

High Anxiety: A Prescription for Compliance Officer Burnout from the Psychoneurotic Institute for the Very, Very Nervous

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Jeff Miller, Esq.

- Attorney since 1995 with an emphasis on corporate and commercial work, regulatory and compliance matters
- Biomet, Johnson & Johnson, Synthes, Mercy Health System of Southeastern PA, private practice
- Large and complex mergers, acquisitions and integrations (>20B), managing DPAs, negotiating and managing CIAs, and designing, building and leading compliance functions worldwide
- Frequent author and speaker; PBI, ABA, AHLA, HCCA, SCCE, Temple, Ethisphere Institute; Member of the Wolters Kluwer Health Law Advisory Board

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Agenda

- Challenges to compliance program efficiency and effectiveness
- Emerging trends in corporate compliance
- Enhancing compliance and increasing efficiency through corporate governance, executive leadership and appropriate financial incentives

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Challenges Cited by Compliance Officers and In-House Counsel

- Keeping current on a vast array of legal, regulatory and industry and professional requirements
- Knowing and keeping current with a broad scope of business strategies and dynamics
- Obtaining and maintaining business buy-in to problems and solutions
- Gaining and maintaining sufficient traction to move compliance initiatives forward priorities
- Avoiding/managing conflicts of interest when supporting compliance-related activities v. monitoring those activities
- Insufficient resources in the department

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Individual Liability - RCO

- Corporate officers and managers can be found liable by reason of their responsibility and authority prevent and correct certain violations
 - In *United States v. Dotterweich* the Supreme Court held that the president of a corporation could be found criminally liable under the FDCA for shipping adulterated or misbranded drugs
 - Criminal liability is extended to anyone with "a responsible share in the furtherance of the transaction which the statute outlaws," and includes the duty to implement measures to ensure that violations do not occur

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Individual Liability - RCO

- United States v. Park* upheld the conviction of the chief executive officer of a national grocery chain for violating the FDCA because a food warehouse of the chain was contaminated by rodents
 - The failure to prevent a violation is a strict liability offense - whether or not the officer or manager was aware of the conduct
 - Exceptions: defendants cannot be held liable where: (1) the defendants were "powerless" to prevent or correct the violations; or (2) correcting or preventing the violations was "objectively impossible."

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Individual Liability - Debarment

- OIG Exclusionary Authority (CMPL) - 42 U.S.C. § 1320a-7(b)**
- An Officer or a Managing Employee**
 - A general manager, business manager, administrator or director **who exercises operational or managerial control** over the entity, or who **directly or indirectly conducts the day to day operations** of the entity
 - Permission exclusion - individual knew or should have known of the sanctioned conduct

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Individual Liability - Other Standards

- Prosecution history generally limited to instances deemed to involve wrongful conduct**
 - Note: Financial services industry = can be liable under a "failure to supervise" standard (failed to take sufficient action where the violation(s) "likely would have been prevented or detected")
- Yates Memo**
 - United States Attorney's Manual in the Principles of Federal Prosecution of Business Organizations
 - Increases emphasis on the prosecution of individuals

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Challenges Cited by Compliance Officers and In-House Counsel

- Keeping current with requirements
- Keeping current with business strategies and dynamics
- Business buy-in (including gaining and maintaining sufficient traction to move initiatives forward)
- Avoiding/managing conflicts of interest
- Insufficient resources in the department
- Potential individual prosecution/liability under the RCO under a "failure to prevent" theory, under the CMPL under a "knew or should have known" theory, or by being deemed to have exercised operational or managerial control over improper activities within a business function

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Emerging Trends in Compliance

1. Boards of Directors
2. Executive Leadership/Oversight
3. Financial Incentives

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Boards of Directors

- Competence
- Responsibility

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Boards of Directors

- Competence
 - Greater than 50% of CIAs since 2009 required 1-3 hours of initial board training, and ongoing training

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Boards of Directors

Responsibility

- Greater than 80% of CIAs since 2009 require annual board resolutions focused on overseeing compliance and compliance program effectiveness

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Common Resolution Language

The Board of Directors has made a **reasonable inquiry** into the operations of []'s Compliance Program including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry, the Board has concluded that, to the best of its knowledge, [] has implemented an **effective Compliance Program** to meet the Federal health care program requirements and the obligations of the CIA.

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Boards of Directors

Who decides whether the CEO and senior management team is effectively supporting the compliance program?

- Setting the tone?
- Setting the example?
- Providing resources?

Directors who are also Executives?	Directors who are not Executives?
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Boards of Directors

Independence -

Independent directors overseeing organizational compliance

v.

Independent experts to advise directors overseeing organizational compliance

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Independent Director Language

The Board of Directors currently has, and shall maintain during the term of the CIA, a Committee or other authorized subcommittee comprised of **independent (i.e., non-executive) directors** (hereinafter Board Committee). The Board Committee is responsible for the **review and oversight of matters related to compliance** with Federal health care program requirements and the obligations of this CIA.

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Independent Expert Language

The Board of Directors shall arrange for the performance of **a review of the effectiveness of []'s Compliance Program** for each Reporting Period. The Board shall retain an **independent individual or entity with expertise in compliance** with Federal health care program requirements to perform this review. This Compliance Expert shall create a work plan, perform the review, and prepare a written report. The written report shall include a description of the review and shall include recommendations with respect to the Compliance Program.

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What does it all mean?

- "I didn't understand" not acceptable
- "I didn't know" not acceptable
 - Accountable to government authorities (and shareholders, etc.)
- Objective viewpoint of compliance program effectiveness required

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2. Executive Team

- Competence
- Responsibility

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Executive Leadership/Oversight

- Competence
 - Over 50% of CIAs since 2009 require 1-2 hours of executive training (in addition to other training)

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Executive Leadership/Oversight

Responsibility

- Greater than 70% of other CIAs since 2009 require annual executive "Certifying Employee" certifications

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Common Senior Executive Certification Language

I have been trained on and **understand the compliance requirements and responsibilities** as they relate to (department or functional area), an area under my supervision. **My job responsibilities include ensuring compliance** with regard to the (department or functional area), and I have taken steps to **promote** such compliance. To the best of my knowledge, except as provided herein, the (department or functional area) of [] **is in compliance** with all applicable Federal health care program requirements and the obligations of the CIA.

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What does this all mean?

- "I didn't understand" not acceptable
- "I didn't know" not acceptable
- "That's the Compliance Department's job (or the Legal Department's job)" not acceptable

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3. Financial Incentives

- Colleagues in Key Risk Areas
- Executives

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Key Risk Areas

- Sales and Marketing
 - Greater than 80% FDCA-related CIAs since 2009
- Billing, Kickback or billing-related
 - Greater than 40% of other CIAs since 2009

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Common Language for Key Risk Areas

Product Promotion - [] will develop and implement mechanisms to **exclude compensation from sales** that may indicate off-label promotion.

Sales/Marketing - [] will develop and implement policies and procedures designed to **ensure that financial incentives do not inappropriately motivate** such individuals to engage in improper promotion, sales, marketing, pricing, or contracting.

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Executive Recoupment

- Over the past 5 years increasing numbers of CIAs include provisions recouping executive compensation
 - Forfeiture/recoupment of 3 years of performance pay (annual bonus, long term incentives) for "significant misconduct"
 - Personal misconduct
 - Misconduct of a subordinate (knew or should have known)
- See Materials for Common Language

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What does it all mean?

- Compensation may not encourage inappropriate activities
 - Including a compliance rating in annual performance reviews is not sufficient
- Increased executive financial accountability for organizational oversight and culture

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