



Post-CIA Compliance: Maintaining the Momentum

**15th Annual Pharmaceutical Regulatory and Compliance Congress
Best Practices Forum**

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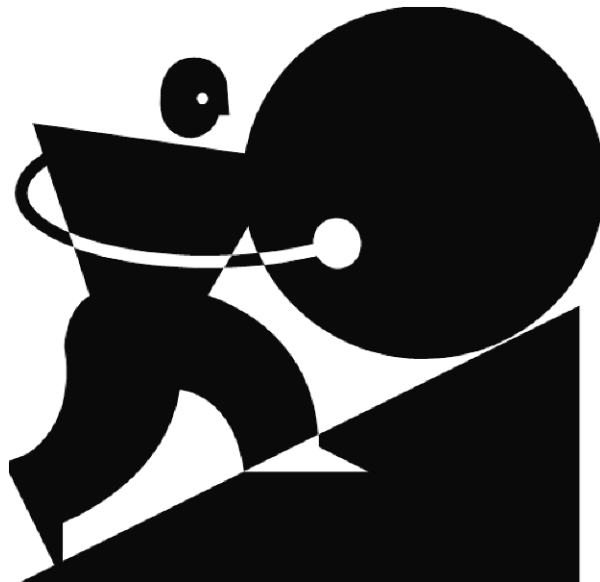
Today's Panelists

- Christopher Fletchall
Senior Advisor Ethics and Compliance
Eli Lilly and Company
Indianapolis, IN
- Wendy C. Goldstein, Esq.
Partner, Health Care & Life Sciences
Regulatory Practice
Cooley, LLP
New York, NY
- Gary Keilty
Managing Director
Huron Consulting Group
Washington, D.C.
- Barbara McCullough
Director for Corporate Integrity Agreement
Operations
AstraZeneca Pharmaceuticals LP
Wilmington, DE
- Lawrence P. Platkin
Vice President and Compliance Officer
Bayer Healthcare LLC
Whippany, NJ

The concepts and recommendations discussed in this presentation are the personal opinions of the panelists and do not represent the opinions of their respective companies or legal advice.

- Life After the CIA
- Culture and Key Communications
- Organizational Implications
- Operational Tactics
- Legal and Risk Implications
- Applying Lessons Learned Outside the US
- Final Thoughts and Questions

- Lessons Learned
- Evaluating the Current Landscape
- A Proactive Plan for Moving Forward
- How to Approach Compliance



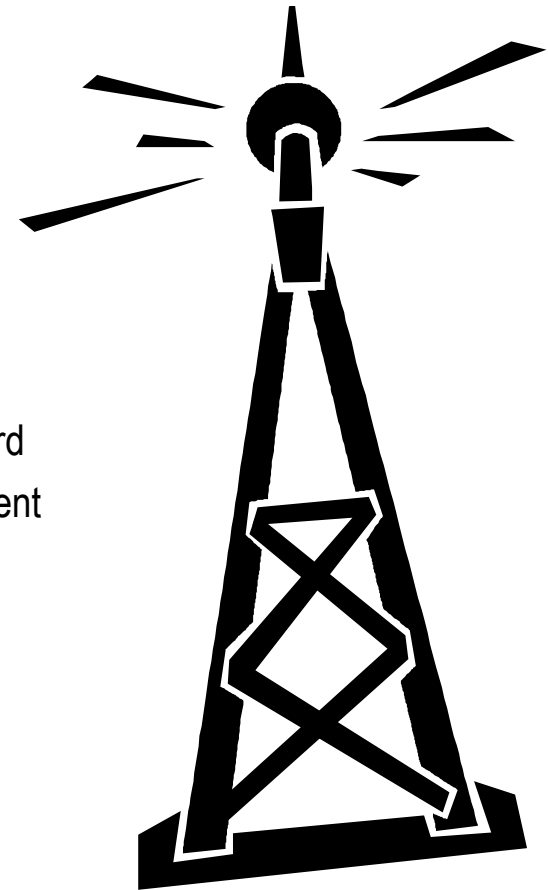
**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN
SERVICES
AND
EXTENDICARE HEALTH SERVICES, INC.
AND
THE PROGRESSIVE STEP CORPORATION**

I. PREAMBLE

Extendicare Health Services, Inc. (“EHSP”), and The Progressive Step Corporation (“ProStep”) (hereafter collectively referred to as “Extendicare”) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Extendicare is entering into a Settlement Agreement with the United States.

MAINTAINING COMPLIANCE

- Messages and Take-Aways
 - How Have You Grown?
 - What Has Been Enhanced?
 - Lessons Learned from the CIA
 - Not Going to Move Backward
- Stick vs. Carrot
 - Compliance as the “Right Thing to Do”
 - Importance of Seeing the Big Picture – Continue to Move Forward
 - Continuing Requirements of a Highly Regulated Work Environment



Organizational Implications

A CHANGED ORGANIZATION/A CHANGED LANDSCAPE

- Where Compliance “Sits”
- Strategic Opportunities: Integration of the business shape
 - No Longer a Need to be Prescriptive
 - Where is the Business Headed?
 - Partnering with the Business (The Internal Consultant)
- Considerations of Top Compliance Risks
 - Regulatory Environment
 - Products/New Products/Product Life Cycles
 - Annual Risk Assessment: Looking through a Different Lens
- Talent Development and Building for the Future
 - Size Structure and Roles Needed
 - Compliance Leadership Team
 - A New Model
 - Executing in New/Different Ways
- Vision for Governance Teams Created or Enhanced as a Result of the CIA



PUTTING A PROCESS IN PLACE

- How to Integrate into the Bigger Picture
- Maintain/Enhance/Streamline/Simplify
 - Policy
 - Procedure
 - Training
- Critical Components of Review
 - Third-Party Management
 - Management Certifications
 - Reportable Events
 - Monitoring and Auditing
 - Corrective Action Plans
 - Data Analytics
 - PhRMA Certifications
 - Transparency/Open Payments/SOX



- Subsequent CIAs
 - Financial Implications
 - Operational Considerations
 - Perception Risks
- BoD Considerations
 - Fiduciary Standards
 - Certifications
- CIAs Requirements: Memorializing the Law vs. Better Practices
 - California, Connecticut, Massachusetts, Nevada
 - Self-Disclosure



Applying Lessons Learned Outside the U.S.

A SPRINGBOARD TO GLOBAL COMPLIANCE OPPORTUNITIES

- Government Expectations
- Process and Procedures
- Cultural Implications
- Evaluating a Global Compliance Structure



Final Thoughts

CLOSING THOUGHTS AND QUESTIONS

- Key Take-Aways
- Final Thoughts From the Panel
- Questions

