WHITE-COLLAR ENFORCEMENT TRENDS AND INTERNAL INVESTIGATIONS

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March 22, 2019
Agenda

• Discussion of DOJ Enforcement Trends in White-Collar Arena
• Review of Recent DOJ Policies that Impact Investigations
• Mitigating Regulatory Enforcement Risks Through Compliance
• Conducting Internal Investigations and Preserving Attorney-Client Privilege
• Review of Recent Cases
• Q&A
DOJ ENFORCEMENT TRENDS IN WHITE-COLLAR ARENA
Government Perspectives on Enforcement

• AGs set priorities, US Attorneys and DOJ components enforce priorities, and career prosecutors keep the ship steady

• Prosecutors are driven to protect patients and consumers, to ensure fairness in the marketplace, and to prevent unnecessary costs from being borne by the government (i.e., the taxpayers)

• Achieving compliance through enforcement

• Parallel criminal and civil investigations are now the norm

• Coordinating and strategizing with domestic and foreign agency partners to develop impact cases
## The Mix of Federal Enforcement Priorities

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DOJ Enforcement Trends in White-Collar Arena

- Foreign Corrupt Practices Act (FCPA)
- Securities and Financial Fraud Enforcement
- False Claims Act (FCA) Enforcement
  - Healthcare Fraud
  - Defense Contractor Fraud
  - Financial Services
- Impact of Immigration, Violent Crime and Opioid Crisis?
- More Activity by State Attorney Generals?
“As we re-double our efforts to combat violent crime, we will still enforce the laws that protect American consumers and ensure that honest businesses aren’t placed at a disadvantage. This Department of Justice will continue to investigate and prosecute corporate fraud and misconduct; bribery; public corruption; organized crime; trade-secret theft; money laundering; securities fraud; government fraud; health care fraud; and Internet fraud, among others.”

“The Department of Justice 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. We will work closely with our law enforcement partners, both here and abroad, to bring these persons to justice.”

“[W]hen we make charging decisions, we will continue to take into account whether companies have good compliance programs; whether they cooperate and self-disclose their wrongdoing; and whether they take suitable steps to remediate problems.”

-- Remarks of Attorney General Sessions at Ethics and Compliance Initiative Annual Conference, April 24, 2017
DOJ Partners on the World Stage

• **US-Based Partners**
  - Securities and Exchange Commission (SEC); Financial Industry Regulatory Authority (FINRA); Commodity Futures Trading Commission (CFTC); Federal Trade Commission (FTC); Federal Reserve System Board of Governors; Health and Human Services – Office of Inspector General (HHS-OIG)

• **Foreign-Based Partners**
  - Serious Fraud Office (SFO); Swedish Prosecution Authority (SPA); Federal Public Minister in Brazil; Office of Attorney General in Switzerland; etc.
US Enforcement Efforts Across Borders

- **Foreign Corrupt Practices Act (FCPA)**
  - Telia, Zimmer Biomet, Odebrecht, General Cable, Teva, Olympus, Rolls-Royce, GSK

- **Residential Mortgage–Backed Securities (RMBS)**
  - Credit Suisse, Deutsche Bank

- **Bank Secrecy Act (BSA)**
  - Banamex USA (subsidiary of Citigroup)

- **London Interbank Offered Rate (LIBOR)**
  - Deutsche Bank, JP Morgan Chase, Bank of America, Barclays, Citibank

- **Foreign Currency Exchange (FX)**
  - Citicorp, JP Morgan Chase, Barclays PLC, The Royal Bank of Scotland, UBS AG

- **DOJ’s Kleptocracy Asset Recovery Initiative**
  - Malaysia

- **Creative Other (RICO, Wire Fraud, Money Laundering)**
  - FIFA (international soccer federation)
The 2018 annual report issued by DOJ’s Fraud Section states that 406 individuals were charged criminally in various corporate enforcement actions in 2018.

Individual prosecution numbers in corporate cases continue to trend upward as 301 individuals were prosecuted in 2017, 300 were prosecuted in 2016, and 225 were prosecuted in 2015.

The individual statistics include FCPA prosecutions with 31 individuals prosecuted in 2018, as compared to 24 in 2017 and 17 in 2016.

In June 2018, DOJ announced the largest healthcare enforcement action in DOJ history with 601 defendants (including 165 doctors, nurses, and other licensed professionals) criminally charged with causing more than $2 billion in false billings, surpassing 412 defendants in 2017 and 301 defendants in 2016.
DOJ by the Numbers: False Claims Act Enforcement Statistics

- The United States spends more than $3 trillion every year on federal healthcare programs.
- In the Trump Administration’s first year, DOJ’s enforcement activity under the FCA remained relatively steady as compared to enforcement activity under the Obama Administration.
- DOJ recovered more than $3.7 billion in settlements and judgments in the fiscal year ending September 30, 2017.
  - Of the $3.7 billion recovered, $3.4 billion came from qui tam actions.
  - Recoveries in FCA cases since 1986 now total more than $56 billion.
- The largest percentage of recovery dollars in FY 2017 came from the health care industry, from which DOJ obtained $2.4 billion in federal settlements and judgments.
  - In addition, DOJ assisted states in recovering millions of dollars for losses to state Medicaid programs.
  - DOJ has now recovered more than $2 billion from the healthcare industry in eight consecutive years.
- $425.8 million of recovery dollars were driven by relators after the government declined to intervene (second-highest amount, behind $512.3 million in FY 2015).
RECENT DOJ POLICIES THAT IMPACT INVESTIGATIONS
Revised DOJ Policy on Corporate Wrongdoing and Individual Accountability (11/30/2018)

• In September 2015, then Deputy Attorney General Sally Yates issued a directive (The Yates Memo) to federal prosecutors designed to strengthen the Department’s pursuit of individuals in criminal and civil investigations of corporate wrongdoing.

• On November 30, current Deputy Attorney General Rod Rosenstein announced refinements and modifications to DOJ’s policy, noting that “pursuing individuals responsible for wrongdoing will be a top priority in every corporate investigation.”

• To receive cooperation credit in criminal cases, companies must undertake “good faith” efforts to identify “every individual who was substantially involved in or responsible for the criminal conduct.”

• In civil cases, cooperation credit is no longer an “all or nothing” proposition, as federal prosecutors “now have discretion to offer some [cooperation] credit even when the company does not qualify for maximum credit.” However, the company “must [still] identify all wrongdoing by senior officials, including members of senior management or the board of directors” to receive any credit.
DOJ’s “No Piling-On” Policy (5/9/2018)

• The “Policy on Coordination of Corporate Resolution Penalties” (now incorporated into the *Justice Manual*) does the following:
  – Reminds DOJ attorneys that they may not use threat of criminal prosecution to extract larger settlements from companies in civil/administrative cases.
  – Instructs DOJ attorneys to “coordinate with one another to avoid the unnecessary imposition of duplicative fines, penalties, and/or forfeiture against the company.”
  – Encourages DOJ attorneys “to coordinate with other federal, state, local, or foreign authorities seeking to resolve a case with a company for the same misconduct.”
  – Sets forth specific factors to consider in assessing “whether multiple penalties serve the interests of justice,” including “the egregiousness of the misconduct; statutory mandates regarding penalties; the risk of delay in finalizing a resolution; and the adequacy and timeliness of a company’s disclosures and cooperation with the Department.”
The “Brand” Memorandum (1/25/2018)

• The “Brand” Memo prohibits DOJ reliance on agency guidance in FCA cases:
  - Forbids prosecutors from relying on “guidance documents”—i.e., “any agency statement of
general applicability and future effect . . . that is designed to advise parties outside of the
federal Executive Branch about legal rights and obligations”—to establish liability under the
FCA.
  - States that “guidance documents” cannot “create binding standards by which [DOJ] will
determine compliance with existing statutory or regulatory requirements.”
  - Instructs prosecutors to “not treat a party’s noncompliance with an agency guidance
document as presumptively or conclusively establishing that the party violated the applicable
statute or regulation.”
  - Guidance documents are not the product of notice-and-comment rulemaking required under
the Administrative Procedures Act for promulgation of legislative rules.
The “Granston” Memorandum (1/10/2018)

- The “Granston” Memo (now incorporated into the *Justice Manual*) encourages government dismissal of non-meritorious qui tam actions:
  - Instructs prosecutors to “consider whether the government’s interests are served . . . by seeking dismissal [of qui tam actions] pursuant to 31 U.S.C. § 3730(c)(2)(A).”
  - Observes that Section 3730(c)(2)(A) is “an important tool to advance the government’s interests, preserve limited resources, and avoid adverse precedent.”
  - Provides a general framework for evaluating when to seek dismissal” with seven non-exhaustive factors for prosecutors to consider:
    1. Whether relator’s legal theory is inherently defective or the allegations are frivolous;
    2. Whether the qui tam action is duplicative of a preexisting government investigation;
    3. Whether the qui tam action threatens to interfere with the administration of agency policy or programs;
    4. Whether the qui tam action interferes with, or is inconsistent with, DOJ’s “litigation prerogatives”;
    5. Whether dismissal is necessary to protect classified information from disclosure and to protect national security;
    6. Whether the expected cost to the government exceeds expected gains;
    7. Whether the relator frustrated the government’s ability to investigate the allegations, for example, by failing to disclose facts to the government.
The **Anti-Bribery Provisions** prohibit companies and individuals from giving anything of value to foreign officials for the purpose of obtaining or retaining business or securing an improper business advantage.

- Applies to US and foreign public companies listed on US stock exchanges or who file reports with the SEC ("issuers"); US businesses and persons ("domestic concerns"); and foreign businesses and persons while in the United States or its territories.

The **Accounting Provisions** require "issuers" with registered securities or who file certain reports with the SEC to make and maintain accurate books and records, and implement adequate internal accounting controls.

DOJ’s New FCPA Enforcement Policy announced in November 2017 creates a “Presumption of Non-Prosecution” where companies disgorge/forfeit improperly obtained monies and “voluntarily self-report [FCPA] issue[s], cooperate fully with prosecutors, and identify and remediate the root causes and gaps in compliance controls that led to the problem.”
DOJ’s Formal FCPA Enforcement Policy  
(November 2017)

• “Presumption of Non-Prosecution” where companies “voluntarily self-report [FCPA] issue[s], cooperate fully with prosecutors, and identify and remediate the root causes and gaps in compliance controls that led to the problem.”

• Companies must identify the individuals responsible for the misconduct and must pay to DOJ (or a relevant regulator like the SEC) all disgorgement, forfeiture, and restitution resulting from the misconduct to receive non-prosecution treatment.

• The presumption of non-prosecution may not apply where “aggravating circumstances” are present (e.g., recidivist status, executive management involvement in misconduct, significant profit generated by misconduct, and/or misconduct pervasive throughout company).

• Sets forth hallmarks of an effective compliance program, including but not limited to fostering a culture of compliance; employing experienced compliance counsel; dedicating sufficient resources to compliance; continuing risk assessments and monitoring; and ensuring compliance personnel have appropriate access to management and the board.
MITIGATING REGULATORY ENFORCEMENT RISKS THROUGH COMPLIANCE
Benefits of a Compliance Program

• The existence of a working compliance program, as referenced in Section 8 of the Sentencing Guidelines, can help you mitigate potential civil and criminal liability

• Credit available where a high-level person (without a direct compliance monitoring role) engages in wrongdoing, but program detects problem, the problem is reported, and compliance officials report to board or subset of board (audit committee)

• Government recognizes that one-size does not fit all in terms of compliance programs (large, medium, small companies and businesses)

• Compliance matters for both first-time and repeat offenders
Compliance Program Guidance

- DOJ and SEC issued FCPA Resource Guide in November 2012, which was revised in June 2015

- DOJ Fraud Section Created “Full-Time Compliance Expert” Position in November 2015 (position was eliminated by DOJ in 2018)


Eleven Areas of Evaluation for Corporate Compliance Programs (DOJ)

1. Analysis and Remediation of Underlying Misconduct
2. Senior and Middle Management
3. Autonomy and Resources
4. Policies and Procedures
5. Risk Assessment
6. Training and Communication
7. Confidential Reporting and Investigation
8. Incentives and Disciplinary Measures
9. Continuous Improvement, Periodic Testing, and Review
10. Third-Party Management
11. Mergers and Acquisitions
Seven Areas to Be Measured When Evaluating a Compliance Program (HHS-OIG)

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors, and Other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Noncompliance
7. Investigation and Remedial Action
Compliance Program Questions

• Historically, does the company have a track record of a “Culture of Compliance”?
  – High-level commitment to compliance where “tone [is set] from the top”
  – Ethical behavior from the “lowest ranking employee through upper management”

• Does the company have clear, well-written policies that are easily understood by employees?
  – Foreign operations: policies should be translated into languages spoken by the employees and third-party vendors in those countries

• Does the company have a compliance officer with actual authority to investigate and address compliance issues?
  – Adequate resources to investigate and remediate problems
  – Unfiltered line of communication to upper management, CEO, Board, etc.
Compliance Program Questions (cont.)

- Does the company proactively investigate and address potential compliance issues?
  - Anonymous hotlines and other reporting mechanisms
  - Remedial steps taken currently and in the past to address identified problems

- Does the company actively train and educate management and its employees as to all legal, regulatory, and ethical requirements?
  - “One and done” compliance and ethics training is not acceptable
  - Training given and updated regularly to address new business risks

- Does the company’s compliance program actually encourage employees to report suspected wrongdoing without fear of retribution?
  - Indifference and retaliation through isolation and demotion as the corporate response
  - Qui tam relators can be created if company ignores relator’s effort to work within the compliance framework to create ethical environment
Compliance Program Questions (cont.)

• Does the company actually discipline employees who engage in unlawful or unethical conduct?
  – High-level employees often formulate, approve, and implement the business plans that caused the problem
  – Both low-level and high-level employees need to be accountable for bad behavior

• Does the company take steps to regularly review and evaluate the effectiveness of its compliance program?
  – Risk assessment is an ongoing process
  – Regular reviews designed to assess and respond to changing business activities, geographic markets, and third-party providers
CONDUCTING INTERNAL INVESTIGATIONS AND PRESERVING ATTORNEY-CLIENT PRIVILEGE
Internal Investigations

• An Internal Investigation is a formal inquiry to determine whether organizational policies, laws, and/or regulations have been violated.

• The alleged misconduct can be:
  – Prompted by a government subpoena, CID, inquiry, or raid
  – Discovered through compliance reviews and/or routine audits
  – Reported internally by whistleblowing employees (directly or anonymously)
  – Discovered through patient complaints
  – Reported externally by business partners, vendors, subsidiaries, competitors, civil litigants, or the media

• It is appropriate to tailor and target an investigation without “boiling the ocean”—subject to making adjustments as new evidence or issues arise.
Internal Investigations Are Fact-Gathering Exercises

- Internal investigations are key components to crisis-management plans and are the primary means to address and respond to credible allegations of misconduct.

- Trying to identify the nature of the alleged misconduct and who is implicated:
  - Are there any steps that you need to take to identify the misconduct (e.g., high-level complaint without much detail but merits further investigation)?
  - Is the misconduct unlawful?
  - Is the misconduct ongoing?
  - Does the misconduct involve senior management or officers?
  - Where did the misconduct occur (geographical location)?

- Legal advice is only as good as the facts on which it is based.
Benefits of a Properly Conducted Internal Investigation

- Early and accurate assessment of potential legal exposure and disclosure obligations.
- Identification, discipline, and/or removal of the bad actors.
- Reflection of the hospital’s/healthcare entities’ commitment to ethics/compliance.
- Protection for directors, officers, and/or senior management.
- Mitigation of reputational impact.
- Enhanced credibility with law enforcement authorities.
- Reduced risk of a more intrusive government investigation.
- Potential of reduced multipliers, damages, fines, penalties, etc.
- Potential of more favorable releases from government in settlement process.
- Potential avoidance of a Corporate Integrity Agreement (CIA).
Four-Step Process to Conducting Internal Investigations

1. Development of an Investigative Plan
2. Collection/Review of Evidence
3. Analysis and Reporting
4. Recommendations/Remedial Actions (varies)
Key Considerations for Every Investigation

• Analyze the materiality of the risks involved and the potential liability in all areas (e.g., civil, criminal, regulatory, reputational).

• Ensure compliance with local laws, regulations, contractual terms, and internal policies including any employment-related policies and procedures, data protection laws, and whistleblower protection.

• Maintain discretion, confidentiality, and privilege. Know the privilege laws in the jurisdiction involved.

• Ensure that every investigation is impartial, independent, fair, and sufficiently rigorous, and is perceived to be of integrity.

• As investigations progress, regularly review potential outcomes and consequences (possible civil, regulatory, or criminal claims; pros and cons of self-reporting; disciplinary actions against employees and potential impact on client’s business, contracts, and other civil law obligations).
Immediate Crisis Response: Key Considerations

• Need to isolate the target from the conduct under investigation to ensure that the hospital/healthcare entity is not exposed to continuing liability.

• Suspend or reassign employees as appropriate, taking into account applicable employment laws and an employee’s terms and conditions of employment.

• Remove and/or secure any potentially relevant physical and electronic documents within the individual’s control, taking into account the applicable privacy laws.

• Assess whether there are any immediate disclosure obligations, and to whom they should be made.

• Assess whether there are any public statements or filings that need potential clarification to protect interests of the client.

• Evaluate the need to communicate with employees, recognizing that maintaining confidentiality should be the preferable outcome so that an effective internal investigation can be conducted.
Framework for Establishing and Protecting Attorney-Client Privilege

- The appropriate client representative (GC, fiduciary, senior manager, etc.) should prepare a memorandum directing in-house or outside counsel to conduct a confidential investigation for purposes of providing legal advice to the hospital/healthcare entity.

- Counsel should confirm in writing that they have received the internal investigation request, along with a brief outline of the direction of the investigation.

- Counsel should advise those working on the investigation in writing that (i) they have been asked to assist with the investigation; (ii) they are to treat all information as privileged and confidential; (iii) they should not discuss their work or findings with others; (iv) they should not make copies of their notes or work papers for sharing with others; and (v) they should mark all investigative notes, reports, documents, and communications, including email correspondence, as “Privileged and Confidential.”

- Employees assisting with the investigation should be instructed to report to the lawyers directly and not through their usual chain of command.
Upjohn Warnings

- *Upjohn Co. v. United States*, 449 U.S. 383 (1981), requires that employees in corporate internal investigations be advised that the lawyer (in-house or outside counsel) represents only the hospital/healthcare entity and not the employee individually, that the attorney-client privilege belongs solely to the hospital/healthcare entity, and that the hospital/healthcare entity may choose to waive the privilege and disclose the employee’s statements to a government agency or other third party.

- Rule 1.13 of the Pennsylvania Rules of Professional Conduct provides that a lawyer retained to represent an organizational client, when “dealing with an organization’s directors, officers, employees, members, shareholders or other constituents, [] shall explain the identity of the client when the lawyer knows or reasonably should know that the organization’s interests are adverse to those of the constituents with whom the lawyer is dealing.”

- Must provide clear *Upjohn* warnings about whom you represent, who possesses the privilege, and the purpose of the interview (gathering facts to provide legal advice to the client).
Witness Interviews and Privilege

• DOJ requires that companies seeking cooperation credit disclose all relevant facts regarding individual misconduct.

• While the Department recognizes the “extremely important function[s]” of the attorney-client privilege and attorney-work-product protection, “[w]hat the government seeks and needs to advance its legitimate (indeed, essential) law enforcement mission is not waiver of those protections, but rather the facts known to the corporation about the putative criminal misconduct under review.”

• Justice Manual provision 9-28.710 contains a clear statement that prosecutors should not ask companies seeking cooperation credit to waive attorney-client privilege and attorney-work-product protection.
Waiver Risks in Self-Disclosures


Strategies to Minimize Waiver Risks

• Seek a confidentiality agreement or protective order.

• Provide information to government with express caveat that any waiver of attorney-client privilege or work-product protection is limited to the subject of the disclosure.

• Take a thematic approach to presentation.

• Use hypotheticals to discuss and outline areas of concerns.

• Focus on providing historical facts without witness-specific quotes and attributions of information.

• Rely on documents and emails to convey facts.
REVIEW OF RECENT CASES
FCPA – Top 5 Issues in Supply Chain Management

1. Increasing international enforcement and coordination in supply chain misconduct cases.

2. Engaging with third-party vendors who are essential to global operations.
   – payment terms, fees for no services rendered, vendor related to employee or relative

3. Avoiding and managing high-risk transactions that can lead to enforcement scrutiny.
   – customs, promotional activities (e.g., travel and entertainment), joint ventures, mergers and acquisitions


5. Operating in high-risk countries where your business model presents no other viable option.
Relevant FCPA Cases

- **March 2018** – A Maryland-based logistical support services company for the transportation of nuclear materials entered into a deferred prosecution agreement (DPA) with DOJ and agreed to pay $2 million to resolve criminal FCPA allegations that it paid bribes to an official of a Russian-owned nuclear company to secure lucrative transportation contracts. Two company executives and the Russian official were individually charged.

- **January 2017** – A Chilean-based chemical and mining company entered into a DPA and agreed to pay more than $30 million to DOJ and SEC to resolve allegations that it violated the anti-bribery, books and records, and internal controls provisions of the FCPA by making illegal payments to politically connected individuals for purposes of securing business, which were disguised in company books and records as legitimate vendor payments even though no goods or services were actually received.

- **January 2017** – A global snack food company agreed to pay $13 million to settle FCPA charges that its India subsidiary violated the internal controls and books-and-records provisions when it retained an agent to engage with government officials for purposes of obtaining licenses and approvals for a new factory. The SEC’s investigation revealed that company employees—not the agent—had actually prepared license applications invoiced by the agent to the company for payment. In addition to failing to maintain accurate books and records as to the agent’s work, the SEC determined that the company failed to implement adequate internal controls, which increased the risk that payments to the agent could be used for improper or unauthorized purposes.
Some More FCPA Cases

• **January 2017** – An Indiana-based medical device manufacturer agreed to pay $30 million to resolve civil and criminal FCPA violations, just five years after it paid a $23 million FCPA settlement. The company pled guilty to knowingly and willfully using a third-party distributor in Brazil to bribe government officials. A Mexican subsidiary also bribed Mexican customs officials through customs brokers and sub-agents to allow the subsidiary to import products without proper registration or labeling.

• **December 2016** – A Kentucky-based wire and cable manufacturer entered into a non-prosecution agreement (NPA) and agreed to pay more than $75 million to DOJ and SEC to resolve anti-bribery and accounting violations related to its foreign subsidiaries using third-party agents and distributors to pay bribes to foreign officials to secure business in Angola, Bangladesh, China, Egypt, Indonesia, and Thailand.

• **September 2016** – A global pharmaceutical company agreed to pay $20 million to the SEC in order to settle FCPA charges that its Chinese subsidiaries transferred money and gifts to healthcare professionals in exchange for increased drug sales to the Chinese government. Third-party vendors, ostensibly providing legitimate services, colluded in the scheme with company employees where the illegal payments were disguised in the company’s books and records as legitimate travel and entertainment expenses, and payments to speakers and medical associations.
October 2017 – Chemed Corp. and its wholly owned subsidiary, Vitas Hospice Services, agreed to pay $75 million to settle allegations that it billed Medicare for services rendered to hospice patients who were not terminally ill as required under Medicare’s hospice benefit rules and regulations, and that the company rewarded employees with bonuses for the number of patients receiving hospice services without regard to whether the patients were actually terminally ill and whether the patients would have benefited from further curative care.

December 2017 – Pine Creek Medical Center, a physician-owned hospital, agreed to pay $7.5 million to settle allegations that it paid kickbacks to physicians in the form of marketing and advertising services in exchange for the physicians referring Medicare and TRICARE patients to the medical center for surgical procedures.

December 2017 – 21st Century Oncology, a provider of integrated cancer care, agreed to pay $26 million following a self-disclosure to settle allegations that it submitted false attestations that its physicians utilized electronic health records (EHR) software under an EHR incentive program that would allow the company to avoid downward adjustments to certain Medicare claims for using EHR technology, and to settle allegations that it submitted claims for certain services rendered by physicians whose compensation did not fall within any exception to the Stark Law.
FCA Healthcare Settlements FY 2018

- **January 2018** — Aegerion Pharmaceuticals Inc. pled guilty to misdemeanor FDCA charges relating to the promotion of its prescription drug, Juxtapid, and also agreed to pay $36 million to settle criminal and civil allegations that it caused false claims to be submitted to the government through its promotion of Juxtapid in violation of the federal and state FCAs.

- **March 2018** — Alere, a medical device company, agreed to pay $33.2 million to settle allegations that it caused hospitals to submit false claims to Medicare, Medicaid, and other federal healthcare programs for point-of-care testing devices that rendered unreliable results and adversely affected clinical decision making, after the company received customer complaints and failed to take corrective actions until FDA inspections prompted a nationwide recall.
October 2016 — Life Care Centers of America Inc., and its owner, Forrest L. Preston, agreed to pay $145 million to settle allegations that they caused skilled nursing facilities to submit false claims for payment to the government for services that were not reasonable, necessary, or skilled, in violation of the FCA.

May 2017 — eClinicalWorks, one of the country’s largest electronic health records software vendors, and certain of its employees, agreed to pay $155 million to settle allegations that they falsely obtained certification for software by concealing from the certifying entity that the software did not comply with the certification requirements.

May 2017 — CareCore, a benefits management company, agreed to pay $45 million to settle allegations that CareCore authorized more than 200,000 medical diagnostic procedures without assessing whether the procedures fell within national coverage criteria.

May 2017 — Freedom Health, a Florida-based provider of managed care services, agreed to pay $31.7 million to settle allegations that the company engaged in an illegal scheme to maximize payments from the government by submitting unsupported diagnosis codes to CMS, which resulted in inflated reimbursements for two of its Medicare Advantage plans operating in Florida.

August 2017 — Mylan Inc. and Mylan Specialty L.P. paid $465 million to settle allegations brought in a qui tam action that they violated the FCA by “misclassifying” EpiPen as a generic drug in an effort to avoid paying rebates owed to Medicaid. The whistleblower in this case, Sanofi-Aventis (a competitor of Mylan’s), received around $38.7 million.
QUESTIONS?
Thanks!

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