



# Enforcement, Compliance Officer, and General Counsel *Roles, Perspectives, and Effective Compliance*



**2022 Enforcement Compliance Conference**  
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*Presented by:*

**Laura Ellis** – Senior Counsel, OIG-HHS

**John Kelly** – Partner and Chair, Healthcare Industry Practice, Barnes & Thornburg LLP

**Shannon Sumner** – Principal and Chief Compliance Officer, PYA, P.C.

# Speaker Introductions



## Laura Ellis

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Laura Ellis has been a senior counsel in the Office of Counsel to the Inspector General at the Department of Health and Human Services (OIG) since 2003.

Her work focuses on advising on health care compliance and monitoring Corporate Integrity Agreements. During her time at OIG, Laura has also handled complex exclusion appeals and negotiated Corporate Integrity Agreements.

When not dreaming of healthcare compliance, she speaks regularly on compliance and a variety of additional topics related to the work of the Office of Counsel to the Inspector General.

# Speaker Introductions



## John Kelly

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John Kelly is a partner, former federal healthcare fraud prosecutor, and chair of the firm's Healthcare Department and Healthcare Industry Practice group. John represents healthcare clients in internal investigations, government investigations, civil False Claims Act litigation, and criminal prosecutions in matters related to healthcare fraud and abuse and compliance issues. John also serves as outside compliance and investigations counsel to health systems and life sciences companies, including some under a Corporate Integrity Agreement. Further, John has extensive experience in the managed care and Medicare Advantage/risk adjustment spaces. John is Chambers ranked and listed as one of Washington, D.C.'s Super Lawyers.

John had a distinguished career as a federal prosecutor with the Department of Justice (DOJ) where he held a number of leadership positions. John is a frequent speaker and writer on healthcare fraud, and he is frequently quoted in national media outlets. His opinions have been published in articles by The Wall Street Journal, The Washington Post, Reuters, Bloomberg News, Modern Healthcare, Law360, and others.

# Speaker Introductions



## Shannon Sumner

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Shannon Sumner manages PYA's Compliance Advisory Services and serves as PYA's Compliance Officer. A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements and Non-Prosecution Agreements, conducts health system merger/acquisition/divestiture due diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight.

At the direction of the DOJ, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.

# Today's Topics

- Compliance and Leadership Structure
- Compliance Officers Who Wear Multiple Hats
- Leading practices and Lessons Learned from Corporate Integrity Agreements (CIAs)
- Leading Practices *NOT* Under CIAs
- Insights from the DOJ and Compliance Program Impact
- Wrap Up – Key Things to Know



# Compliance Leadership Structure – General Counsel & the Compliance Officer

## OIG Perspective



## Pitfalls to Avoid



# Compliance Leadership Structure – the Compliance Officer

- New CIA language:

*“The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG’s discretion, may interfere or conflict with the Compliance Officer’s ability to perform the duties outlined in this CIA.”*



What does *“may interfere or conflict”* really mean?

# Compliance Leadership Structure – the Compliance Officer

- Wearing multiple hats...
  - Risks to the organization and blending of roles (e.g., compliance, quality, risk management)
  - Considerations for smaller facilities where this occurs frequently





# Compliance Leadership Structure – the Role of Leaders



Boards



CEO and Other Executives



Other Managers

# Compliance Leadership Structure – the Compliance Committee

- Next Generation CIA:

*“The Board has made a reasonable inquiry into the operations of Biotronik’s compliance program including the performance of the Compliance Officer and the Compliance Committee.”*

- ❓ What are the expectations of the board to evaluate the effectiveness of the compliance committee?
- ❓ What are some best practices for compliance committees?
- ❓ Is this a high-level committee or a “working committee”?

Source: CIA, OIG and Biotronik, Inc., Sec. III.A.3

# Compliance Leadership Structure – the Compliance Committee

- Next Generation Language:

*“The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process.”*



What should organizations do to actively involve the compliance committee in the risk assessment process?

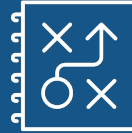
# Leading Practices and Lessons Learned from CIAs

- **Key themes in parties to CIAs, now and into the future:**
  - ✓ Pharma
  - ✓ Telehealth
  - ✓ Medicare Managed Care Organizations (MCOs)
  - ✓ Behavioral Health
  - ✓ Other parties?
  - ✓ And more...

# Leading Practices of Entities *Not* Under CIAs



Management  
Certifications



Compliance Incentives and  
Compensation Structures



Compensation Incentives  
*(up or down)*



Focused Training  
for High-Risk Areas



“Mock IRO Audits”  
In Key Areas  
*(e.g. physician arrangements)*



Organization-Wide  
Celebrations/Recognition  
for Compliance “Wins”

# Insights from DOJ Criminal Division and Compliance Program Impact

- Insights from DOJ’s “Further Revisions to Corporate Criminal Enforcement Policies” and impact upon compliance programs:
  - ✓ **Root cause analysis**
  - ✓ **Compensation clawbacks**
  - ✓ **Restitution**
  - ✓ **Management restructuring**
  - ✓ **Self-disclosures**
  - ✓ **Impact upon corporate monitors**
  - ✓ **And more...**

Prosecutors should evaluate the corporation's commitment to fostering a strong culture of compliance at all levels of the corporation – not just within its compliance department.

For example, as part of this evaluation, prosecutors should consider how the corporation has incentivized or sanctioned employee, executive, and director behavior, including through compensation plans, as part of its efforts to create a culture of compliance.

# Key Things to Know

1. OIG Perspective
2. Consulting Perspective
3. Counsel Perspective



# Thank You!



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