-*qui tam* actions have fluctuated from 160 new cases in 2008 down to 100 new cases in 2014 and back up to 149 in 2016. 2018's 122 new cases sits on the lower end of the range over the past decade.

As in years past, the Healthcare and Life Sciences Sector made up a majority of the FCA recovery in 2018, with the government collecting over $2.5 billion of the total $2.8 billion for the Department of Health and Human Services. In 2018, however, the recovery from healthcare and life sciences companies made up the largest percentage of the total recovery—87.2%—of the last decade. Only 2013, when recovery from the Healthcare and Life Sciences Sector made up 85.8% of the total amount, comes close to the percentage in 2018. (See chart on page 28.)

HEALTHCARE FRAUD IS A DOJ ENFORCEMENT PRIORITY

That trend is likely to continue in light of signals from the DOJ that healthcare fraud is an enforcement priority. The DOJ has been focused on curbing the opioid epidemic and has turned to the FCA as an enforcement tool. The DOJ's 2018 Healthcare Fraud Takedown ("Takedown") resulted in 601 defendants being charged over alleged fraud schemes resulting in more than $2 billion in false claims to the government, with 162 of the individual defendants alleged to have engaged in improper prescribing or distributing of opioids. According to the DOJ, the focus of the Takedown was the billing of unnecessary prescription or compounded drugs to government programs (like Medicare, Medicaid, and TRICARE) and to private insurance companies. The DOJ noted in particular 165 licensed medical professionals that were charged, explaining that medical professionals are necessary for healthcare fraud schemes to work, suggesting an emphasis on pursuing individuals, rather than corporate entities.

The DOJ also has expanded its Medicare Fraud Strike Force initiative to Newark, New Jersey and Philadelphia, Pennsylvania in an effort to address the opioid epidemic in those regions. This joint law-enforcement effort between federal prosecutors and investigative agencies will target particularly healthcare fraud and the role it plays in the proliferation of opioid abuse.

THE DOJ HAS BEGUN IMPLEMENTING THE GRANSTON MEMO

Solicitor General Tells The Supreme Court That The DOJ Will Move To Dismiss *Qui Tam* Case Upon Remand

Following a request to provide his opinion about whether the Supreme Court should review a Ninth Circuit decision regarding the requirements to successfully plead materiality in an FCA case, in *Gilead Sciences v. United States ex rel. Campie*, the Solicitor General not only recommended that the Supreme Court not review the Ninth Circuit decision, he told the U.S. Supreme Court that the DOJ intended to intervene in the case and file a motion to dismiss over the relators' objections. Echoing the Granston Memo, the Solicitor General stated that the government came to its decision after a thorough investigation of the merits of the case. According to the Solicitor General, dismissal was also appropriate because the case would likely result in burdensome discovery requests on the government if allowed to move forward.

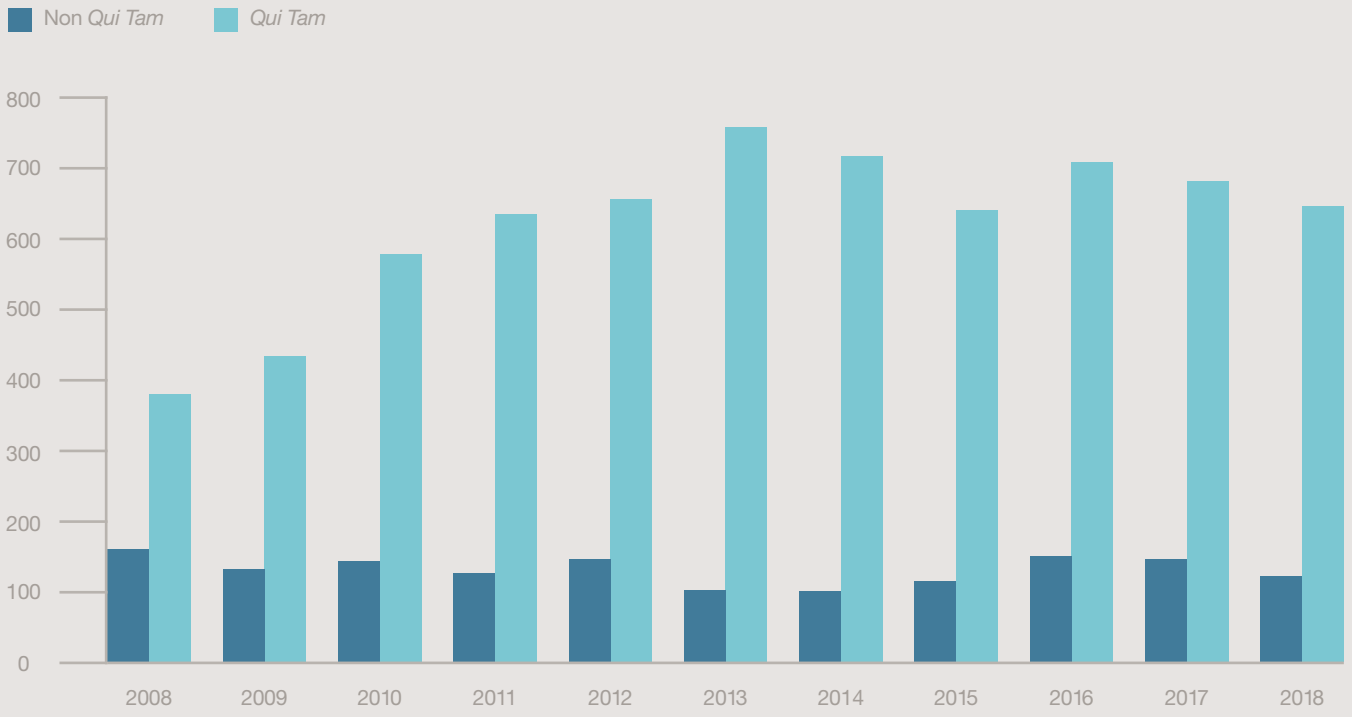
In January 2019, the Supreme Court followed the Solicitor General's recommendation and denied Gilead's request to review the Ninth Circuit order.

The DOJ Moved To Dismiss Numerous *Qui Tam* Cases Brought By "Professional Relator"

Gilead is not the only example of the DOJ taking a more proactive approach to intervening and dismissing *qui tam* cases. The DOJ also intervened in 11 cases brought by what the DOJ termed a "professional relator" and moved to dismiss the actions.[14] The relator alleged that the pharmaceutical company defendants had violated the Anti-Kickback Statute, which prohibits the payment of kickbacks for payments using government funds. The relator claimed that services provided by the defendants, such as patient education and assistance to physicians with insurance forms, constituted kickbacks.

SEE V&E'S E-LERT ON THE SOLICITOR GENERAL'S BRIEF IN *GILEAD SCIENCES V. UNITED STATES EX REL. CAMPIE*:

NEW FCA MATTERS 2008-2018



In cases in the Third, Fifth, and Seventh Circuits, which have not settled on a standard that the DOJ must meet to dismiss *qui tam* cases, the DOJ argued that the district courts should adopt the D.C. Circuit's "unfettered right" standard, under which the government has an "unfettered right to dismiss an action" brought by a relator. The DOJ nevertheless presented arguments for dismissal in case the district courts adopted the Ninth Circuit's approach that the DOJ must show a "valid government purpose." In support of its motion, the DOJ offered arguments from the Granston Memo: dismissal would aid 1) the preservation of government resources, and 2) the protection of "important policy prerogatives" of the government's healthcare programs.

In three of the cases, the relators have voluntarily dismissed their actions.[15] As the DOJ's remaining motions get decided, and those decisions potentially get appealed, more circuit courts in the near future will have to determine what standard to adopt to evaluate the DOJ's *qui tam* dismissals.

Notable Healthcare and Life Sciences FCA Actions

The Healthcare and Life Sciences Sector saw numerous FCA actions being both initiated and resolved in the past year. With resolutions in this sector accounting for nearly 90% of the total FCA recovery in 2018, it is unsurprising that there are several notable settlements and verdicts, including several large recoveries by the government. Below are the enforcement actions from the past year that we think are instructional for future enforcement trends.

HEALTHCARE AND LIFE SCIENCES FCA RECOVERY STATISTICS 2008-2018

Year	Total Recovery	Healthcare/Life Sciences Recovery	Percentage
2008	1,385,454,645	1,132,285,682	81.7
2009	2,466,467,417	1,636,756,398	66.3
2010	3,030,790,230	2,519,135,301	83.1
2011	3,072,057,112	2,449,721,612	79.7
2012	5,003,856,374	3,105,368,534	62.0
2013	3,185,494,190	2,734,383,649	85.8
2014	6,144,799,665	2,432,550,952	39.6
2015	3,149,643,990	2,127,269,985	67.5
2016	4,930,640,490	2,724,504,467	55.3
2017	3,465,098,692	2,184,131,652	63.0
2018	2,880,520,711	2,513,355,647	87.2

Source: DOJ FCA Statistics

HEALTHCARE PRODUCTS

AMERISOURCEBERGEN RESOLVES FCA CLAIMS FOR $625 MILLION In October 2018, AmerisourceBergen Corporation ("ABC") and several of its subsidiaries agreed to pay $625 million to resolve civil FCA allegations brought through three *qui tam* complaints. The settlement comes after an ABC subsidiary pleaded guilty in 2017 to charges related to similar FCA allegations. The government alleged that ABC caused false claims for various injectable cancer treatments to be submitted to federal agencies by repackaging syringes it received from manufacturers. According to the government, ABC emptied pre-filled syringes that had "overfill" into a common container and then repackaged the medicine into syringes with the exact dose. The government claimed that this process allowed ABC to sell more doses of the pharmaceuticals than it purchased from manufacturers.

The government alleged that this process broke the products' sterility and did not comply with FDA regulations and inspections, a fact which ABC allegedly concealed from the physicians who purchased the products. The government contended that because portions of one vial ended up in multiple different syringes, ABC effectively billed providers twice for the same vial of medicine. According to the government, those providers in turn billed federal healthcare programs twice for the same vial of medicine.

The settlement also resolved allegations that ABC gave kickbacks to physicians in the form of pharmacy credits, which did not appear on invoices.

As part of the settlement agreement, ABC admitted that its subsidiaries had engaged in the pooling and refilling of syringes and that the subsidiaries had provided rebates to physicians who bought the repackaged vials. ABC also entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services. Pursuant to the agreement, ABC will put in place a Chief Compliance Officer and a Compliance Committee, and certain of its executives must regularly certify the company's compliance with federal healthcare requirements. ABC will also provide annual reports for the five-year term of the agreement describing its compliance efforts. As this case originated with *qui tam* complaints, the whistleblowers are entitled to recover more than $93 million.

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– *Global Competition Review* 2019

ALERE INC. SETTLES FCA CLAIMS FOR $33.2 MILLION In March 2018, Alere Inc. and a subsidiary agreed to settle FCA allegations for $33.2 million. The government alleged that Alere caused false claims to be submitted to the government by selling testing devices used to diagnose serious coronary syndromes and drug overdoses that produced inaccurate results. According to the government, Alere was put on notice of the problems with the devices through customer complaints, but the company allegedly continued to sell the defective products. The government claimed that Alere only recalled the products after the FDA began investigating.

As this case originated with a *qui tam* complaint, a whistleblower is entitled to recover more than $5.5 million. Alere did not make any admissions under the settlement agreement.

MEDICAL BILLING

HEALTHCARE PARTNERS HOLDINGS RESOLVES CIVIL FCA ALLEGATIONS FOR $270 MILLION In October 2018, HealthCare Partners Holdings LLC, doing business as DaVita Medical Holdings LLC ("DaVita"), settled civil FCA allegations for $270 million. DaVita self-reported conduct by an independent physician association that it acquired in 2012. The association purportedly submitted false diagnostic information to Medicare Advantage Organizations[16] covering its patients, in turn causing "upcoded" diagnoses to be submitted to the federal government. The effect was to increase the amount of the Medicare Advantage Organizations' payments from the government, some of which flowed back to DaVita.

The settlement also resolved a whistleblower allegation that the physician group performed "one-way" reviews of patient charts. Under this process, the group allegedly would review the charts for any diagnoses missed during the initial billing to the Medicare Advantage Organizations and would submit those additional diagnoses, but would not delete inaccurate diagnoses discovered during the same review.

As the "one-way" chart review case originated with a *qui tam* complaint, a whistleblower is entitled to recover more than $10 million.

THE DOJ SETTLES CIVIL AND CRIMINAL CASES AGAINST HEALTH MANAGEMENT ASSOCIATES FOR $260 MILLION The DOJ reached a $260 million resolution with hospital chain Health Management Associates, LLC ("HMA") in September 2018 to resolve allegations of billing unnecessary medical expenses and using kickbacks to physicians for patient referrals. The DOJ alleged that, in an effort to increase revenue, HMA had set mandatory quotas for physicians in its emergency departments to admit patients into the hospital, even if the patients did not require inpatient services. The DOJ also alleged that several of the hospitals in HMA's system had made improper payments to physicians in exchange for referrals of the physicians' patients to the hospitals.

To resolve the criminal allegations, HMA entered into a three-year Non-Prosecution Agreement ("NPA"). Under the NPA, HMA agreed to cooperate fully with the investigation, report any future violations, and review and improve its compliance and ethics policy. In addition, HMA had to pay a $35 million penalty, and one HMA subsidiary pled guilty to conspiracy to commit health fraud.

To resolve the civil allegations, HMA agreed to pay $216 million. Of that amount, more than $7 million went to states in which the alleged kickbacks had occurred. The rest of the penalty went to the federal government.

As this case originated with *qui tam* complaints, whistleblowers are entitled to recover $27.4 million.

PRIME HEALTHCARE ASSOCIATES, CEO RESOLVE CIVIL FCA CASE FOR $65 MILLION Healthcare provider Prime Healthcare Associates, Inc. ("Prime"), its CEO, and associated entities resolved allegations by the DOJ that they had billed federal agencies for unnecessary medical expenses. According to the Department, Prime implemented a corporate policy to increase inpatient admissions of Medicare patients even though less expensive outpatient care was an option. The government further alleged that Prime had engaged in "up-coding" to increase its revenue by adding complications or other illnesses to patients' reimbursement requests from Medicare.

As part of the settlement, Prime entered into a Corporate Integrity Agreement that requires it to undertake significant compliance improvements over the course of five years, including submitting to audits of its Medicare claim submissions by an independent review organization. Prime had to pay $61.75 million in fines, and its CEO had to pay $3.25 million.

As this case originated with a *qui tam* complaint, a whistleblower is entitled to recover $17 million.

KICKBACKS

ACTELION RESOLVES KICKBACK ALLEGATIONS FOR $360 MILLION In December 2018, Actelion Pharmaceuticals US, Inc. ("Actelion") settled civil FCA violation allegations for $360 million. According to the government, Actelion used a non-profit 501(c)(3) organization to fund patient copays for its products to induce patients, especially those on Medicare, to use its products. The government alleged that after receiving information from the 501(c)(3) organization about how much it had spent on copays for its products, Actelion made contributions to the organization to cover those amounts. According to the government, Actelion funneled Medicare patients to the foundation by excluding them from Actelion's free drug program for financially needy patients.

The government claimed that Actelion violated the FCA by offering remuneration to patients through the non-profit organization to induce the patients to use Actelion's products. Offering payments to induce individuals to use products paid for by the government is prohibited by the Anti-Kickback Statute and is also an FCA violation.

INSYS THERAPEUTICS REACHES RESOLUTION-IN-PRINCIPLE FOR CRIMINAL, CIVIL FCA ALLEGATIONS FOR $150 MILLION In August 2018, Insys Therapeutics Inc. announced an agreement-in-principle to resolve civil and criminal FCA investigations for at least $150 million. Insys allegedly induced healthcare providers with kickbacks to prescribe its opioid product Subsys. According to the government, Insys disguised payments to prescribing physicians as speaker's fees for speeches that never took place, jobs for friends and relatives, and entertainment expenses.

In early January 2019, Insys's former CEO pleaded guilty in federal district court in Massachusetts to conspiracy and mail fraud charges related to the allegations.[17] His plea came just before he and other former Insys executives were set for trial in late January 2019. As part of the plea agreement, the former CEO will cooperate with the DOJ during the trial.

DOJ WINS $114 MILLION JUDGMENT ON KICKBACK ALLEGATIONS In May 2018, in *United States ex rel. Mayes v. Berkeley HeartLab Inc., United States ex rel. Riedel v. Health Diagnostic Laboratory, Inc.*, and United States, et al. ex rel. Lutz, et al. v. Health Diagnostic Laboratory, Inc., the government won a $114 million FCA judgment against three individuals for paying kickbacks to physicians in exchange for referring patients to two blood testing laboratories, in some cases for medically unnecessary testing. Evidence showed that the defendants paid physicians between $10 and $17 per patient referred to the labs, disguising the bribes as "processing and handling fees." This case originated from *qui tam* complaints, but the amount of the whistleblowers' complaints had not been calculated at the time the DOJ announced the judgment.

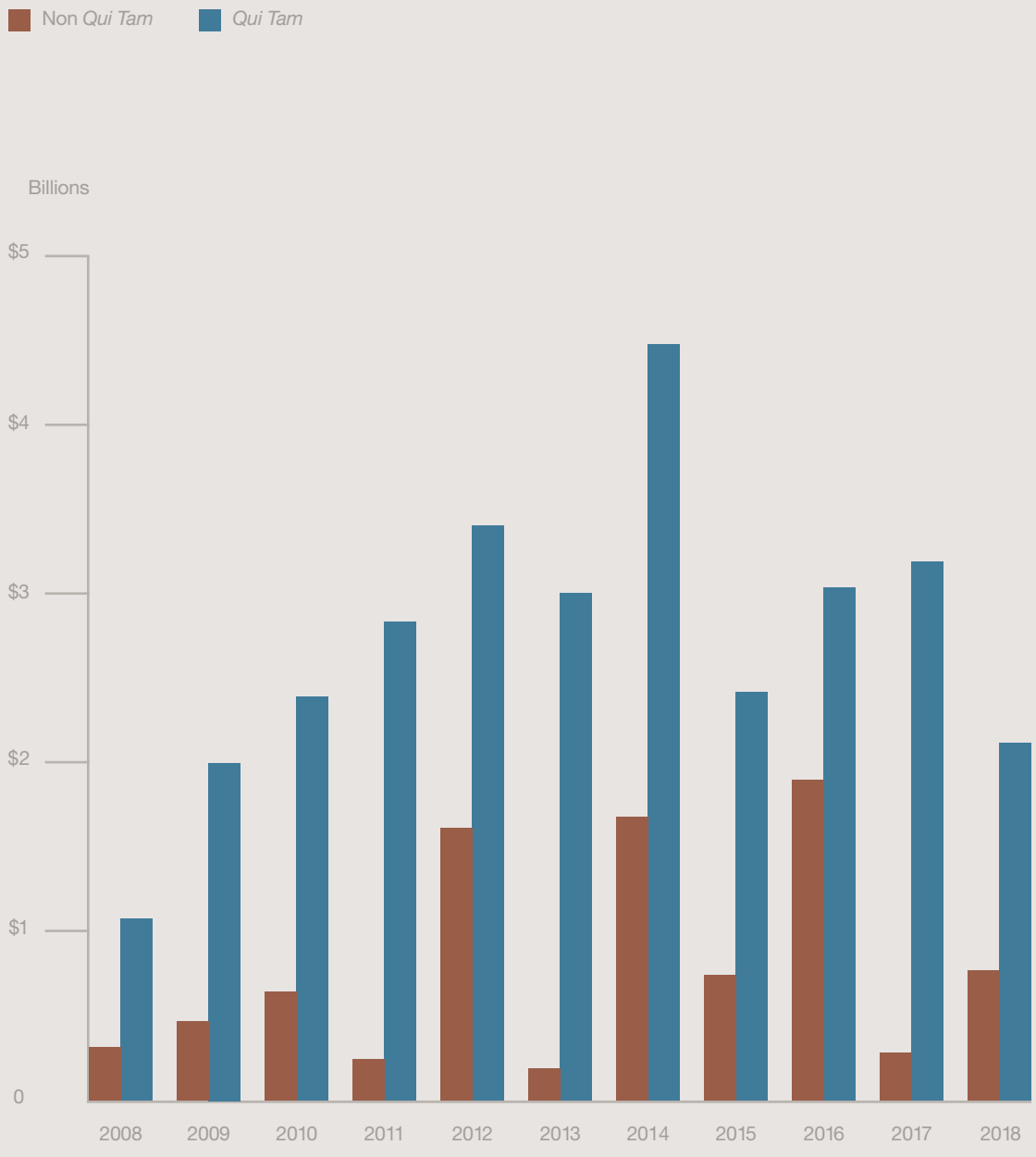
WILLIAM BEAUMONT HOSPITAL SETTLES CIVIL FCA ALLEGATIONS FOR $84.5 MILLION In August 2018, William Beaumont Hospital ("Beaumont") settled FCA allegations for $84.5 million stemming from allegedly improper financial arrangements with physicians. The government claimed that Beaumont submitted claims for services it provided to patients who were referred to the hospital from physicians who had received remuneration from Beaumont for the referrals. The government alleged that Beaumont provided free or below-market office space and employee services to the referring physicians, in addition to providing above market compensation. The government also alleged that Beaumont misrepresented whether one of its facilities was an outpatient center in claims it submitted to federal healthcare payors.

In addition to the settlement amount, Beaumont agreed to enter a five-year Corporate Integrity Agreement under which an independent review organization will review Beaumont's arrangements with physicians to ensure Anti-Kickback Statute and FCA compliance.

COVIDIEN RESOLVES CIVIL FCA ALLEGATIONS FOR $13 MILLION In December 2018, Covidien LP settled allegations that it had provided remuneration to physicians and hospitals in exchange for using its Solitaire medical device, which helps stroke patients. According to the government, Covidien paid fees to hospitals and healthcare providers who participated in a registry to report clinical data when using the Solitaire device. The government alleged that this scheme was designed to improperly incentivize providers to use and purchase Solitaire over a competitor's product. Covidien agreed to pay $13 million to resolve the allegations.

As this case originated with a *qui tam* complaint, a whistleblower is entitled to recover $2 million.

FCA RECOVERY 2008-2018



FALSE CLAIMS ACT: NOTABLE CASE LAW

Circuit courts issued a wave of FCA decisions that are likely to affect the Healthcare and Life Sciences Sector. Although these developments came in the context of private *qui tam* actions, many of the holdings are likely to affect cases brought or taken over by the DOJ. These cases primarily elaborated on the requirements to state an FCA claim and interpretations of the FCA statute.

WHAT YOU NEED TO KNOW

- The Sixth and Ninth Circuits offered interpretations of the materiality standard from the Supreme Court's 2016 *Escobar* decision that suggest a lenient application of the standard.
- The circuit courts continue to weigh in on what relators must allege to satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b). The Seventh Circuit requires specific allegations that the defendant knew the claims being submitted were false. The Ninth Circuit permits group allegations for defendants accused of identical conduct. The Eleventh Circuit requires details about the submission of the claims to the government.
- The Tenth Circuit held that medical judgment can satisfy the falsity element of an FCA claim.
- The Eleventh Circuit held that relators cannot intervene in criminal forfeiture proceedings arising from parallel FCA criminal cases.

Background: Supreme Court's 2016 *Universal Health Services v. United States ex rel. Escobar* Decision

Because several of the circuit court decisions this year discuss or reference the Supreme Court's 2016 *Universal Health Services, Inc. v. United States ex rel. Escobar*[18] decision, we provide a brief summary of the holdings of that case. In *Escobar*, the Supreme Court considered two elements of an FCA case: falsity and materiality. The Court held that the falsity element can be satisfied by an "implied certification" theory, which occurs when a party's failure to inform the government of its violations of statutory, regulatory, or contractual requirements renders the representations it does make to the government misleading. The Court held that such a theory is viable "at least where two conditions are satisfied": 1) the claim "makes specific representations about the goods or services provided" and not just requests payment; and 2) the failure to disclose "noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[19]

For the materiality element, the Court addressed whether noncompliance with a contractual, statutory, or regulatory requirement that the government stated was a condition of payment necessarily means that the violation was "material." The Court decided that such a violation did not automatically satisfy the materiality factor. Instead, materiality requires a "likely or actual" effect on the government's payment decision, and is a "rigorous" and "demanding" standard.[20] The Court provided three examples of circumstances tending to show or not show materiality: 1) where the government regularly refuses to pay on claims where there is noncompliance with a particular statute, regulation, or contractual provision, such provision would likely be material; 2) where the government pays on a particular claim despite having actual knowledge of noncompliance with certain provisions, those provisions are likely immaterial; or 3) where the government regularly pays on similar claims with knowledge of noncompliance with specific provisions and has not indicated any change in its procedure, such provisions are likely immaterial.[21]

Requirements To Allege FCA Claims

SIXTH CIRCUIT REVERSES DISMISSAL, FINDING MATERIALITY ELEMENT WAS SATISFIED

In United States v. Brookdale Senior Living Communities, Inc.,[22] the Sixth Circuit reversed the trial court's dismissal for failure to sufficiently plead the materiality element. The relator had alleged that the defendant was submitting bills to Medicare for treatment that had not been certified by a physician. The district court had dismissed the case, finding that the relator had failed to sufficiently allege that the violations were material. In so holding, the district court found in part that the relator's failure to allege that the government had refused to pay claims in the past for similar violations meant that the relator had failed to allege materiality.

The Sixth Circuit rejected that reasoning. Observing the difficulty for a relator to obtain such information, the court found that inferring that the provision was not material merely because of an absence of information reversed the burden that a relator must meet to win on a motion to dismiss. The district court should have viewed the allegations in the light most favorable to the relator, including the lack of allegations. The Sixth Circuit also expressly rejected the defendants' argument that the government's failure to intervene in the case suggested that the provision was not material, noting that the government did not intervene in *Escobar*.

The defendants have filed a petition for the Supreme Court to review the Sixth Circuit's decision.

THE NINTH CIRCUIT ADDRESSES ESCOBAR'S MATERIALITY, IMPLIED CERTIFICATION HOLDINGS

The Ninth Circuit considered *Escobar's* materiality and implied certification holdings to affirm the district court's denial of summary judgment in *United States ex rel. Rose v. Stephens Institute*.[23] The district court had found that the relator had offered sufficient evidence of materiality and under an implied certification theory of falsity for the case to proceed to trial.

The Ninth Circuit first noted that, under two prior cases within the circuit, the relator had to show for an implied certification theory the two conditions stated in *Escobar*: 1) that there were representations about the goods or services, not just a request for payment, and 2) that failing to disclose violations made those representations "misleading half-truths." The court held that the district court correctly determined that the relator had offered sufficient evidence to satisfy *Escobar*'s two-part test.

The defendant argued that the district court had erred because the defendant had offered evidence that in dozens of claims involving the same kind of violation, the government had not prohibited the parties who had committed the violations from obtaining federal funds. This, the defendant argued, showed that the government had paid claims with actual knowledge of violations and, therefore, the violations were not material. In a potential easing of *Escobar*'s "rigorous" and "demanding" standard, the Ninth Circuit disagreed, noting that the government had issued penalties against other claimants that had engaged in similar violations. That fact combined with evidence that complying with the underlying provision was an express condition of payment as well as the large size of the alleged violation was sufficient for the relator to proceed to trial on the allegations.

TENTH CIRCUIT HOLDS MEDICAL JUDGMENT CAN SATISFY FCA'S FALSITY ELEMENT In *United States ex rel. Polukoff v. St. Mark's Hospital*,[24] the Tenth Circuit addressed whether a doctor's certification that a procedure was medically necessary could be the basis of an FCA claim. The district court had held that "medical judgments and conclusions about which reasonable minds may differ cannot be false for purposes of an FCA claim."[25]

The Tenth Circuit disagreed. According to the court, medical judgments can be false statements for purposes of the FCA for three reasons: 1) the FCA's scope is broad; 2) the fact that the statement is an opinion does not mean it cannot be the basis for liability under the FCA; and 3) medically unnecessary claims can be the basis for FCA liability. The Tenth Circuit pointed to *Escobar*'s instruction of "strict enforcement" of the materiality and scienter elements as a means of ensuring that such a broad interpretation of falsity was properly cabined.

Requirements Under The Heightened Pleading Standard For FCA Cases

SEVENTH CIRCUIT APPLIES HEIGHTENED PLEADING STANDARD TO SCIENTER ELEMENT

In *United States ex rel. Berkowitz v. Automation Aids, Inc.*,[26] the Seventh Circuit affirmed the district court's dismissal of an FCA case on grounds that the relator failed to satisfy the heightened pleading standard under Federal Rule of Civil Procedure 9(b) that is required for FCA claims. Under this heightened standard, the Seventh Circuit held that the relator failed to sufficiently allege that the defendants had the requisite knowledge, or scienter, to have violated the FCA. The FCA requires not only that a false claim was presented to the government, but that the defendant knowingly submitted the false claim. The Seventh Circuit held that the relator failed to allege "specific facts demonstrating what occurred at the individualized transactional level for each defendant" and therefore the complaint failed. The court observed that although the complaint offered allegations that the defendants had sold the government noncompliant products, it did not allege that the defendants knowingly did so.

NINTH CIRCUIT PERMITS GROUP ALLEGATIONS UNDER HEIGHTENED PLEADING STANDARD In *United States ex rel. Silingo v. WellPoint, Inc.*,[27] the Ninth Circuit reversed the district court's dismissal of an FCA claim, holding that the relator had successfully alleged fraudulent conduct against multiple defendants. The defendants argued that under Federal Rule of Civil Procedure Rule 9(b), the relator had to differentiate each defendants' role in the alleged fraud.

The Ninth Circuit disagreed, holding that collective allegations were appropriate to "describe the actions of multiple defendants who are alleged to have engaged in precisely the same conduct."[28] Using the analogy of the spokes of a wheel, the Ninth Circuit noted that where the defendants conspired with the same party, like "spokes" to a "hub," identical allegations for the different defendants satisfy Rule 9(b).

ELEVENTH CIRCUIT REQUIRES DETAILS OF CLAIM SUBMISSION TO SATISFY HEIGHTENED PLEADING STANDARD In *Carrel v. AIDS Healthcare Foundation, Inc.*,[29] the Eleventh Circuit held that relators failed to satisfy the heightened pleading standard under Federal Rule of Civil Procedure 9(b) because they failed to allege any details about the submission of an actual claim to the government. The relators offered only general allegations that the defendant made frequent requests for reimbursement from the government for medical services, but the relator never connected any specific false statement to any actual claim that the defendant submitted to the government. The Eleventh Circuit held as a result that the allegations were insufficient.

The Eleventh Circuit acknowledged that in some circumstances it has allowed cases to move forward even when the relator could not allege the specifics of a particular submission, but those cases generally involved relators who were involved in the alleged misconduct and could offer other "indicia of reliability" that defendants actually submitted the claims. According to the Eleventh Circuit, the relators did not offer such details in this case.

Requirements Regarding Intervention Into FCA And FCA-Related Cases

FIFTH CIRCUIT HOLDS WHEN GOVERNMENT FAILS TO INTERVENE, IT SHOULD NOT BE SUBJECT OF DISMISSAL ORDER In *United States ex rel. Vaughn v. United Biologics, LLC*,[30] the Fifth Circuit rejected the defendant's argument that the government should be subject to an order dismissing the case with prejudice where the relators dismissed the case with prejudice but the government did not intervene.

The government had declined to intervene in the *qui tam* action, and eventually relators moved to voluntarily dismiss the case with prejudice. The relators and the government asked the court to dismiss the case without prejudice as to the government so as to not affect the DOJ's parallel case in another district. The district court granted the motion, and the defendant appealed, challenging the dismissal as an abuse of discretion because the defendant's motion for summary judgment was pending at the time of the relator's request to voluntarily dismiss the case. The defendant argued that the government was bound to the judgment in the case and, thus, should be subject to claim preclusion in its other cases against the defendant.

The Fifth Circuit upheld the dismissal, finding no abuse of discretion and no plain prejudice regardless of the pending motion for summary judgment. However, the court agreed

that the district court had erred in dismissing the government without prejudice from the case—not because the government was bound by the judgment, but because the government had never been a party to the case. The Court also observed that the government is typically not bound by judgments in False Claims Act cases that are not decided on the merits, but left the question open for the court hearing the parallel case to decide.

ELEVENTH CIRCUIT HOLDS RELATORS CANNOT INTERVENE IN CRIMINAL FORFEITURE ACTIONS

The Eleventh Circuit held in *United States v. Couch*[31] that a relator could not intervene in criminal forfeiture proceedings resulting from parallel criminal FCA claims. The relator sought to intervene in the forfeiture action to argue for her whistleblower portion of any recovery by the DOJ.

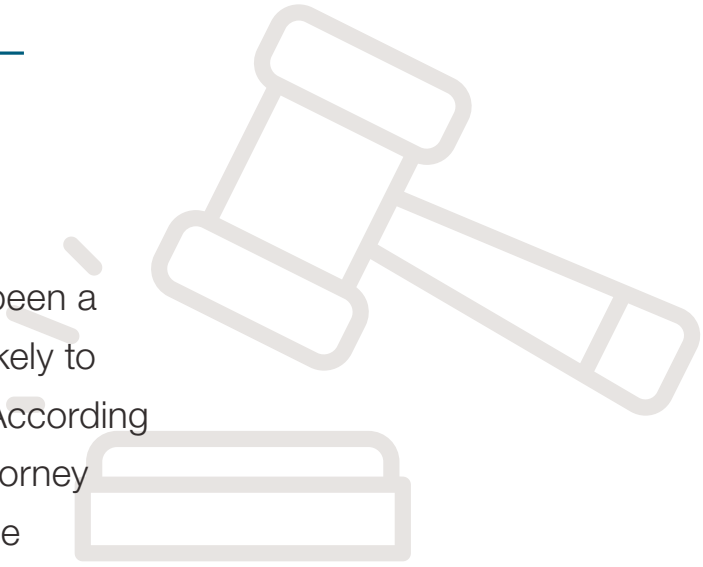
The Eleventh Circuit first disagreed with a Ninth Circuit decision finding that relators lack standing to intervene in criminal forfeiture proceedings. The Eleventh Circuit concluded that the relator had standing to intervene but that intervention was prohibited by the statutes governing forfeiture. Looking to those statutes, the court determined that each one barred third parties from intervening in forfeiture proceedings unless they either had a legal right to the underlying property prior to the defendant's criminal act or were "bona fide purchasers for value."[32] Because the relator did not fall into either of those exceptions, the Eleventh Circuit found that intervention in the forfeiture proceedings was proscribed.

Despite ruling against the relator, the Eleventh Circuit offered its encouragement to the DOJ to ensure that the whistleblower received the appropriate recovery from any forfeiture the DOJ achieved.

"First of all, their quality of work is excellent. What I like about them is they have people with business backgrounds and they appreciate what the client is going through – what they're thinking. They just have a good business-orientation, rather than a strictly legal approach."

– Chambers USA, Litigation: White Collar Crime & Government Investigations – California 2017

ANTITRUST



The Healthcare and Life Sciences Sector has been a priority for the DOJ's Antitrust Division and is likely to continue to see antitrust scrutiny by the DOJ. According to a May 2018 speech by Deputy Assistant Attorney General Barry Nigro of the Antitrust Division, the Healthcare and Life Sciences Sector is an enforcement priority. Mr. Nigro listed several enforcement areas on which the DOJ is focused, including alleged collusion in the sale of generic drugs; market allocation agreements; and anti-steering provisions. These enforcement priorities are evident in two notable settlements and one ongoing DOJ investigation involving healthcare companies.

WHAT YOU NEED TO KNOW

- The DOJ continues to prioritize the Healthcare and Life Sciences Sector for antitrust scrutiny.
- Anti-steering provisions in agreements between healthcare providers and insurers are likely to result in DOJ enforcement.
- The DOJ considers agreements among competitors to restrict or limit marketing activities to be anticompetitive and will likely engage in enforcement actions to prevent such agreements.
- Rising drug prices are a priority for the DOJ and the subject of an ongoing investigation.

DOJ REACHES ANTI-STEERING SETTLEMENT WITH ATRIUM HEALTH

In November 2018, the DOJ announced a settlement with Atrium Health ("Atrium"), a hospital group in North Carolina, that prevents Atrium from enforcing steering restrictions in its contract with health insurers.

In its agreements with insurers Aetna Health of the Carolinas, Inc., Blue Cross and Blue Shield of North Carolina, Cigna HealthCare of North Carolina, Inc., Medcost, LLC, and UnitedHealthCare of North Carolina, Atrium included clauses that prohibited the insurers from steering patients to other providers. According to the DOJ, Atrium's clauses were anticompetitive agreements that violated Section 1 of the Sherman Act, a federal antitrust law.

The settlement comes after the Supreme Court's decision in *Ohio, et al. v. American Express Co., et al.*,[33] in which the Court held that American Express's ("Amex") steering rules for merchants did not violate the Sherman Act. Since the 1950s, Amex has prohibited merchants from steering—or directing—customers to use rival cards such as Visa or Mastercard. The DOJ and several state attorneys general argued that Amex's steering restrictions violated Section 1 of the Sherman Act. The Supreme Court determined that Amex's steering restrictions were subject to a "rule of reason" analysis under the Sherman Act, which requires courts to evaluate market power and market structure to determine whether an agreement has an anticompetitive effect. In reaching its holding, the Supreme Court went through a fairly extensive analysis of the credit card market, ultimately determining that Amex did not have sufficient market power for the anti-steering restrictions to be anticompetitive.

Despite the DOJ's loss at the Supreme Court, the settlement with Atrium reveals that the Department still believes that steering rules violate the Sherman Act. As the Supreme Court determined in *Ohio*, to determine whether anti-steering rules are anticompetitive, courts must analyze them under the "rule of reason," which requires an evaluation of market power and structure. Given the fact-intensive inquiry under this analysis, the DOJ may continue to argue in each case that the facts suggest that particular steering rules are anticompetitive. In other words, *Ohio* should not be read as broad clearance for companies to include steering restrictions in agreements.

DOJ SETTLES CLAIMS OF GEOGRAPHIC MARKET DIVISION WITH HENRY FORD ALLEGIANCE

In February 2018, the DOJ reached an agreement with hospital Henry Ford Allegiance Health ("Allegiance") arising out of allegations that Allegiance had entered into an agreement with a competitor hospital not to engage in marketing activities in each other's regions. The DOJ already had settled with other hospitals in the region for similar allegations.

Under the settlement, Allegiance is prohibited from entering into agreements with other hospitals to geographically limit its marketing or to otherwise allocate services by region. Allegiance is also prohibited from discussing with another hospital its marketing practices in its own or any other county. The settlement includes an exception for "Joint Provision of Services" between Allegiance and another hospital, such as through joint ventures or a physician hospital organization.

The settlement also requires that Allegiance hire an antitrust compliance officer, whom the DOJ must approve. In addition to conducting compliance trainings, the compliance officer must log all communications regarding marketing with any other hospital and certify every year for the five-year period covered by the settlement that the compliance training has been completed.

STATE ATTORNEYS GENERAL CONTINUE ANTI-COMPETITIVE CONDUCT LITIGATION

In 2016, the state attorneys general from several states sued six generic drug companies, alleging that the companies had engaged in a scheme to price fix two generic drugs. In August 2017, the Judicial Panel on Multidistrict Litigation ("MDL Panel") transferred their action to the Eastern District of Pennsylvania, to which the MDL Panel also transferred numerous private class actions similarly alleging price fixing among the generic drug companies.

Revealing a difference in strategies between the federal and state enforcement agencies, in October 2017, the DOJ intervened in the consolidated case and asked the district court to stay discovery for all of the actions while the DOJ pursued its criminal investigation.[34] In its request, the government explained that it was in the midst of a criminal investigation into the price-fixing allegations and was working with two cooperators who had pled guilty to price-fixing, market allocation, and bid-rigging. The DOJ argued that a stay of civil discovery was necessary to encourage the target companies to cooperate in the government's investigation.

A month later, the state attorneys general—who opposed the DOJ's request—asked the district court if they could file an amended complaint that would expand their case significantly. They alleged an over-arching price-fixing and/or a market allocation scheme among twenty defendants and involving 15 different drugs.[35] The state attorneys general also asked the district court to put their case on a separate track from the civil cases.

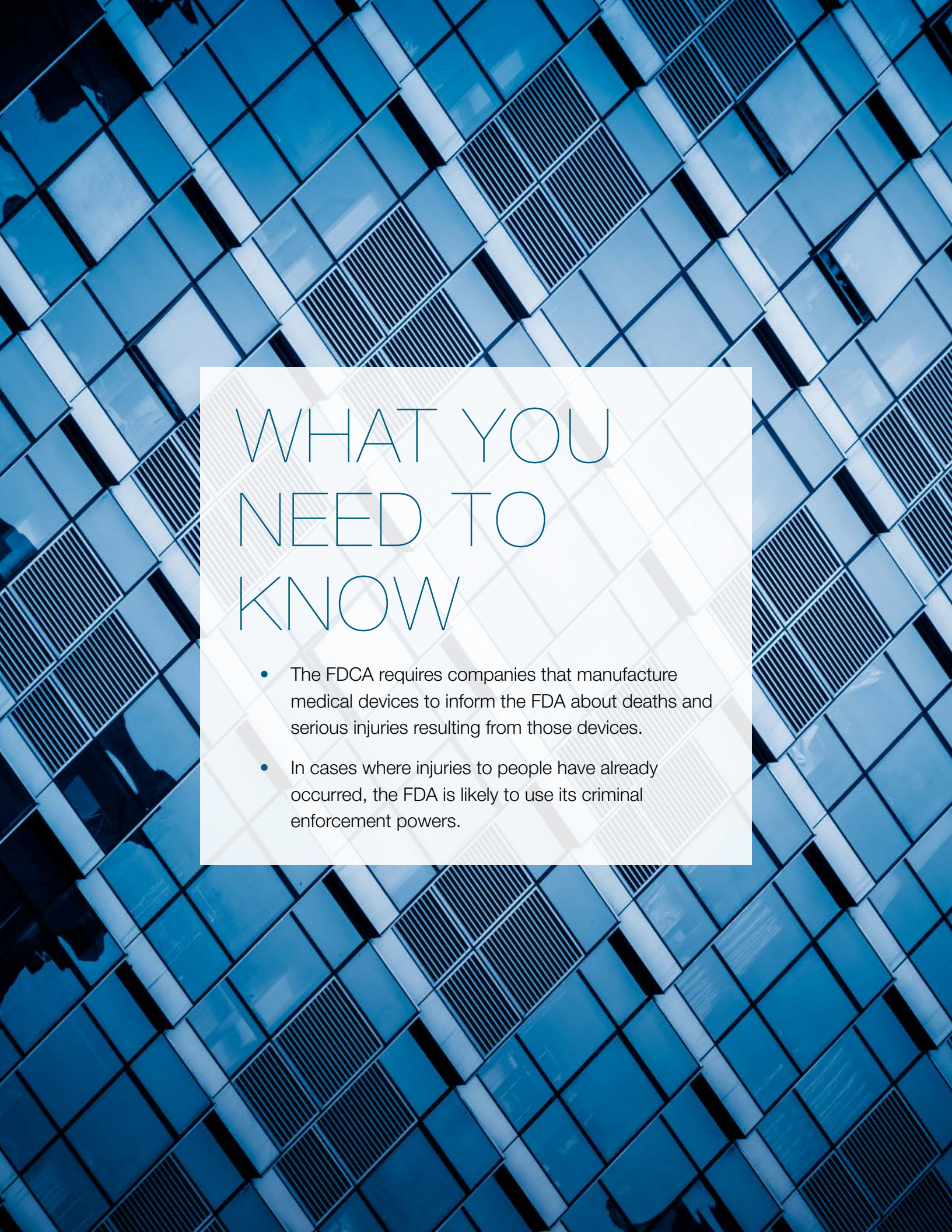
In February 2018, the district court denied the DOJ's request for a complete stay, instead permitting limited discovery but not allowing inquiries into anything involving the DOJ's investigation.[36] In June 2018, the district court granted the state attorneys general's request to amend their complaint to allege overarching antitrust schemes among the 16 generic drug company defendants.[37]

The case nevertheless remains at an early stage: The deadline for motions to dismiss the various complaints was February 21, 2019, and the parties are still negotiating protocols for searching for and producing discovery.[38] The stay on general discovery was supposed to end March 8, 2019. On February 14, 2019, the court extended the general stay on discovery until July 2019 and required the DOJ to attend all status conferences.

FOOD, DRUG, AND COSMETICS ACT: NOTABLE ENFORCEMENT ACTIONS

In a February 2018 speech, then-Deputy Assistant Attorney General Ethan Davis of the DOJ Civil Division's Consumer Protection Branch remarked that the Department's enforcement priority under the Food, Drug, and Cosmetics Act ("FDCA") is conduct that threatens patient safety. Mr. Davis emphasized that cases involving "technical regulatory violations" would not be a DOJ priority because those cases are inefficient for both the DOJ and for the Healthcare and Life Sciences Sector. Consistent with the priority of public safety, Mr. Davis noted that the opioid crisis remains a top enforcement priority, and the Consumer Protection Branch anticipates using the FDCA as a means of regulating companies that produce opioids.

Given Mr. Davis' remarks, to the extent there are criminal or civil enforcement actions under the FDCA, they are likely to involve patient harm and not technical violations. Two criminal actions and a potential new investigation under the FDCA in 2018 illustrate this policy priority.



WHAT YOU NEED TO KNOW

- The FDCA requires companies that manufacture medical devices to inform the FDA about deaths and serious injuries resulting from those devices.
- In cases where injuries to people have already occurred, the FDA is likely to use its criminal enforcement powers.

OLYMPUS CORP., FORMER EXECUTIVE PLEAD GUILTY TO FDCA VIOLATIONS

Olympus Corp. ("Olympus") and its former Division Manager for the Quality and Environment Division both pled guilty in a New Jersey federal district court to failing to file adverse event reports with the Food and Drug Administration ("FDA") as required under the FDCA. According to the government, Olympus and the executive failed to file medical device reports ("MDRs") about deaths or serious injuries caused by a medical device manufactured by the company. The government claims that Olympus and the executive learned about infections associated with its device in three hospitals in Europe but failed to file any MDR regarding one of the hospital infections and failed to file supplemental MDRs for the other two hospitals. According to the DOJ and the FDA, the failure to file the MDRs rendered the devices "misbranded." Under the FDCA, shipping misbranded medical devices through interstate commerce is a misdemeanor, subjecting individuals to up to one year in prison and $1,000 in fines.

Pursuant to its plea agreement, Olympus paid $80 million in fines and $5 million in criminal forfeiture. Olympus also agreed to retain an independent expert—essentially a corporate monitor—who will oversee and review its policies and procedures for filing MDRs and will report to the FDA and the DOJ on Olympus's compliance for three years. The former Olympus executive is awaiting sentencing.

At the time of these charges, Olympus was already subject to deferred prosecution agreements for FCPA violations and kickback schemes to U.S. doctors and hospitals.

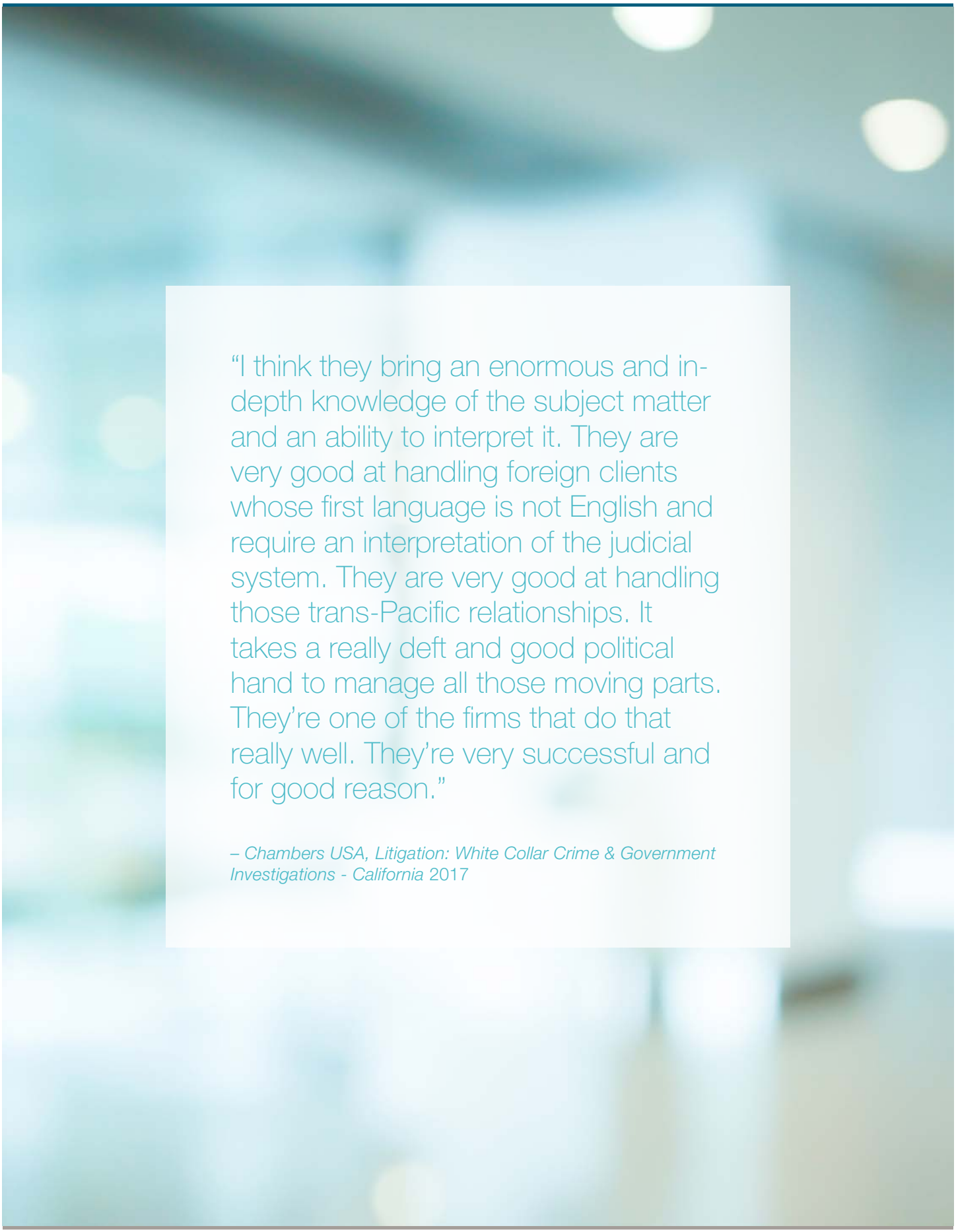
ev3 PLEADS GUILTY TO CHARGES OF DISTRIBUTING ADULTERATED DEVICE

In December 2018, ev3, a medical device company, pled guilty in a Massachusetts federal district court to a misdemeanor count of distributing an adulterated device in violation of the FDCA. The government alleged that, despite the FDA approving the device only for use inside the brain, ev3 sales representatives instructed surgeons on using the device outside of the brain in ways that the FDA determined were potentially dangerous. The company purportedly had set up a sales quota and bonus system that rewarded sales representatives for selling the device for unapproved purposes. According to the government, the company continued these practices even after the FDA warned it about the risks of using the device in an unapproved way.

As part of its plea agreement, ev3 will pay $17.9 million. Its parent company, Medtronic, agreed to review and put in place a different compensation structure to remove incentives for unapproved uses of the device.

FDA INVESTIGATING JOHNSON & JOHNSON BABY POWDER

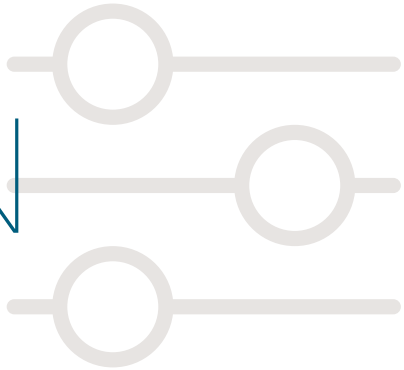
Following reports in December 2018 by *The New York Times* and *Reuters* that Johnson & Johnson allegedly knew that its talc baby powder had tested positive for small quantities of asbestos between the 1970s and early 2000s, the company may potentially face an investigation by the FDA. In 2009, the FDA did an "exploratory survey" of both cosmetic-grade raw material talc and cosmetic products that contain talc and found no asbestos in the samples. In more recent statements, however, the FDA has said that it "continues to investigate and monitor reports of asbestos contamination in certain cosmetic products" and is looking into the *Reuters* and *The New York Times* allegations.



"I think they bring an enormous and in-depth knowledge of the subject matter and an ability to interpret it. They are very good at handling foreign clients whose first language is not English and require an interpretation of the judicial system. They are very good at handling those trans-Pacific relationships. It takes a really deft and good political hand to manage all those moving parts. They're one of the firms that do that really well. They're very successful and for good reason."

– Chambers USA, Litigation: White Collar Crime & Government Investigations - California 2017

INTERNAL INVESTIGATION PARAMETER CHANGES



This year, developments in both the Supreme Court and in lower court cases suggest shifts in the landscape of internal investigations. From the (in)ability to recover the costs of an investigation from criminal defendants to new incentives for whistleblowers to go straight to the government and new scrutiny over government roles in internal investigations, companies are likely to need to evolve their internal investigation practices in the coming years.

WHAT YOU NEED TO KNOW

- The Supreme Court limited the ability of companies to recoup the costs of internal investigations under the Mandatory Victims Restitution Act of 1996 but kept open the question of whether restitution is available when the government requests the investigation.
- The Supreme Court also held that the Dodd-Frank Act's whistleblower protections only apply to individuals who report violations directly to the SEC, and not to whistleblowers within a company.
- The government has faced court scrutiny over its role in company internal investigations and is likely in 2019 to face rulings about whether it is converting private actors into arms of the state.
- The GDPR limits how personal data can be taken out of the EU, leading to possible barriers in internal investigations.

SUPREME COURT RULES CRIMINAL DEFENDANTS NOT RESPONSIBLE FOR COSTS OF INTERNAL INVESTIGATIONS

Companies can no longer obtain restitution from convicted criminals under the Mandatory Victims Restitution Act of 1996 ("MVRA") for the costs of their independent investigations into criminal conduct.

In May 2018, the Supreme Court held in *Lagos v. United States*[39] that the MVRA did not entitle a company to recover the cost of its investigation conducted before turning over information to the government. In that case, the defendant pled guilty to wire fraud after using false documents to secure loans from General Electric Capital Corporation ("GE"). As part of his sentence, the defendant paid restitution to GE. The government argued that the MVRA required the restitution to include the costs of GE's investigation of the matter, as well as GE's costs from participating in the bankruptcy proceedings of the defendant's company.

The Supreme Court unanimously disagreed, overruling the precedent of five circuit courts and holding that the MVRA only requires the restitution of costs incurred by those participating in the government's investigations and involvement in criminal prosecutions.

Also interesting is an issue the Court did not address: whether the MVRA covers the costs of a private investigation conducted at the "government's invitation or request."[40] In response to the government's argument that GE's investigation costs should be reimbursed because it shared the product of its investigation with the government, the Court noted that GE incurred its investigation costs *prior* to coordinating with the government, placing those costs outside the statute's coverage.

In light of the programs the government has adopted to encourage companies to voluntarily self-report wrongdoing, there is the possibility that companies could argue that participation in one of those programs acts as a government "invitation" to investigate, thereby falling within the MVRA. Of course, as other cases this year have highlighted, close interaction with the government may give rise to an argument that a company has become a state actor. Until the Supreme Court returns to this question, companies will face a degree of uncertainty in these areas.

WHISTLEBLOWERS HAVE MORE INCENTIVE TO REPORT TO THE SEC

There could be an increase in the number of whistleblower reports to the SEC under the Dodd-Frank Act ("Dodd-Frank"). In February 2018, the Supreme Court held that Dodd-Frank's anti-retaliation whistleblower protections only apply after a whistleblower reports a securities law violation directly to the SEC. *Digital Reality Trust v. Somers*[41] was about a whistleblower who was fired after internally reporting suspected violations. The whistleblower's former employer ultimately prevailed in the Supreme Court, securing the suit's dismissal on the grounds that Dodd-Frank does not protect a whistleblower who does not report the potential violation to the SEC.

This holding incentivizes whistleblowers to bypass internal reporting procedures and go directly to the SEC with reports of suspected securities law violations. To help counter this incentive, companies should reevaluate and recirculate their whistleblower protection policies to emphasize to employees the protections they will receive by using internal reporting structures.

WHEN A PRIVATE COMPANY IS AN ARM OF THE STATE

The government recently has faced scrutiny by courts about its role in internal investigations. As detailed elsewhere in this report, the government has increasingly incentivized companies with promises of leniency in exchange for full cooperation, including responding to government requests for information and witness interviews. Although the government sidestepped adverse rulings this year, these cases suggest that the rules of government involvement in private internal investigations may be about to change.

In the two cases, *United States v. Connolly*[42] and *United States v. Blumberg*,[43] defendants argued that the government's role in their respective former employers'

internal investigations transformed the investigators into state actors, subjecting companies and their outside counsel to the same obligations that bind government prosecutors. In *Connolly*, the issue was whether statements made by one of the co-defendants to the internal investigators under the threat of termination were effectively compelled by the government in violation of the Fifth Amendment. In *Blumberg*, the issue was whether the internal investigation team was required to produce any exculpatory documents in its possession, as would be required of a government prosecutor. In both cases, the government was able to avoid potentially adverse rulings by agreeing in *Connolly* not to call a witness to testify about the defendant's statements and in *Blumberg* by offering the defendant a fairly lenient plea agreement.

The district court continues to scrutinize the government's role in *Connolly*, tasking the government with differentiating its investigation from the company's in response to the defendant's argument that the government's entire case is tainted by his purportedly compelled statements. In March 2019, possibly in response to the recent court scrutiny, the DOJ added to its guidance for federal prosecutors that the "Department will not take any steps to affirmatively direct a company's internal investigation." In the meantime, companies should keep records of their interactions with the government, including government requests, and should consider getting counsel for employees who are the targets of an investigation.

THE GDPR LIMITS ACCESS TO PERSONAL DATA IN THE EUROPEAN UNION

The GDPR applies to internal investigations too, not just personal data collected as a part of regular business. The regulation's requirements for the lawful processing of EU individuals' personal data apply whenever such data is lawfully processed by private parties.

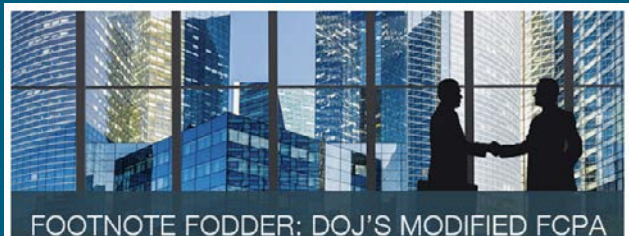
Chapter V of the GDPR governs when data can be transported outside the EU. Personal data may be transferred outside of the EU where: (1) there is a determination by the European Commission that the country where the data is sent adequately ensures data protection measures are in place pursuant to Article 45(3); (2) the controller or processor seeking to transfer the data complies with a number of requirements for safeguarding the data pursuant to Article 46; or (3) the transfer is subject to one of the derogations listed in Article 49. Notably, Article 49(e) permits taking personal data out of the EU if necessary for establishing or defending a legal claim. According to the European Data Protection Board's Guidance on Article 49, this can include for the negotiated resolution of criminal fines.

Special note should also be paid to the strict limitations imposed by the GDPR on the collection of criminal history data, such as prior prosecutions or convictions, during investigations.

SEE V&E'S E-LERTS AND BULLETINS ON THIS TOPIC:

BECOMING AN ARM OF THE STATE: RECENT CHALLENGE TO STATEMENTS MADE IN INTERNAL INVESTIGATIONS SHINES A SPOTLIGHT ON THE ROLE OF THE GOVERNMENT IN INTERNAL INVESTIGATIONS

DISTRICT COURT TELLS GOVERNMENT TO SHOW ITS WORK IN CHALLENGE TO ITS ROLE IN INTERNAL INVESTIGATION



FOOTNOTE FODDER: DOJ'S MODIFIED FCPA GUIDANCE INCLUDES FOOTNOTE THAT APPEARS TO BE RESPONDING TO CRITICISM

LOOKING AHEAD

The Supreme Court has on its docket two criminal procedure cases that are likely to have an impact on the Healthcare and Life Sciences Sector when it faces state and federal enforcement actions.

WHAT YOU NEED TO KNOW

- The Supreme Court will tackle whether the Sixth Amendment's Double Jeopardy clause prohibits states from pursuing identical criminal charges after the federal government has had an opportunity and whether the Eighth Amendment's prohibition against excessive fines applies to states.

States, in addition to the federal government, can use their enforcement powers to bring criminal and civil cases. But two cases on the Supreme Court's docket this year are likely to affect the scope of the states' enforcement powers.

WILL STATES BE ABLE TO PURSUE IDENTICAL CRIMINAL ACTIONS AS THE FEDERAL GOVERNMENT?

In *Gamble v. United States*, the Supreme Court is considering whether it should overrule the separate sovereigns exception to the Sixth Amendment's Double Jeopardy Clause. The separate sovereigns exception states that because the federal and state governments are "separate sovereigns," the Double Jeopardy Clause does not apply to prosecution of the same crime under both federal and state laws. Oral argument indicated that the majority of the justices are likely to uphold the exception and seem reluctant to change long-standing precedent. If the justices decide not to overturn the separate sovereigns exception, companies will continue to be subject to both federal and state prosecution.

ARE STATES, LIKE THE FEDERAL GOVERNMENT, LIMITED IN HOW THEY FINE DEFENDANTS?

In *Timbs v. Indiana*, the Court considered whether the Eighth Amendment's Excessive Fines Clause applies to the states. The excessive fines clause prohibits the federal government from imposing "excessive fines" on defendants. The issue before the Supreme Court was whether that clause applies to states as well. Amendments to the Constitution do not, on their face, apply to state governments. The Supreme Court has held in the past that the Fourteenth Amendment requires states to respect many, but not all, of the rights engendered in the Constitution.

In February 2019, the Supreme Court held that the Excessive Fines Clause applies to state governments.[44]

SEE V&E'S E-LERT ON U.S. SUPREME COURT RULES STATES CAN'T IMPOSE EXCESSIVE FINES

V&E Government Investigations Update, February 21, 2019

Yesterday, in *Timbs v. Indiana*, the U.S. Supreme Court ruled that the Eighth Amendment's prohibition on excessive fines applies to the states. In an opinion drafted by Justice Ginsburg, the Court held the Excessive Fines Clause is "fundamental to our scheme of ordered liberty" with "deep roots in our history and tradition."[1] Until *Timbs*, the U.S. Constitution's prohibition on excessive fines only applied to the federal government.

CONCLUSION

As our report details, the Healthcare and Life Sciences Sector is likely to face a shifting enforcement landscape. As these enforcement trends develop, we will provide ongoing updates.

ENDNOTES

1 In 2018, the DOJ updated and renamed the U.S. Attorneys Manual to the Justice Manual.

2 Jody Godoy, "DOJ Expands Leniency Beyond FCPA, Lets Barclays off," Law360.com (Mar. 1, 2018).

3 The Breuer Memo provided a procedure for the selection of monitors. The new policy technically supersedes the Breuer Memo but largely maintains the same structure for selecting monitors.

4 These statistics are drawn from the DOJ Fraud Section's Related Enforcement Actions webpages (*see* https://www.justice.gov/criminal-fraud/related-enforcement-actions) and the SEC Enforcement: FCPA Cases webpage (*see* https://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml), both of which list FCPA resolutions by year. In calculating the resolutions, settlements with a company and its subsidiaries are counted as one settlement.

5 *See* https://www.justice.gov/criminal-fraud/pilot-program/declinations (last visited Feb. 5, 2019).

6 332 F. Supp. 3d 575 (E.D.N.Y. 2018).

7 581 U.S. --- (2017).

8 861 F.3d 760 (2017).

9 31 U.S.C. § 3730(c)(2)(A).

10 *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998).

11 *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003).

12 The United States' Motion To Dismiss Relator's Second Amended Complaint at 10, *United States, et al. ex rel. Health Choice Group, LLC v. Bayer Corp., et al.*, No. 5:17-cv-126-RWS-CMC, Dkt. No. 116 (E.D. Tex. Dec. 17, 2018) (describing other cases that the United States moved to dismiss).

13 Department of Justice Fraud Statistics, *available at* https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery (last visited Jan. 23, 2019).

14 The United States' Motion To Dismiss Relator's Second Amended Complaint at 2, *United States, et al. ex rel. Health Choice Group, LLC v. Bayer Corp., et al.*, No. 5:17-cv-126-RWS-CMC, Dkt. No. 116 (E.D. Tex. Dec. 17, 2018) (describing other cases that the United States moved to dismiss).

15 *U.S. ex rel. SAPF; UC v. Amgen, Inc.*, No. 16-cv-5203 (E.D. Pa.); *U.S. ex rel. Miller v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex.); *U.S. ex rel. Carle v. Otsuka Holdings Co.*, No. 17-cv-966 (N.D. Ill.).

16 Medicare Advantage Organizations are private companies that offer insurance coverage to individuals through the Medicare Advantage plan. The Medicare program in turn pays the private companies for the care provided to individuals.

17 Chris Villani, "Ex-Insys CEO Pleads Guilty, May Testify In Bribery Trial," Law360.com (Jan. 9, 2019)

18 579 U.S. ---, 136 S. Ct. 1989 (2016).

19 136 S. Ct. 1989, 2001 (2016).

20 *Id.* at 2002-03.

21 *Id.* at 2003-04.

22 892 F.3d 822 (6th Cir. 2018).

23 909 F.3d 1012 (9th Cir. 2018).

24 895 F.3d 730 (10th Cir. 2018).

25 *Id.* at 742.

26 896 F.3d 834 (7th Cir. 2018).

27 904 F.3d 667 (9th Cir. 2018).

28 *Id.* at 677.

29 898 F.3d 1267 (11th Cir. 2018).

30 907 F.3d 187 (5th Cir. 2018).

31 906 F.3d 1223 (11th Cir. 2018).

32 *Id.* at 1228.

33 585 U.S. --- (2018).

34 Intervenor United States' Motion to Stay Discovery, *In re Generic Pharm. Pricing Antitrust Litig.*, Case No. 16-md-02724-CMR, Dkt. No. 279 (E.D. Pa. May 1, 2017).

35 Memorandum of Law ISO Mot. by Plaintiff States for Separate Gov. Track, *In re Generic Pharm. Pricing Antitrust Litig.*, Case No. 16-md-02724-CMR, Dkt. No. 525-2 (E.D. Pa. Nov. 14, 2017).

36 Pretrial Order No. 44, *In re Generic Pharm. Pricing Antitrust Litig.*, Case No. 16-md-02724-CMR, Dkt. No. 566 (E.D. Pa. Feb. 9, 2018).

37 Pretrial Order No. 44, *In re Generic Pharm. Pricing Antitrust Litig.*, Case No. 16-md-02724-CMR, Dkt. No. 603 (E.D. Pa. June 5, 2018).

38 Joint Proposed Agenda for Feb. 8, 2019 Status Conference, *In re Generic Pharm. Pricing Antitrust Litig.*, Case No. 16-md-02724-CMR, Dkt. No. 843 (E.D. Pa. Feb. 1, 2019).

39 584 U.S. ____ (2018).

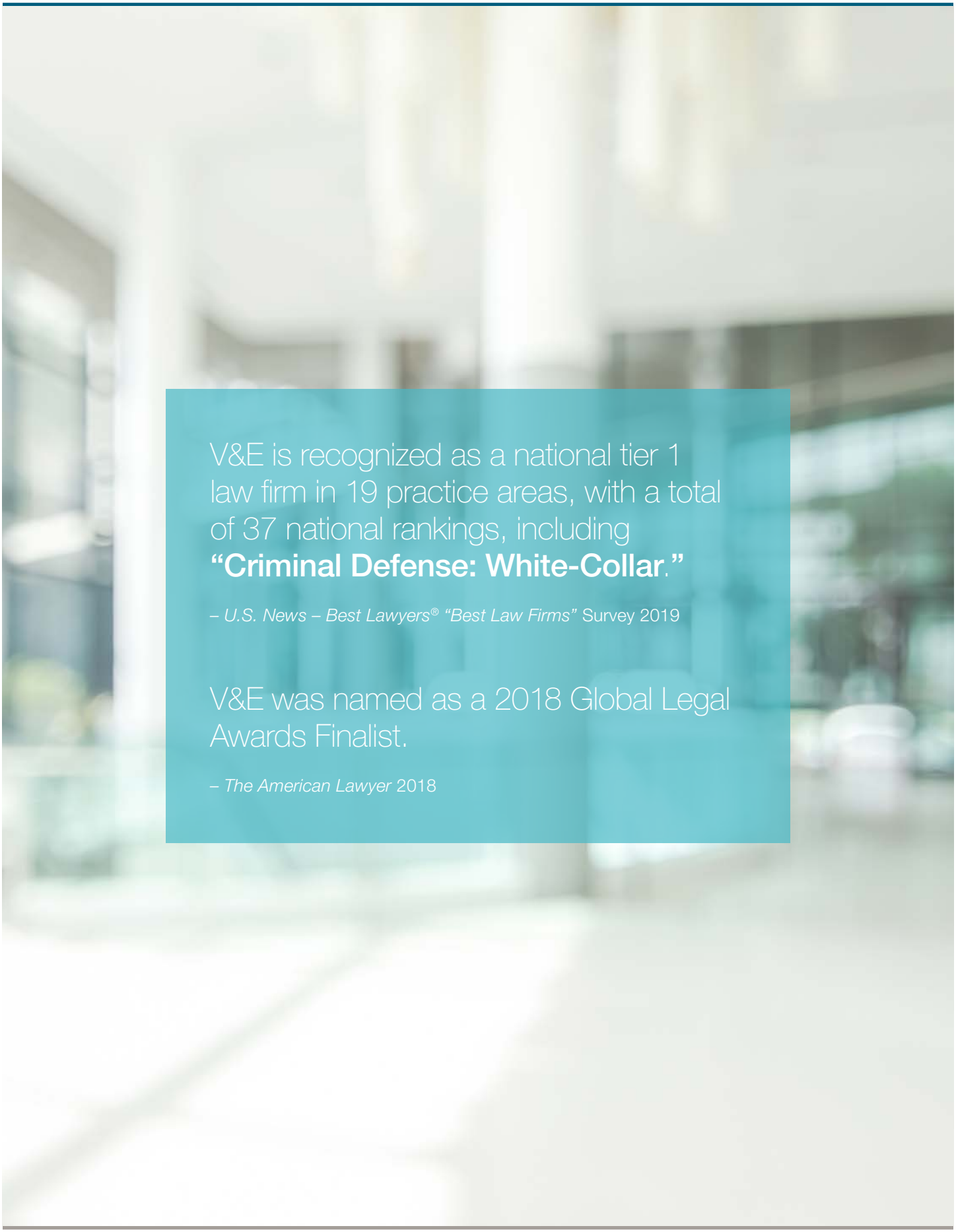
40 *See id., slip op.* at 7.

41 583 U.S. ____ (2018).

42 No. 1:16-cr-00370-CM.

43 No. 14-cr-00458-JLL.

44 139 S. Ct. 682 (2019). The Court did not provide guidance on how to determine whether a fine is excessive.



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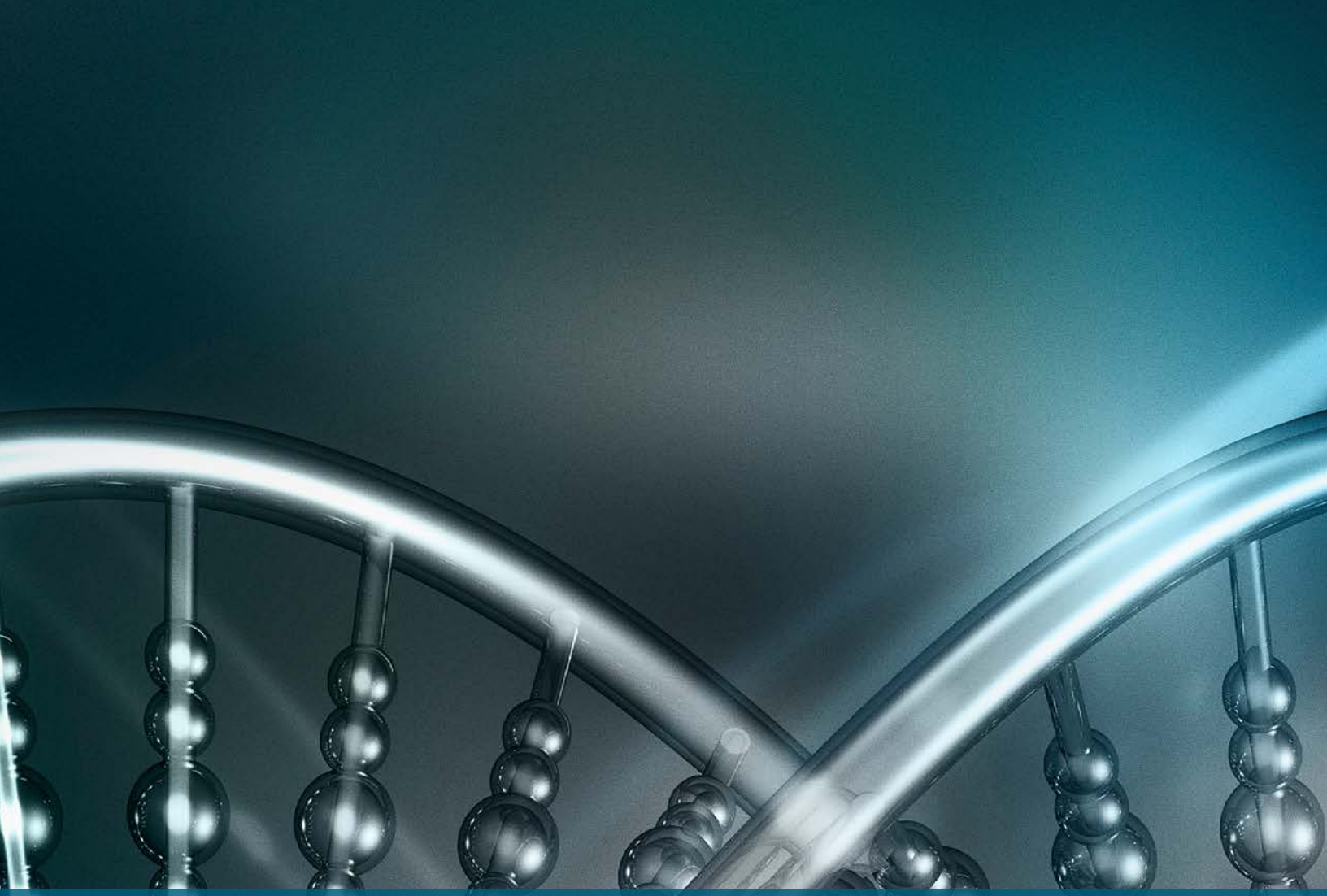

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