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<p><b>Compliance Education and Enforcement:  Engaging Leadership Amid Government Scrutiny</b></p> <p><b>November 6, 2018</b></p>	
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<p><b>Agenda</b></p> <ul style="list-style-type: none"> <li>▪ Setting the Table: What is the Enforcement Environment?</li> <li>▪ Corporate Board Responsibilities</li> <li>▪ Special Considerations Amid Government Scrutiny</li> <li>▪ Takeaways and Recommendations</li> </ul>
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<p><b>What Is The Enforcement Environment?</b></p>
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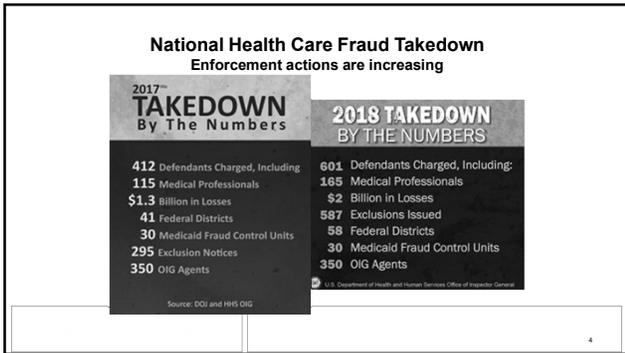
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### The Yates Memo

- Issued in 2015
- Directs prosecutors to:
  - Focus on **individuals** in investigating allegations of corporate misconduct, and
  - To hold **individuals** accountable in resolving criminal prosecutions and civil actions arising out of corporate misconduct.



The Yates Memo is a memorandum from the U.S. Department of Justice, Office of the Deputy Attorney General, dated November 9, 2015. It is addressed to the Assistant Attorneys General, Assistant Deputy Attorneys General, and the Assistant Attorneys General, National Offices. The memo states that the Department will hold individuals accountable in resolving criminal prosecutions and civil actions arising out of corporate misconduct. It emphasizes that the Department will focus on individuals in investigating allegations of corporate misconduct, and that it will hold individuals accountable in resolving criminal prosecutions and civil actions arising out of corporate misconduct. The memo also states that the Department will continue to hold individuals accountable in resolving criminal prosecutions and civil actions arising out of corporate misconduct.

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### FY2017 Civil Enforcement Increasing Focus on Individual Accountability

- Drug manufacturer **Mylan Inc.** paid approximately \$465 million to resolve allegations that it underpaid rebates owed under the Medicaid Drug Rebate Program by erroneously classifying its patented brand name drug EpiPen – which has no therapeutic equivalents or generic competition – as a generic drug to avoid its obligation to pay higher rebates.
- Life Care Centers of America Inc.** and its owner agreed to pay \$145 million to settle allegations that it caused skilled nursing facilities to submit false claims for rehabilitation therapy services that were not reasonable, necessary, or skilled.
- eClinicalWorks (ECW)** – a national electronic health records software vendor – and certain of its employees paid \$155 million to resolve allegations that they falsely obtained certification for the company's electronic health records software
- Shire Pharmaceuticals LLC** paid \$350 million to settle allegations that kickbacks were used to promote its skin substitute product Dermagraft, resulting in the submission of false claims to the government.

Justice Department Recovered Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017, DOJ Press Release (Dec. 21, 2017)

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**FY2017 Civil Enforcement  
Increasing Focus on Individual Accountability**

- Drug manufacturer **Mylan Inc.** paid approximately \$465 million to resolve allegations the Program by el – which has n – by **Mylan board members and executives** in generic drug to avoid its obligation to pay higher rebates.
- **Life Care Centers of America Inc. and its owner** agreed to pay \$145 million to settle allegations that it caused skilled nursing facilities to submit fals nee
- **Shire**: In addition to this landmark civil settlement, Mr. Bentley's office continues to work diligently to bring to justice those individuals responsible for these illegal actions. Already, the MDPL has obtained the criminal convictions of three high-level executives who supervised the implementation of the illegal kickback scheme, as well as a number of healthcare providers who received kickbacks.

Justice Department Recovered Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017, DOJ Press Release (Dec. 21, 2017)

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**Opioid Enforcement**

- **Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose** (OEI-02-17-00560)
  - provides detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose
  - Medicare Part D plan sponsors, private health plans, and State Medicaid Fraud Control Units
- **Opioid Use in Medicare Part D Remains Concerning** (OEI-02-18-00220), identified about 71,000 Part D beneficiaries who were at serious risk of misuse or overdose.
  - receiving extreme amounts of opioids
  - "doctor shopping," i.e., receiving high amounts of opioids from multiple prescribers and multiple pharmacies

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**CORPORATE BOARD RESPONSIBILITIES**

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**Corporate Governance Responsibilities  
Fiduciary Duties of Directors**

- A Director has three basic duties to a Corporation:  
**Duty of Loyalty    Duty of Care    Duty of Obedience**
- A Director must perform his/her duties:
  - In good faith; and
  - In a manner he/she reasonably believes to be in the best interests of the corporation; and
  - With the care an ordinarily prudent person would exercise under similar circumstances.

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**Corporate Governance Responsibilities  
Duty of Care**

- **Use reasonable care** in making organizational decisions.
- **Exercise a degree of skill and diligence** that reasonably can be expected from someone of the director's knowledge and expertise.
- **Attend meetings and diligently review materials** provided in advance of meetings.

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**Corporate Governance Responsibilities  
Duty of Care**

- Examine, Understand and Monitor:**
- All governance documents and policies
  - Corporate purposes and mission
  - Organizational structure, activities and key management personnel
  - Financial statements and reports
  - Key laws that impact organizational activities

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**Corporate Governance Responsibilities  
Oversight and Monitoring**

**In re Caremark International Inc. Derivative Litigation,**  
**964 A.2d 106 (Del. Ch. 1996)**

- Caremark International's shareholders sued the Board of Directors for a breach of fiduciary duty.
- The alleged breach involved a failure to prevent payments made by employees in exchange for patient referrals in violation of the anti-kickback law.
- The underlying conduct resulted in the company entering into a \$250 million settlement agreement with the government.

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**Corporate Governance Responsibilities  
Oversight and Monitoring**

**In re Caremark International Inc. Derivative Litigation**  
(continued)

- The oversight responsibilities encompassed by the duty of care extend to compliance programs.
- The mere establishment of a compliance program is not enough.
- "It is important that the board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations."
- Failure to provide adequate oversight can render a director liable for losses caused by non-compliance.

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**Corporate Governance Responsibilities  
Reasonable Inquiry**

- Board not required to exercise "proactive vigilance" or "ferret out" corporate wrongdoing absent a "Red Flag".
- Reliance on others for information and answers is appropriate:
  - Competent officers and employees
  - Legal counsel, accountants, and others with professional expertise
  - Board committees as to matters within their designated authority

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**Corporate Governance Responsibilities  
Reasonable Inquiry**

- Cannot be passive and must make reasonable inquiries when "Red Flags" come to the director's attention:
  - Healthy skepticism and questioning
  - Clarification regarding issues and impact of decisions
  - What would an ordinarily prudent person want to know under the circumstances?

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**Corporate Governance Responsibilities  
Business Judgment Rule**

- No liability where a director acts in good faith and with the belief that a decision is in the company's best interests.
- Presumption of good faith absent "reckless indifference or deliberate disregard" of information (i.e., Red Flags).
- Director may not be held liable for unfavorable outcomes or "bad decisions" when he/she acts in good faith and in the same manner as a reasonably prudent person.
  - Insulate from court intervention those management decisions which are made by directors in good faith in what the directors believe is the organization's best interest.
  - Limit retroactive judicial "second guessing" even if the directors were wrong.

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**SPECIAL CONSIDERATIONS  
AMID GOVERNMENT SCRUTINY**

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### Internal Reporting to the Board

- Who is involved in the following?
  - Identifying compliance risks
  - Investigating compliance risks
  - Identifying and implementing appropriate corrective actions and decision-making
- How do the departments in your organization communicate throughout the process?
- How is the Board informed?

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### What Information Reaches the Board?

- No right answer. It will depend on size, structure, resources, industry.
- Consultation with outside regulatory, compliance, or legal professionals
- Regular reporting of predetermined data
- Risk-based reporting
- Multiple reporting streams
- Dashboards with pre-defined risk areas

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### What Constitutes a Red Flag?

- Internal complaint
- Patient complaint
- Letter or call from a competitor
- Concerning audit results
- Employee wrongdoing
- Unflattering news coverage?
- Subpoena or search warrant
- Payment suspension
- Receipt of a redacted complaint
  - Top executives are named as defendants
- Presentation or offer of settlement

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### Unique Challenges

- When company is reliant on Board for financing.  
– *e.g., investors, donors, and volunteers.*
- Allegations of misconduct by executives or executives named as defendants.
- When a decision is made to make employment changes due to or during an investigation.

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### Reporting Amid Government Scrutiny

- What are the triggers for Board notification?
- Do reporting standards change based on circumstances?
- When does outside counsel report to the Board?
- When is it appropriate for the Board to engage outside independent counsel, as opposed to working with their general counsel or regular outside counsel?
- Do allegations of executive misconduct create a conflict that necessitates external or independent investigation and reporting?

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### Big Red Flags

- If the government specifically asks to speak with the Board, including while under a CIA.
- Allegations by the government of executive involvement or executives named as defendants.
- If the company is informed that there is an active criminal investigation of the company or its employees.  
– Potential for mandatory exclusion
- "Warnings" of Counsel ("potential violation, but likelihood of enforcement is low or no enforcement to date")

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**TAKEAWAYS AND RECOMMENDATIONS**

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**Takeaways and Recommendations**

1. Adopt a Compliance Program

- Corporate compliance program is foundational.
- Program should be structured based on the OIG Compliance Program Guidance and the Seven Elements.
- Board must ensure that the program operate in practice and not simply exist on paper.

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**Takeaways and Recommendations**

Benefits of Robust Corporate Compliance Program:

- Detect Noncompliance Early
- Lesser Criminal Penalties for an Organization under the Federal Sentencing Guidelines
- Potentially Mitigates Corporate Liability, Resulting in Reduced Civil Penalties Imposed by OIG or DOJ
- Evidence that the Board is Meeting its Fiduciary Duty (Reducing Risk of Personal Liability for Board Members)

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**Takeaways and Recommendations**

2. Monitor Potential Risk Areas

- Internal audit work plans should reflect the risk areas and enforcement priorities identified by the OIG.
- Industry trends and practices should be closely watched and addressed.
- Establish reporting mechanisms
  - Risk-based reporting
  - Multiple streams of information

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**Takeaways and Recommendations**

3. Respond to "Red Flags"

- Reasonable inquiry when suspicions arise.
- Establish a direct reporting relationship between the company's Chief Compliance Officer and the Board.
- Establish special reporting processes when triggering events occur.
- Management's response to compliance issues should be well-documented.

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**Takeaways and Recommendations**

4. Ensure Board Compliance Education

- A Board needs to be educated and engaged on compliance-related matters.
- Directors should familiarize themselves with:
  - Various OIG guidance for governing Boards; and
  - Industry trends.

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**Takeaways and Recommendations**

- 5. Engage Outside Consultants and Experts
  - A Board should use outside experts on compliance-related matters when necessary.
  - Engaging consultants can demonstrate a Board's commitment to ensuring that compliance-related issues are addressed in an independent manner.
  - *Particularly important when under investigation.*

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**Takeaways and Recommendations**

- 6. Address Conflicts Between Companies and their Officers/Employees
  - Yates Memo threatens to create conflicts between corporations and their officers and employees.
  - Provide clear direction to employees.
  - Possible need to exclude key stakeholders from internal investigations.

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**Takeaways and Recommendations**

- 7. Modify a Compliance Program to Address Individual Liability
  - A compliance program that targets and remedies systemic failures may no longer be enough.
  - Review policies/practices to ensure that individuals are required to cooperate in investigations, and assess what the company may do with information gained through internal audits.

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**Takeaways and Recommendations**

- 8. Limitation on Ability to Conduct Detailed Internal Investigations
  - Time is short to maximize cooperation credit.
  - "Once a company has made a preliminary assessment that criminal conduct has likely occurred, it should promptly report the matter to the government if it desires mitigation credit for voluntary self-disclosure."

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**Takeaways and Recommendations**

- 9. Threats to Attorney-Client Privilege/Attorney Work Product Doctrine
  - A company's investigation regarding potential misconduct is usually done under the attorney-client privilege and attorney work product protection.
  - Waivers when turning over results of internal investigations.
  - Yates Memo raises the stakes since a company that is unwilling to share investigative work may not get any cooperation credit.

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**Takeaways and Recommendations**

- 10. Review Indemnity and Insurance Protections
  - Review corporate bylaws to assess if company is obligated to indemnify and advance expenses to employees and management.
  - Review insurance coverages to ensure that policy limits and language are adequate to cover the company's risk profile in the new enforcement environment.

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**Questions?**

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206-615-2092

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**HHS-OIG Resources**

1. *Practical Guidance for Health Care Governing Boards on Compliance Oversight (2015)*, available at <https://oig.hhs.gov/compliance/compliance-guidance/docs/practical-guidance-for-health-care-boards-on-compliance-oversight.pdf>
2. *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007)*, available at <https://www.oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>
3. *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors (2004)*, available at <https://oig.hhs.gov/fraud/docs/complianceguidance/tab%204e%20appendx-final.pdf>
4. *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (2003)*, available at <https://oig.hhs.gov/fraud/docs/complianceguidance/040203corpresprsceguide.pdf>

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**DOJ Resources**

U.S. Department of Justice, Evaluation of Corporate Compliance Programs (February 2017), available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

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