



# Transforming Advanced Analytics into Reality

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# Rachel Batykefer



Senior Director,  
Integrity &  
Compliance  
Operations  
Mallinckrodt  
Pharmaceuticals

Visionary, results-oriented, and accomplished Global Compliance & Ethics Leader in Pharmaceutical industry with extensive experience in all aspects of ethics compliance, training and development, and project management.

Extensive knowledge of change management and program implementation, focused on protecting business operations and supporting revenue growth.

Builds strong partnerships and rapport with customers to produce win-win results between the company and its clients. Articulate and effective communicator with strong leadership, problem-solving, and negotiation skills.

# Michele Girdharry



Executive  
Director, Compliance  
Amryt Pharma

I am a highly accomplished leader with experience designing, implementing and managing compliance and risk initiatives in a variety of functional areas within an organization and across multiple geographic markets. I am skilled at implementing strategies for addressing compliance risk areas proactively and in response to federal enforcement inquiries and requirements mandated by enforcement authorities.

I have significant experience leading teams that operationalize compliance initiatives and investigate matters related to potential fraud and abuse in the US and several global markets, notably the Middle East, India, Bangladesh, West Africa and Australia. I have worked with companies of various sizes and specialize in the Pharmaceuticals, Medical Device, Biotech and Consumer Products industries.

My areas of expertise include:

Compliance, anti-bribery/anti-corruption (“ABAC”) and anti-fraud advisory, global risk assessments, corporate investigations, auditing and monitoring, compliance operations (e.g., fair market value, transparency, healthcare professional and patient/customer interactions, third party interactions), communication and training, policies and procedures, design and development of data analytics for ABAC and compliance, third party due diligence and reporting program effectiveness.



# Holly Kramen



*Former Vice President,  
Legal & Compliance at  
G1 Therapeutics*

Holly has worked passionately at building and evolving life science compliance programs for over 20 years, focusing on culture, partnership, operational integration, practicality, common sense and a lot of humor. She has led compliance and legal departments tailoring, designing, implementing, assessing writing, reporting, advising, auditing and enhancing every aspect of corporate, commercial and medical affairs compliance in companies ranging from biotech start-ups to devices and diagnostics to big pharma.

Her most recent roles as Chief Compliance Officer (or similar) include G1 Therapeutics, Circassia, and Given Imaging; simultaneously performing Counsel and Privacy functions as well. Holly has taught multiple courses in the Seton Hall MSJ and Compliance Certification programs. She has also had leading advisory positions at PwC and Porzio.

# John Poulin



Chief Technology  
Officer,  
Helio Argos

John is a Technology Executive with many years of product development and pharmaceutical management consulting experience. He is a successful software start-up technology entrepreneur with the distinction of being the Chief Technology Architect to a vertical search start-up sold to Forbes Media and the Chief Technology Architect to a social media start-up sold to the New York Times. John is currently focused on data analytics for use in operational compliance monitoring.

# The Vision and Execution of Monitoring

Proactive Compliance is the key to preventing reputational damage and costly settlements and sanctions.

Most enterprises are currently reactive in nature with their compliance programs and lack the tooling or expertise to allow for them to proactively identify and prevent compliance issues.

ABILITY TO EXECUTE

OPERATIONALLY EFFICIENT	ENTERPRISE INTEGRATION
Aggregate data into a central datastore, workflow management and reporting tools to monitoring activity, using the same heuristics and policies.	Risk-Informed decision at the point of HCP Engagement or other high-risk activity.
Retrospectively monitor sales and marketing activities based on heuristics and policies directly from their data silos.	Move away from "policy only" monitoring. Proactively seek behavioral trends and anomalies across various sales and marketing activities.
REACTIVE	PROACTIVE

COMPLETENESS OF VISION



# Reactive

Retrospectively monitor sales and marketing activities based on heuristics and policies directly from their data silos.

- Monitor Meals directly from T&E Data
- Monitor speaker program attendance and meals
- Monitor live events using Excel-based forms
- Monitor email using generic, non-industry specific tools
- Have difficulty measuring the effectiveness of programs
- Lack of centralized work-flow solution



# Reactive – Operationally Efficient

Bring data together into a centralized database, workflow management and reporting tools to monitoring activity, using the same heuristics and policies.

- Aggregate transactional data in one place
- Introduce actionable workflow and tracking of observations and findings
- Centralize live monitoring and automate the live monitoring form collection process
- *Automated Reporting*

# How do you collect and organize your enterprise data?



Email



Patient Data



Text  
Message



Ride Along



Phone  
Conversation



Speaking  
event



Meal  
Transaction



Enterprise  
messaging

# Can you proactively identify issues?



Do "Emails" and "Ride Alongs" show a pattern of abnormal behavior for my sales force?

# Proactive

Move away from "policy only" monitoring. Seek behavioral trends and anomalies across various sales and marketing activities.

- Is this email communication unique compared to others?
- Are the same groups of attendees moving around to different speaking engagements?
- Are pockets of employees requesting grants, contributions, charitable giving to the same institution?



# Enterprise Integration

## RISK-INFORMED DECISIONS

Integrated at the point of interaction with HCPs

- Scheduling a Speaker Program
- Contracting with an HCP
- Sending an email
- Providing an in-office meal
- Delivering drug samples

# Does the Compliance Program Work in Practice?

Objective	Solution	Metrics
Continuous Improvement, Periodic Testing, and Review	Assess risk, plan, perform monitoring, perform investigations, measure performance	Trend identified observations vs. Remediations over time.
Investigation of misconduct	A workflow management tool that allows for allocation of investigative resources	Track the time taken for identified risk areas to completion of investigations
Incentives & Disciplinary Measures	Incentivize sales reps using MBOs for remaining within policy	Determine sales reps that stay within policy of expense submission and meal caps

- **Incentive System** – Has the company considered the implications of its incentive: rewards on compliance? How does the company incentivize compliance and behavior? Have there been specific examples of actions taken (e.g., promotion awards denied) as a result of compliance and ethics considerations? Who determines the compensation, including bonuses, as well as discipline and promotion compliance personnel?

### III. Does the Corporation's Compliance Program Work in Practice?

The Principles of Federal Prosecution of Business Organizations require prosecutors to assess "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision." JM 9-28.300. Due to the backward-looking nature of the first inquiry, one of the most difficult questions prosecutors must answer in evaluating a compliance program following misconduct is whether the program was working effectively at the time of the offense, especially where the misconduct was not immediately detected.

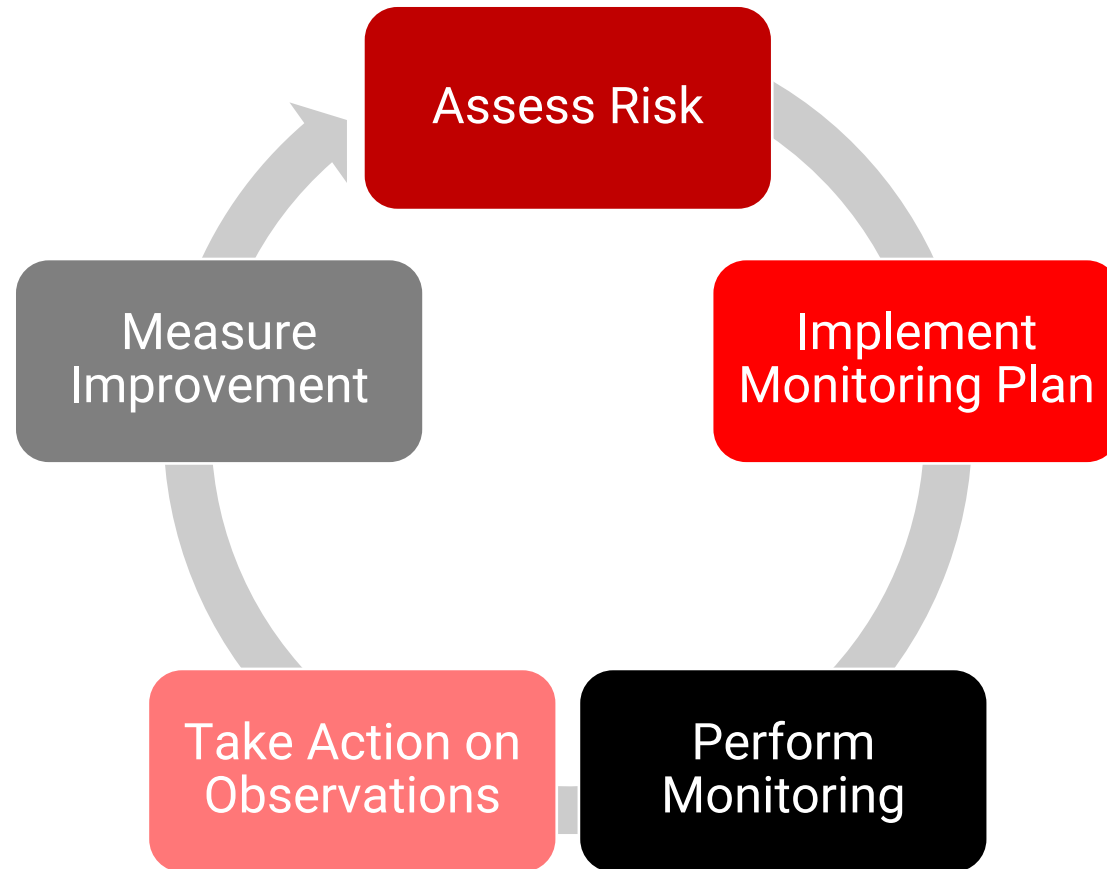
In answering this question, it is important to note that the existence of misconduct, not, by itself, mean that a compliance program did not work or was ineffective at the time of the offense. See U.S.S.G. § 8B2.1(a) ("[t]he failure to prevent or detect the instant offense does not mean that the program is not generally effective in preventing and deterring misconduct. Indeed, "[t]he Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees." JM 9-28.800. Of course, if a compliance program effectively identifies misconduct, including allowing for timely remediation and self-reporting, a prosecutor should view the occurrence as a strong indicator that the compliance program is working effectively.

In assessing whether a company's compliance program was effective at the time of the offense, prosecutors should consider whether and how the misconduct was detected, whether investigation resources were in place to investigate suspected misconduct, and the nature and thoroughness of the company's remedial efforts.

To determine whether a company's compliance program is working effectively at the time of a charging decision or resolution, prosecutors should consider whether the program evolved over time to address existing and changing compliance risks. Prosecutors should also consider whether the company undertook an adequate and honest root cause analysis to understand what contributed to the misconduct and the degree of remediation needed to prevent similar events in the future.

# Continuous Improvement Cycle of a Risk-Based Compliance Program

“Can you improve what you can’t measure?”



# The End



- Questions?
- Comments?



# Appendix

# Continuous Improvement Cycle of a Risk-Based Compliance Program



## Plan

Assess your risk, plan your monitoring activities for the year



## Detect

Use enterprise data to prospectively determine compliance risk. Don't wait for analysis of retrospective risk.



## Respond

Take action on monitoring observations, make adjustment and improvements to your plan retrospectively

# DOJ Guidance on the Evaluation of Corporate Compliance Programs

U.S. Department of Justice  
Criminal Division  
Evaluation of Corporate Compliance Programs  
(Updated June 2020)

## Introduction

The “Principles of Federal Prosecution of Business Organizations” in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include “the adequacy and effectiveness of the corporation’s compliance program at the time of the offense, as well as at the time of a charging decision” and the corporation’s remedial efforts “to implement an adequate and effective corporate compliance program or to improve an existing one.” JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. See U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, the memorandum entitled “Selection of Monitors in Criminal Division Matters” issued by Assistant Attorney General Brian Benczkowski (hereafter, the “Benczkowski Memo”) instructs prosecutors to consider, at the time of the resolution, “whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems” and “whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future” to determine whether a monitor is appropriate.

This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation’s compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitoring or reporting obligations).

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company’s risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company’s size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company’s operations, that might impact its compliance program. There are, however, common questions that we may ask in the course of making an individualized determination. As the Justice Manual notes, there are three “fundamental questions” a prosecutor should ask:

Last updated in June of 2020

**As the Justice Manual (JM 9-28.800) notes, there are three “fundamental questions” a prosecutor should ask:**

- “Is the corporation’s compliance program well designed?”
- “Is the program being applied earnestly and in good faith?” In other words, is the program adequately resourced and empowered to function effectively?
- “Does the corporation’s compliance program work” in practice?

# Is the program well designed?

- Risk Assessment
- Policies & Procedures
- Training & Communications
- Confidential Reporting Structure & Investigation Process
  - Effectiveness of Reporting Mechanism
  - Properly Scoped Investigations by Qualified Personnel
  - Investigation Response
  - Resources and Tracking of Results
- Third Party Management
- Mergers & Acquisitions

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