Corporate Law Forum:
It’s Time for Corporate Counsel to Get Smart on Crime
DOJ Enforcement Trends & Developments

• There have not been major changes in DOJ enforcement priorities since President Trump took office.

• At the outset of the Trump Administration, the message coming from DOJ was that it would be very focused on national security, terrorism, illegal immigration, violent crime, murder, cartels, gangs, human traffickers, and drug offenses.

• However, DOJ’s more recent words and actions have indicated that it will still vigorously investigate and prosecute white collar crime.

• Statistics show, for example, an aggressive DOJ Fraud Section.

Fraud Section Statistics in 2017

• 301 individuals charged
• 207 individuals pleaded guilty
• 27 individuals convicted at trial
• 10 corporate criminal enforcement actions
• $4.6 billion in corporate U.S. criminal fines, penalties, forfeiture and restitution, and total enforcement action amounts payable to U.S. and foreign authorities of $6.8 billion

Fraud Section Statistics in 2016

• 300 individuals charged
• 201 individuals convicted
• 15 corporate resolutions
• $1.51 billion in corporate U.S. criminal fines, penalties, and forfeiture, and total resolution amounts payable to U.S. and foreign authorities of $7.8 billion
Foreign Corrupt Practices Act Enforcement

• The Foreign Corrupt Practices Act of 1977 (“FCPA”) was enacted for the purpose of making it unlawful for certain persons and entities to make payments to foreign government officials to in order to obtain or retain business.

• In 2012, President Trump called the FCPA “a horrible law” that “should be changed,” and one that puts U.S. companies at a “huge disadvantage.”

• However, 2017 was a significant year for FCPA enforcement by DOJ.
  – The largest FCPA settlement in history was announced in September 2017 – a resolution with Sweden’s Telia Company AB for over $965 million.
  – A 2017 settlement with Singapore’s Keppel Offshore & Marine Ltd. for $422 million was also among the top 10 largest FCPA resolutions of all time.

• Top DOJ officials have repeatedly stressed their commitment to enforcing the FCPA.
  – Atty. Gen. Jeff Sessions said in April 2017 that the DOJ would “continue to strongly enforce the FCPA and other anti-corruption laws.”
  – Then-Acting Principal DAG Trevor McFadden reiterated this message of continued FCPA enforcement at two conferences in April 2017, stating that, “the department remains committed to enforcing the FCPA and to prosecuting fraud and corruption more generally.”
  – In December 2017, the DOJ’s FCPA Unit Chief Daniel Kahn called 2017 a “historic year” for FCPA enforcement and reiterated that enforcement was not down.
  – That same month, Deputy Atty. Gen. Rod Rosenstein stressed that the FCPA was “the law of the land” and that the DOJ would “enforce it against both foreign and domestic companies that avail themselves of the privileges of the American marketplace.”
FCPA Corporate Enforcement Policy

• On April 5, 2016, DOJ announced a one-year FCPA enforcement pilot program designed to incentivize companies to voluntarily self-report FCPA misconduct to DOJ.

• Under the program, companies could receive expanded credit from DOJ for: (1) making an early, voluntary disclosure, (2) fully cooperating with investigation, and (3) taking prompt remedial action.

• In March 2017, DOJ announced that it would continue the program in full while it determined whether to extend or modify it.

• On November 29, 2017, Deputy Atty. Gen. Rosenstein announced a revised FCPA Corporate Enforcement Policy that would essentially make permanent certain elements of the Pilot Program.

• Rosenstein stated that the Pilot Program “proved to be a step forward in fighting corporate crime” but that “there were opportunities for improvement,” among them “greater certainty for companies struggling with the question of whether to make voluntary disclosures of wrongdoing.”
FCPA Corporate Enforcement Policy (con’t)

• The Corporate Enforcement Policy offers increased incentives to companies who voluntarily self-disclose, fully cooperate, and timely and appropriately remediate issues.
  – If a company voluntarily self-discloses misconduct, fully cooperates, and timely and appropriately remediates, there is “a presumption that the company will receive a declination.”
  – Even where aggravated circumstances are involved, DOJ will recommend a 50% reduction from the low end of the Sentencing Guidelines range.

• In announcing the Policy, Rosenstein emphasized favorable outcomes in recent cases involving self disclosure.
  – He highlighted that only two of the 17 FCPA-related criminal resolutions since 2016 were voluntary disclosures under the FCPA pilot program; of those, both were resolved through a non-prosecution agreement without the requirement for a compliance monitor.
  – In contrast, 10 other resolutions did require a monitor.

• Policy also offers further guidance on DOJ’s evaluation of appropriate compliance programs.
FCPA Enforcement

- DOJ remains very active in this area, as the following statistics from the Fraud Section’s FCPA Unit demonstrate.

**FCPA Unit Statistics in 2017**

- 24 individuals charged
- 18 individuals pleaded guilty
- 3 individuals convicted at trial
- 7 corporate criminal enforcement actions, resulting in $822 million in corporate U.S. criminal fines, penalties, and forfeiture, and total enforcement action amounts payable to U.S. and foreign authorities of $2.5 billion
- 2 declinations under the former FCPA Pilot Program in which the companies agreed to disgorge illicit profits totaling more than $15.2 million to either the Department or the SEC

**FCPA Unit Statistics in 2016**

- 17 individuals charged or pleaded guilty
- 13 corporate resolutions
- $1.36 billion in corporate U.S. criminal fines, penalties, and forfeiture, and total resolution amounts payable to U.S. and foreign authorities of $7.3 billion
- 5 Pilot Program declinations in which the companies agreed to disgorge illicit profits totaling more than $15 million to either the Department or the SEC
Healthcare Fraud Enforcement

• In a May 2017 Speech, then-Acting AAG Kenneth Blanco stressed the DOJ’s commitment to healthcare fraud enforcement.
  – “[L]et me be clear: health care fraud is a priority for the Department of Justice. Attorney General Sessions feels very strongly about this. I can tell you that he has expressed this to me personally. The investigation and prosecution of health care fraud will continue; the department will be vigorous in its pursuit of those who violate the law in this area.”

• Statistics from DOJ’s Health Care Fraud Unit demonstrate the Department’s continued activeness in this area.

HCF Unit Statistics 2017

• 220 individuals charged
• $1.6 billion in loss charged
• 156 individuals pleaded guilty
• 16 individuals convicted at trial
• 162 individuals sentenced

HCF Unit Statistics 2016

• 233 individuals charged
• 152 individuals convicted
• 1 corporate resolution requiring a U.S. criminal penalty of $144 million, and a total resolution amount paid to U.S. and state authorities of $512 million
Financial Fraud Enforcement

• Statistics from DOJ’s Securities & Financial Fraud Unit suggest that DOJ is aggressively investigating financial fraud.

SFF Unit Statistics 2017
• 57 individuals charged
• 33 individuals pleaded guilty
• 8 individuals convicted at trial
• 3 corporate criminal enforcement actions resulting in $3.8 billion in U.S. criminal fines, penalties, forfeiture, and restitution and total enforcement action amounts payable to the U.S. of $4.38 billion

SFF Unit Statistics 2016
• 52 individuals charged
• 34 individuals convicted
• 1 corporate resolution resulting in $1.6 million in U.S. criminal penalties
Individual Prosecution & the Future of the Yates Memo

• In September 2015, then-Deputy Atty. Gen. Sally Yates announced a new policy guidance, emphasizing that identifying culpable individuals in corporate investigations and holding them accountable was a DOJ priority (“Yates Memo”).

• In April 2017, Atty. Gen. Sessions said that DOJ “will continue to emphasize the importance of holding individuals accountable for corporate misconduct. It is not merely companies, but specific individuals, who break the law.”

• In October 2017, Deputy Atty. Gen. Rosenstein also emphasized continued focus on individual prosecutions, stating that any changes in DOJ policy would “reflect our resolve to hold individuals accountable for corporate wrongdoing.”
  – “Federal prosecutors should be cautious about closing investigations in return for corporate payments, without pursing individuals who broke the law.”
  – “Corporate settlements do not necessarily deter individual wrongdoers.”

• In November 2017, Rosenstein further stressed that “effective deterrence of corporate corruption requires prosecution of culpable individuals.”
Individual Prosecution & the Future of the Yates Memo (con’t)

• While the actual impact of the Yates Memo remains unclear, some individuals were charged in 2017 in connection with high-profile corporate corruption cases:
  – November 7, 2017: Three Rolls-Royce employees, an intermediary, and an engineering executive who worked with Rolls-Royce were charged with involvement in a scheme to bribe officials of a state-owned energy joint venture between China and Kazakhstan. This followed Rolls-Royce’s January 2017 DPA with DOJ and an $800 million penalty.
  – November 6 and 9, 2017: Two SBM Offshore executives pleaded guilty to one count each of conspiracy to violate the FCPA. The guilty pleas followed SBM’s agreement with DOJ to pay $238 million in charges related to the alleged bribery of officials in Angola, Brazil, Equatorial Guinea, Iraq, and Kazakhstan.
  – In total, there were 21 convictions or guilty pleas involving FCPA violations in 2017.
  – Individual enforcement abroad also appears to be on the rise; approx. 80 individuals were charged around the world in connection with the Odebrecht case in 2017.
SEC Enforcement Trends & Developments

• SEC Chair Jay Clayton has said that “[t]here’s not going to be some dramatic shift in priorities at the SEC.”

• Clayton reaffirmed in September 2017 the Commission’s commitment to enforcing FCPA and identified individual liability as “extremely important” to him personally.
  – The SEC’s emphasis on individual accountability could increase under the theory that shareholders are unfairly hurt when companies are punished for acts of employees.

• With respect to FCPA enforcement, Steven R. Peikin, Co-Director for the Division of Enforcement, stated in November 2017 that “[c]ombatting corruption . . . remains an important government mission, including at the SEC’s Enforcement Division,” due to the ultimate harm that corruption did to investors by distorting the marketplace.

• In November 2015, then-Director of Enforcement Andrew Ceresney announced that companies would have to self-report potential foreign bribery violations in order to be considered for a deferred or non-prosecution agreement.
  – It is unclear whether the SEC will continue the policy.
  – In September 2017, Peikin stated that the SEC would continue to weigh “very seriously” a company’s decision to self-report when considering an enforcement action.
SEC Whistleblower Program

• The SEC Whistleblower Program remains a key component of the Commission’s enforcement efforts.
  – In March, the SEC announced its highest-ever whistleblower awards, with two whistleblowers sharing a nearly $50 million award and a third receiving more than $33 million.
  – Last week, the SEC announced the first award of $2.2 million to a whistleblower who submitted information to another federal agency prior to going to the SEC within 120 days, under the Exchange Act’s “safe harbor” rule.

• The SEC has awarded $264 million to 54 whistleblowers since the inception of the Whistleblower Program.

• Top 10 whistleblower awards:
  1. March 19, 2018 — $50 and $33 million
  2. September 22, 2014 — $30 million
  3. August 29, 2016 — $22 million
  4. November 14, 2016 — $20 million
  5. June 9, 2016 — $17 million
  6. November 30, 2017 — $16 million
  7. September 30, 2013 — $14 million
  8. January 23, 2017 — $7 million
  9. January 6, 2017 — $5.5 million
  10. May 17, 2016 — $5 million to $6 million
SBM FCPA Matter

• In November 2017, SBM Offshore N.V. ("SBM"), a Netherlands-based company specializing in the manufacture and design of offshore oil drilling equipment, and its U.S. subsidiary, SBM Offshore USA Inc. ("SBM USA"), agreed to resolve criminal charges that they conspired to violate the anti-bribery provisions of the Foreign Corrupt Practices Act ("FCPA").

• The companies were accused of conspiring to bribe foreign officials in multiple countries (including Brazil, Angola, Equatorial Guinea, Kazazhstan and Iraq) from 1996-2012.

• The companies allegedly conspired to pay more than $180 million in "commissions" to sales intermediaries, knowing that a portion of these commissions would be used to bribe foreign officials in these countries, with the purpose of securing improper advantages and obtaining and retaining business from these countries’ state-owned oil companies.

• SBM acknowledged that it earned at least $2.8 billion from projects that it obtained from the state-owned companies at issue during the period in question.
Resolution

• SBM entered a deferred prosecution agreement (“DPA”) with the DOJ, while SBM USA pled guilty.

• SBM paid a total criminal penalty of $238 million, including:
  – A $500,000 criminal fine
  – $13.2 million in criminal forfeiture that SBM agreed to pay on behalf of SBM USA

• The resolution with the DOJ followed guilty pleas by two SBM executives who admitted to conspiring to violate the FCPA:
  – Anthony Mace, a former SBM CEO and member of the SBM USA Board
  – Robert Zubiate, a former SBM USA executive

• The resolution also followed SBM’s payment of settlements and criminal penalties totaling $475 million to various other governments over related conduct.
Types of Bribery Conduct

- SBM’s alleged bribery took more than one form, and included:
  - Paying commissions to sales intermediaries who would in turn use a portion of this money to bribe foreign officials.
  - Making bribes directly to foreign officials.
  - Paying for foreign officials’ travel and entertainment, including travel to sporting events.
  - Paying tuition and living expenses of foreign officials’ relatives.
  - Employing and overpaying foreign officials’ relatives, including poor performers.
  - Using bribes both to get business directly and to purchase confidential information to help SBM get business.
  - Using its access to foreign officials as leverage in dealings with other companies.
Management of the Scheme

- The worldwide bribery scheme was elaborately managed. SBM allegedly:
  - Had a small handful of executives oversee the worldwide bribery scheme.
  - Maintained physical records of the scheme in a safe to which few people had access.
  - Gave its marketing and sales staff discretion to pay smaller bribes directly to foreign officials, while requiring high-level approval for larger bribes.
  - Developed a system of codes to refer to foreign officials who received bribes.
  - Used methods of communication that would leave no email trace on SBM servers.

- However, the scheme was not always subtle or well-hidden.
  - Multiple emails were found relating to the bribery scheme labeled “strictly confidential,” or “for your eyes only,” and some noted that they should be deleted after the recipient had read or printed it.
  - In one email exchange, an employee proposed that the brother of the senior executive of Sonangol (Angola’s state-run gas and petroleum company) should be “regularly entertained” so as to “pass good vibrations to his brother.”
  - An SBM employee submitted an expense report for reimbursement for hundreds of Euros in gifts he had purchased, and the report included handwritten, coded notes indicating that certain gifts were for Equatorial Guinean officials.
Factors in Resolution

• DOJ concluded that SBM was entitled to a 25% reduction off the bottom of the U.S. Sentencing Guidelines range based on the following:
  – SBM brought the improper conduct at issue to the attention of the Criminal Division’s Fraud Section and Dutch authorities.
  – SBM cooperated with the DOJ investigation, including an accelerated investigation into bribery conduct related to Kazakhstan and Iraq.
  – SBM undertook significant remedial measures, including terminating and demoting employees involved in the charged conduct.
  – SBM implemented new and enhanced internal controls.
  – Ability to pay.
  – However, SBM did not provide a complete disclosure for approx. one year after bringing its conduct to the authorities’ attention.
Lessons

• Pay attention to what is happening in your industry. If a scandal breaks involving one of your competitors or business partners, ask yourself: (a) could that have happened here, and (b) have we been exposed to those bad actors?
  – Prepare yourselves to answer those questions before the government asks.

• Think expansively when conducting internal investigations.
  – Bribery schemes and other crimes may be multifaceted and involve various countries, parties and types of conduct.

• Cooperation may be rewarded.
  – As this case shows, voluntarily coming forward and taking remedial action can earn you credit from the government.
United Therapeutics Matter

• In December 2017, Maryland-based pharmaceutical company United Therapeutics (“UT”) entered a settlement with the DOJ resolving allegations arising from its relationship with a 501(c)(3) charitable organization.

• Specifically, UT agreed to pay $210 million to resolve claims that it violated the federal Anti-Kickback Statute and the False Claims Act by using a charitable “patient assistance program” (“PAP”) to pay the copays of Medicare patients taking UT drugs.

• There was no determination of liability.

• United Therapeutics also entered into a five-year corporate integrity agreement (“CIA”) with the Office of the Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”). The CIA required, among other things, that UT implement measures to ensure that its interactions with third-party patient assistance programs were compliant with the law.
Overview of United Therapeutics

• United Therapeutics was founded in 1996 by Martine Rothblatt, the creator of Sirius Radio, in order to find a treatment for her daughter’s pulmonary arterial hypertension (“PAH”).
  – PAH is a rare, often fatal, disease, which, at that time, had no available treatments.

• After six years of research and development, UT launched its first product in 2002 and has since launched three additional PAH products:
  – Adcirca (2009)
  – Tyvaso (2009)
  – Orenitram (2013)

• In 2015, UT launched Unituxin, an ultra-orphan therapy that is the only treatment for a rare, pediatric cancer called neuroblastoma.
Legal Overview

• Under the Anti-Kickback Statute (“AKS”), a drug manufacturer may not give Medicare recipients money to buy the manufacturer’s drugs.
  – Thus, a company cannot give a patient the money to pay his or her copay for a drug and then have Medicare pay the balance.

• However, OIG guidance states that it is not illegal for a drug manufacturer to fund a patient assistance program, i.e., a 501(c)(3) charity that uses donations to pay patients’ copays.

• Nevertheless, the guidance stresses that while a company can legally donate to such a program if the latter is a bona fide independent charity, AKS concerns arise where the latter is a mere conduit for passing money to patients (for example, if the charity is under the drug manufacturer’s influence and control).

• Under the Affordable Care Act, AKS violations constitute violations of the False Claims Act (“FCA”).
Allegations Against UT

• The government’s allegations concerned UT’s donations to Caring Voice Coalition (“CVC”), a 501(c)(3) charity that operated funds that paid the copays for certain patients, including Medicare patients. One of these funds was for PAH patients.

• The government alleged that, from 2010-2014, UT made donations to CVC’s PAH fund in order to use CVC as a “conduit” to pay the copay obligations of thousands of Medicare patients taking UT drugs.

• The government further alleged that UT donated to CVC in order to “eliminate price sensitivity” in PAH patients and prescribing physicians and “induce” patients to purchase UT drugs.

• The government also alleged that, during this time, UT routinely obtained data from CVC detailing how many patients on each drug CVC had assisted and how much CVC had spent on those patients.

• The government contended that, when UT decided how much to donate to CVC, it considered how much revenue it would receive from patients receiving CVC’s copay assistance, and used CVC’s data to confirm that UT’s revenue from these patients far exceeded the amount that it was donating to CVC.

• The government additionally alleged that UT did not permit Medicare patients to participate in its free drug program (which was open to other financially needy patients), but instead referred these patients to CVC so that they would ultimately buy UT drugs and help generate revenue (with federal healthcare programs covering the drugs’ cost).
Settlement

• When the settlement was announced, Acting U.S. Attorney for Boston William D. Weinreb said the following:

  – “UT used a third party to do exactly what it knew it could not lawfully do itself . . . . According to the allegations in today’s settlement agreement, UT understood that the third-party foundation used UT’s money to cover the co-pays of patients taking UT drugs. UT’s payments to the foundation were not charity for PAH patients generally, but rather were a way to funnel money to patients taking UT drugs. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these that leave Medicare holding the bag for the costs of expensive drugs.”
Lessons

• Legal gray areas are hazardous.

• The government may bring an enforcement action even if you have a compelling story – such as providing a way for patients to get life-saving drugs that they potentially could not afford.

• Compliance is not a one-time event.
  – Monitor and re-check.
  – Pay attention to changes in the law.

• Pay attention to related investigations and look for weak spots or violations in your company.
  – This may give you an opportunity to find something first, fix it, and self-report.
Volkswagen Emissions Scandal

- In January 2017, Volkswagen AG ("VW") pled guilty to three criminal felony counts (conspiracy, obstruction of justice and entry of goods by false statement) in connection with its sale of approx. 590,000 diesel vehicles in the U.S. that failed to comply with EPA and state emissions standards.

- Specifically, the company pled guilty to conspiring to violate the Clean Air Act and defraud the U.S. and VW customers by deliberately misleading regulators and customers for most of a decade about whether its diesel vehicles met emissions standards.

- The company admitted to installing “defeat devices” in its diesel vehicles – software that allowed the cars to cheat emissions tests required by the EPA and the California Air Resources Board (CARB).

- The company also admitted to lying and obstructing justice in order to further the above scheme, including destroying documents.

- VW agreed to pay a $2.8 billion criminal fine and $1.5 billion in civil damages in connection with its January 2017 plea. This followed two substantial 2016 settlements in civil actions with federal and state regulators and car owners ($14.7 billion and $1 billion, respectively) and was shortly followed by another $1.2 billion settlement with car owners.

- The civil settlements that accompanied the 2017 plea resolved actions against Volkswagen entities (including VW, Audi AG and Volkswagen Group of America) by the EPA, CPB and DOJ.
Origin of the Scheme

• In 2006, VW engineers sought to design a new diesel engine to meet stricter U.S. NOx emissions standards that would take effect in 2007.

• When they failed to produce an engine that would both meet stricter standards and attract sufficient U.S. customer demand, VW decided to install software in its diesel cars to cheat emissions tests. Defeat devices were installed in diesel cars from model years 2009-2016 under the Volkswagen, Audi and Porsche brands.

• While concealing the existence of the defeat device from federal and state authorities and U.S. customers, VW marketed its “clean diesel” vehicles as environmentally friendly.
How the Defeat Device Worked

- Volkswagen and its affiliates offered two types of diesel vehicles: models with 2.0 liter diesel engines and larger and higher-end models with more powerful 3.0 liter diesel engines.
- The defeat device software recognized whether a vehicle was undergoing standard U.S. emissions testing or it was being driven on a road under normal driving conditions.
- If the device in a 2.0 liter vehicle detected that the car was being tested on a dynamometer, it would operate in a mode that satisfied NOx emissions standards (“dyno mode”).
  - If the software detected the vehicle was being driven under normal conditions, its emissions control systems were substantially reduced, causing it to emit NOx up to 35-40 times the permissible limit.
  - In 2012, VW engineers and executives redesigned this defeat device after concluding that operating cars in dyno mode could put stress on their exhaust systems and cause hardware failures.
  - VW improved the defeat device to more accurately detect when cars were being subjected to emissions tests and put cars into dyno mode for shorter periods of time.
- The defeat device in a 3.0 liter diesel vehicle regulated when the car would inject a solution of water and urea (“AdBlue”) into the exhaust gas system to reduce the NOx output, injecting the solution when the car was undergoing testing but doing this less when it was on the road.
  - This allowed 3.0 liter vehicles to have smaller AdBlue tanks and, in turn, greater trunk space.

Source: The New York Times
Discovery of the Defeat Device

• In May 2014, West Virginia University’s Center for Alternative Fuels, Engines and Emissions published a study on diesel cars commissioned by the International Council on Clean Transportation (ICCT).

• The study identified substantial discrepancies in the NOx emissions from VW vehicles with 2.0 liter diesel engines when tested on the road compared to when these vehicles were undergoing standard drive cycle tests on a dynamometer.
  – When on the road, the diesel cars tested emitted NOx approx. 40 times the permissible limit.

• The EPA and CARB took notice and began investigating. While agencies repeatedly sought information from VW, its employees actively concealed the existence of the defeat device while appearing to cooperate.
  – For example, VW employees provided misleading explanations and software and hardware “fixes” to disguise the company’s active involvement in cheating emissions tests.

• In September 2015, after 18 months, a VW employee revealed the existence of the defeat device during a meeting with the EPA and CARB.

• The EPA soon after issued a notice accusing VW of violating the Clean Air Act by manufacturing and installing defeat devices in its 2.0 liter diesel vehicles and by selling these vehicles.

• Later that month, VW disclosed that as many as 11 million VW cars could contain defeat devices, and VW CEO Martin Winterkorn resigned.
The Scandal Broadens

• According to VW’s plea agreement, Volkswagen AG designed and concealed the defeat device for vehicles with 2.0 liter diesel engines, while subsidiary Audi AG designed and concealed the defeat device for 3.0 liter vehicles.

• After the West Virginia University report was released in May 2014 exposing emissions problems with VW’s 2.0 liter vehicles, Audi AG repeatedly misrepresented that its 3.0 liter vehicles did not have the same issues, which led CARB to approve the sale of these cars’ 2016 models.

• In November 2015, the EPA issued a notice of violation accusing VW and Audi AG of installing defeat devices in 3.0 liter vehicles.

• According to VW’s plea agreement, Audi AG representatives only admitted to the device’s existence later that month, and made further admissions in July 2016.
Obstruction of Justice

• VW employees obstructed justice in August-September 2015 by destroying documents related to the emissions scandal.

• In August 2015, it became apparent that VW and its American subsidiary would issue litigation hold notices to preserve documents relevant to diesel emissions issues.

• Immediately before and shortly after VW issued a hold notice, approx. 40 VW and Audi AG employees (including attorneys) coordinated the deletion of thousands of documents.

• VW employees also encouraged employees at an automotive engineering company that helped design the defeat device to delete relevant files.

• Many of the deleted documents were subsequently recovered during an internal investigation.
Aftermath

- Investigations were launched by multiple governments in the Americas, Europe and Asia.
- A VW engineer who helped develop the defeat device was indicted and pled guilty to conspiring to defraud regulators and car owners in late-2016, and was sentenced to a 40-month prison term in August 2017.
- Six VW employees were indicted at the same time that the company pled guilty in January 2017. One pled guilty, and was sentenced to a seven-year prison term in December 2017.
- Civil actions brought by U.S. federal and state agencies and car owners resulted in multiple settlements, including a $14.7 billion settlement in June 2016, a $1 billion settlement in December 2016, and a $1.2 billion settlement in May 2017.
- In February 2017, The New York Times estimated that VW would pay $20 billion to resolve civil and criminal claims, while The Wall Street Journal’s estimate was $25 billion. In September 2017, Reuters and Bloomberg estimated that “Dieselgate” had cost VW $30 billion.
- VW had to undertake a number of expensive actions in resolving disputes with regulators and customers, including instituting vehicle recalls and buybacks, offering car owners compensation, and funding programs to mitigate the company’s harm to the environment.
- Litigation with car owners is still ongoing (one case settled in February on the eve of trial).
- Two days ago, The New York Times reported that VW was set to oust current CEO Matthias Müller, and surmised that this was due to Müller’s “stalled” efforts to lead the company out of the emissions scandal.
Lessons

• Make sure your board of directors is diverse – not only in age, race, and gender, but in experience and expertise.
• Implement an effective conflict-of-interest policy.
• Ensure that the Tone at the Top of the organization is appropriate.
• Strive for an overall corporate culture that is compliance-minded.
• Have a document retention policy in place.
• Swiftly issue litigation holds.
• Spoliation of documents / obstruction will be punished.
Theranos Securities Matter

- Theranos is a privately-held Silicon Valley company founded in 2003 by then-19-year-old Elizabeth Holmes, who dropped out of Stanford to start the company.

- Theranos’ key product was a portable blood analyzer (the “Edison”) that the company claimed could conduct comprehensive blood tests on a few drops of blood from a finger, thus revolutionizing the blood-testing industry.

- In 2014, the company was valued at $9 billion, and Forbes named Holmes America’s richest self-made woman based on her 50% stake in the company.

- While Theranos enjoyed what the SEC later called “exuberant media attention,” some journalists and researchers questioned the company’s claims, in part because its methods were never submitted to peer-reviewed journals and only one of its proprietary tests (a test for detecting herpes simplex virus) ever received FDA approval.

Source: Recode
• In October 2015, *The Wall Street Journal* published an article that immediately changed the company’s fortunes.

  – The article claimed that the company’s proprietary blood analysis system could perform only a small fraction of the tests that the company offered.
  
  • Instead, Theranos performed the majority of its tests using traditional testing machines purchased from other companies.
  
  – Furthermore, the article claimed, some employees doubted the Edison system’s accuracy.
  
  – Additionally, an employee had complained to regulators that Theranos had failed to report test results that raised questions about its system’s precision.
Scandal Unfolds

- The scrutiny and negative publicity that followed the WSJ article eroded Theranos’ business.
  - In January 2016, following an inspection of Theranos’ California laboratory, the Centers for Medicare & Medicaid Services (CMS) issued a letter stating that the lab had violated several clinical safety standards and that its deficient practices “pose[d] immediate jeopardy to patient health and safety.”
  - In May 2016, Theranos informed CMS that it had voided two years’ worth of blood test results. The company stated that it had issued tens of thousands of corrected blood-test reports to doctors and patients, nullifying some prior results and revising others.
  - In June 2016, Walgreens, a major Theranos business partner, severed ties with the company. Walgreens immediately closed all 40 of the Theranos testing centers (called “Wellness Centers”) in its Arizona drugstores, which were the source of most of Theranos’ customers.
  - In July 2016, CMS revoked the California laboratory’s certification to perform laboratory testing, stripping the lab’s ability to receive Medicare and Medicaid payments for testing services and prohibiting Holmes from owning, operating or directing a clinical lab for two years.
  - In October 2016, Holmes announced that Theranos would close its blood-testing labs and its remaining Wellness Centers.
  - In November 2016, Walgreens sued Theranos for $140 million for breach of contract, later settling for an undisclosed amount.
  - In February 2017, CMS imposed sanctions on Theranos’ (then-closed) Arizona lab after the lab failed a September 2016 CMS inspection.
  - In April 2017, Theranos settled civil actions with the State of Arizona and CMS for $4.65 million and $30,000, respectively, and vowed to stay out of blood testing for two years.

Source: Drug Store News
SEC Charges & Resolution

• On March 14, 2018, the SEC charged the company, Chairman & CEO Holmes and former President & COO Ramesh Balwani with conducting a “massive fraud,” alleging that the company exaggerated or made false statements about the company’s “technology, business, and financial performance” in raising $700 million from investors from 2013-onward.

• Theranos and Holmes had agreed to settle the charges at the same time they were filed, neither admitting nor denying the SEC’s allegations. Balwani’s case remains pending.

• As part of her settlement, Holmes agreed to give up majority voting control over the company and reduce her equity; agreed to return 18.9 million shares of stock; paid a $500,000 fine; and was barred from serving as an officer or director of a public company for 10 years.

Press Release

Theranos, CEO Holmes, and Former President Balwani Charged With Massive Fraud

Holmes Stripped of Control of Company for Defrauding Investors

FOR IMMEDIATE RELEASE
2018-41
Specific SEC Allegations*

• Theranos (and Holmes/Balwani) claimed that the company’s portable blood analyzer could perform comprehensive blood tests from a tiny amount of blood from a finger prick.
  – In reality, Theranos’ proprietary analyzer only performed 12 of the hundreds of tests that Theranos claimed that it could perform.

• Theranos et al. claimed that it manufactured all of its own blood analyzers.
  – In reality, Theranos conducted the majority of its blood testing on commercially-available analyzers manufactured by other companies.

• Theranos et al. claimed that its products were used by the U.S. Department of Defense on the battlefield, in Afghanistan and on medevac helicopters.
  – In reality, Theranos’ technology was never deployed by the Defense Department on the battlefield, in Afghanistan or on medevac helicopters.

• Theranos et al. claimed that it had generated or would generate over $100 million in revenues in 2014 and that it was on track to make $1 billion in revenues in 2015.
  – In reality, Theranos recorded approx. $100,000 in revenue in 2014, and its revenue projection of $1 billion for 2015 was unreasonable.

*These are merely the SEC’s allegations, and none of the defendants have admitted or denied them.

Source: The Wall Street Journal
Lessons

• Be careful about making overstatements or misstatements to investors in the hopes that reality will catch up with your promises.
  
  – A narrative that has emerged in some commentary about Theranos is that Silicon Valley’s startup culture encourages young companies to make embellishments to investors and hope for them to come true.

  • Jina Choi, SEC’s Regional Director for San Francisco, called the Theranos story “[A]n important lesson for Silicon Valley.” In a statement, Choi warned that “[i]nnovators who seek to revolutionize and disrupt an industry must tell investors the truth about what their technology can do today, not just what they hope it might do someday.”

  – The government can and will prosecute fraudulent misrepresentations even in the absence of “harm.”

• Do not rely on what is commonplace in your industry or what has repeatedly been allowed to happen.
  
  – Again, some commentators have suggested that Theranos was typical for Silicon Valley in that it generated hype that exceeded what it could presently deliver.

  – Regardless of what your peers and competitors do (or have done without interference), the government may not be understanding or consistent in how it scrutinizes you for a common practice.
Lessons (con’t)

- Your public image and visibility may dictate the government’s response.
  - Compare Elizabeth Holmes and Martin Shkreli.
  - Shkreli was prosecuted, convicted and sentenced to seven years in prison for defrauding investors whom he claimed he later repaid.
    - Shkreli was held responsible for $10 million in actual and intended investor losses.
  - The wrongdoing with which Theranos was charged was an order of magnitude worse.
    - According to the SEC, Theranos (a) netted $700 million from investors while being brazenly fraudulent and (b) potentially endangered people who used its blood-testing technology in reliance on the company’s false promises.
    - So far, Holmes has had to settle with the SEC without admitting wrongdoing, give up control of her company, pay a fine and agree not to take a leadership role in a public company.
  - A key distinction is that Shkreli made himself hated.
    - Benjamin Brafman, Shkreli’s attorney, told the press following Shkreli’s trial: “I’ve never had a client who did more to hurt his own standing with the court than Martin Shkreli.” Shkreli’s behavior and comments “probably added several years to his sentence.”

Source: The New York Times
Lessons (con’t)

• It is desirable to have board members (at least some of them) that know your industry.
  – From 2011-2015, Theranos’ board of directors included a number of prominent public figures who lacked medical or sciences backgrounds.
    • This included former Secretaries of State Henry Kissinger and George P. Shultz, former Secretary of Defense William Perry, former Senator Sam Nunn, and attorney David Boies.
    • An exception was former Senator Bill Frist, who had been a practicing heart surgeon.
    • The question arises whether this type of board could actually detect problems with the company’s promised technology.
  – The makeup of the board came under heavy criticism almost immediately after *The Wall Street Journal* published its article.
  – The board was ultimately overhauled in 2016. Among other changes, the board added a former director of the CDC and a former executive at Amgen, Inc.
  – While it is essential to have a diverse board, having directors with relevant experience in your field is critical to insuring that it is run properly and compliantly.
  – Having industry veterans on your board can also help provide outsiders with reassurance when a problem does arise.
Questions?
María Gonzalez Calvet is Executive Counsel, Global Investigations, for General Electric. María leads and manages government, regulatory, and internal investigations that could raise legal or reputational risk globally with a regional focus on Latin America, and represents GE before enforcement agencies, in public policy discussions relating to enforcement priorities, and at external conferences.

Prior to joining GE, María served for four years as a trial attorney at DOJ in the FCPA Unit. Prior to DOJ, María worked at Morgan Lewis & Bockius for six years, where she focused on white collar defense and complex litigation. After receiving her law degree from the University of Pennsylvania, María clerked for U.S. District Judge Legrome Davis in the Eastern District of Pennsylvania. María received her Bachelor of Arts from the University of Pennsylvania, where she majored in English and minored in Spanish, and received her Master’s degree in English from Penn State.

María is the recipient of numerous academic awards from the schools she attended. She has also served in leadership positions in the Pennsylvania and National Hispanic Bar Associations. Most notably, she was counsel to the HNBA in connection with the then-President’s testimony before the Senate Judiciary Committee during the confirmation hearings of Justice Sonia Sotomayor. She is a 2010 recipient of the Women of Distinction Award from The Legal Intelligencer and a 2008 recipient of the Pennsylvania Bar Association’s Pro Bono Award.
Lewis Rhodes is the Director of Contract Management & Compliance at Valiant Integrated Services. Valiant provides expeditionary logistics and mission support for peacekeepers, relief workers, and emergency responders, as well as technical services to U.S. military bases in the United States. In this role, Mr. Rhodes creates and manages a robust contract management and oversight system, while handling or supervising legal issues throughout the company. Mr. Rhodes also implemented and manages the company’s ethics and compliance program. Mr. Rhodes is also a Lieutenant Colonel in the Marine Corps Reserves with combat deployments to Iraq and Afghanistan.
Kristin Graham Koehler
Partner – Sidley Austin LLP

A member of the firm’s Executive Committee, Kristin was commended by Chambers USA: America’s Leading Lawyers for Business as a leader in White-Collar Crime and Government Investigations Litigation as “very practical, collaborative and strategic.”

Kristin has handled numerous United States Department of Justice (DOJ) criminal and civil investigations involving healthcare fraud, antitrust, securities fraud, and violations of the Foreign Corrupt Practices Act (FCPA). She has significant experience representing clients in qui tam matters, State AG investigations, and congressional investigations, and has negotiated numerous Corporate Integrity Agreements with the HHS Office of Inspector General. Kristin routinely counsels clients on the creation, enhancement, and implementation of compliance programs.

In addition to her recognition in Chambers USA: America’s Leading Lawyers for Business (2013, 2014, 2015, 2017), Kristin is recognized in the 2016 and 2017 editions of The Best Lawyers in America as a leading litigator in white-collar criminal defense, and has been recognized every year since 2013. She has also been named one of the “Top 250 Women in Litigation” (2017) and a “Local Litigation Star” in Washington, D.C. (2015–2017) by Benchmark Litigation. Kristin also has been acknowledged by The Legal 500 (2013) for her white collar criminal defense work and was named by Washington DC Super Lawyers as one of the capital region’s “Top 50 Women” lawyers (2014 & 2015) and a top lawyer in 2017. The Corporate Crime Reporter also recognized Kristin as one of the top 150 Women in White Collar (2016). In 2015, she also was recognized as a “Rising Star” in the white collar category by Euromoney LMG.
Fiona A. Philip
Partner – Sidley Austin LLP

Fiona Philip is a partner in Sidley’s Securities & Derivatives Enforcement and Regulatory practice group. She represents multi-national corporations, regulated entities, officers and directors, and financial industry professionals in a range of government and regulatory investigations, including those focused on trading and underwriting practices, insider trading, the Foreign Corrupt Practices Act (FCPA), accounting and internal controls irregularities, disclosure fraud, and corporate governance issues. Fiona also conducts internal investigations and provides compliance counseling to corporations designed to help prevent the need for such investigations.

Fiona's practice is informed by experience gained during her government service from 1999 to 2005. As Enforcement Counsel to the Chairman of the Securities and Exchange Commission (SEC), Fiona worked closely with the Division of Enforcement and Office of the General Counsel to craft policy and guidance for SEC Enforcement staff and to ensure consistency in Commission policy. She also advised the Chairman on various rulemakings under the Sarbanes-Oxley Act, the Investment Advisers Act and the Securities and Exchange Acts. Prior to her work with the Chairman's Office, Fiona spent three years as Counsel in the SEC's Division of Enforcement, where she was one of the original members of the Division's Financial Fraud Task Force.

In 2017, Fiona was named to the Enforcement 40 by Securities Docket, which recognizes lawyers who have been key players in the most significant SEC enforcement matters over the past few decades. In 2010, Fiona was named as a “Nation’s Best Advocates: 40 under 40 Lawyers” by the National Bar Association’s and named to The Root 100. While at the SEC, she received the Chairman's Award for Excellence and the Division of Enforcement Directors Award.

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