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Board Fiduciary Duty of Care and Individual Liability

Health Care Compliance Association
Regional Compliance Conference

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Agenda

- Enforcement Environment
- Corporate Board Governance Responsibilities
- OIG/DOJ Guidance
- Recent Enforcement Actions Involving Individuals
- Takeaways and Recommendations

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Enforcement Environment

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Enforcement Environment

National Health Care Fraud Takedown
Enforcement Actions Increasing

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CORPORATE BOARD GOVERNANCE RESPONSIBILITIES

Corporate Board 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.

Corporate Board 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.

Corporate Board Governance Responsibilities

Duty of Care

- **Examine, Understand and Continually 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

Corporate Board 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.

Corporate Board 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.

Corporate Board 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 Board Governance Responsibilities

Reasonable Inquiry

What Information Reaches the Board?

- No one answer. It will depend on size, structure, resources, industry.
- Regular reporting of predetermined data
- Risk-based reporting
- Multiple reporting streams
- Dashboards with pre-defined risk areas

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Corporate Board Governance Responsibilities

Reasonable Inquiry

- Cannot be passive
- 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 Board Governance Responsibilities

Reasonable Inquiry

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
- Presentation or offer of settlement

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Corporate Board Governance Responsibilities

Reasonable Inquiry

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.
- "Warnings" of Counsel ("potential violation, but likelihood of enforcement is low or no enforcement to date")

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Corporate Board 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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OIG/DOJ Guidance

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OIG/DOJ Guidance

OIG Compliance Program Guidance

- Based on Federal Sentencing Guidelines
- Internal Controls – 7 Elements of an Effective Corporate Compliance Program:
  - ✓ Compliance Leadership
  - ✓ Policies & Procedures
  - ✓ Training & Education
  - ✓ Lines of Communication
  - ✓ Monitoring & Auditing
  - ✓ Publicized Disciplinary Guidelines
  - ✓ Responding to Problems

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OIG/DOJ Guidance

OIG Guidance for Health Care Governing Boards

- Various Resource Documents Issued by OIG Since 2003 for Boards of Health Care Organizations
- Overview of the Fundamental Duties Owed by Board Members with Regard to Operation of a Compliance Program
- Focus on Risk Areas, Reporting and Use of Outside Experts

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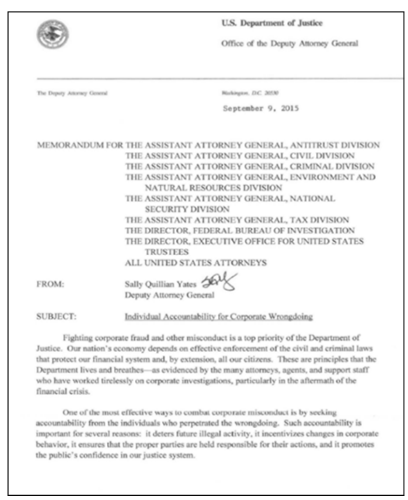
OIG/DOJ Guidance

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.


U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

September 9, 2015

MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION
THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION
THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND NATURAL RESOURCES DIVISION
THE ASSISTANT ATTORNEY GENERAL, NATIONAL SECURITY DIVISION
THE ASSISTANT ATTORNEY GENERAL, TAX DIVISION
THE DIRECTOR, FEDERAL BUREAU OF INVESTIGATION
THE DIRECTOR, EXECUTIVE OFFICE FOR UNITED STATES TRUSTEES
ALL UNITED STATES ATTORNEYS

FROM: Sally Quillian Yates
Deputy Attorney General

SUBJECT: Individual Accountability for Corporate Wrongdoing

Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.

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OIG/DOJ Guidance

Yates Memo

Principle #1 - To be Eligible for Any Cooperation Credit, Corporations Must Provide to DOJ All Relevant Facts About the Individuals Involved in Corporate Misconduct

- Companies under investigation must provide full disclosure of all facts and individuals involved in the misconduct in order to receive any cooperation credit from the government.
- If a company refuses to divulge information, or only provides minimal information about the individuals involved, the company will not receive any partial credit for its cooperation in an investigation.
- Continued cooperation in ongoing investigations involving individuals will be a condition for any corporate resolution.
- Prosecutors are instructed to proactively scrutinize board members' roles and review all disclosures from companies in detail to ensure that no director's role has been minimized.

OIG/DOJ Guidance

Yates Memo

Principle #2 - Criminal and Civil Corporate Investigations Should Focus on Individuals From the Inception of the Investigation

- DOJ attorneys are instructed to focus on individual wrongdoing from the beginning of a corporate investigation to its resolution.
- Potential for leveraging lower level employees with knowledge of the alleged wrongdoing to cooperate with DOJ and identify more senior corporate officials with alleged culpability.
- Approach may increase the likelihood that the final resolution of an investigation uncovering misconduct involving a company will include civil or criminal charges against individual wrongdoers.
- Officers and board members can be a focus from the outset of investigations.

OIG/DOJ Guidance

Yates Memo

Principle #3 - Criminal and Civil Lawyers Handling Corporate Investigations Should be in Routine Communication with One Another

- Criminal and civil prosecutors to stay in close contact with each other on matters that they're jointly investigating.
- Intended to assist DOJ in fact gathering and enforcement efforts.
- This directive has a goal of guaranteeing that the full breadth of remedies are available in each case of corporate wrongdoing.

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OIG/DOJ Guidance

Yates Memo

Principle #4 - Absent Extraordinary Circumstances, No Corporate Resolution Will Provide Protection from Criminal or Civil Liability for Any Individuals

- Absent "extraordinary circumstances," a resolution or settlement agreement between the DOJ and a corporation will not dismiss civil or criminal liability for individuals involved in the misconduct.
- Prosecutors are required to seek written approval from the Attorney General's Office or United States Attorney's Office before releasing individuals from criminal or civil liability as part of resolving a corporate investigation.
- Civil DOJ investigators are now firmly discouraged from agreeing to release officers, directors, and employees from individual civil liability as a condition of a corporate resolution.

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OIG/DOJ Guidance

Yates Memo

Principle #5 - Corporate Cases Should Not be Resolved Without a Clear Plan to Resolve Related Individual Cases Before the Statute of Limitations Expires, and Declinations as to Individuals in Such Cases Must be Memorialized

- Investigators should not resolve corporate cases without a plan to pursue potential claims against individuals.
- Plans should set forth the status of the action, what investigative work remains, and a schedule to complete the investigation before the applicable statute of limitations runs.
- The investigating office must memorialize why charges were not pursued against individuals.

OIG/DOJ Guidance

Yates Memo

Principle #6 - DOJ Civil Lawyers Should Consistently Focus on Individuals as Well as the Company and Evaluate Whether to Bring Suit Against an Individual Based on Considerations Beyond That Individual's Ability to Pay

- An individual's ability to pay potential fines or penalties is no longer to be considered when deciding whether to pursue claims or charges against them.
- Change from past policy where DOJ civil attorneys considered an individual's financial resources and ability to pay damages before naming them as a defendant in a civil lawsuit.
- The decision to file charges should reflect factors such as the seriousness of the individual misconduct, whether it is actionable, whether a judgment could be obtained against the individual, and whether an important federal interest is served by bringing an action against the individual.

Recent Enforcement Actions Involving Individuals

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Recent Enforcement Actions Involving Individuals

- **U.S. v. Reichel**, D. Mass., No. 1:15-cr-10324 -The former President of pharmaceutical manufacturer Warner-Chilcott was indicted on criminal charges for an alleged kickback scheme, DOJ News Release (Oct. 29, 2015).
- **U.S. ex rel. Kieff v. Wyeth Pharmaceuticals, Inc.**, D. Mass., No. 03-cv-2366, 06-cv-11724 - This case involved an alleged failure to provide the Medicaid program with appropriate drug price rebates. A settlement with the government in April 2016 resulted in a Corporate Integrity Agreement requiring the company to cooperate with ongoing and future investigations of individuals who were not released in the settlement, and to make directors, officers and employees available to the government for interviews and produce non-privileged documents concerning conduct covered in the settlement.
- **Tuomey Healthcare** - Following a corporate resolution, the former CEO settled his own liability for $1 million and agreed to a four-year period of exclusion from participating in federal health care programs, DOJ News Release (Sept. 27, 2016).
- **MD2U** - Company executives included in a False Claims Act settlement where a home health agency allegedly administered home care visits to patients who weren't homebound, DOJ News Release (July 7, 2016).

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Recent Enforcement Actions Involving Individuals

- **Mylan** - 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 as a generic drug. CIA imposes specific compliance obligations for Board Members.
- **Life Care Centers of America Inc.** - Company 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. No releases for individuals. Criminal convictions of three executives overseeing the kickback scheme.

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

TAKEAWAYS AND RECOMMENDATIONS

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.
- 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)

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

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.

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.

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.

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."

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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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

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.

Questions?

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