Accelerated Learning – Healthcare Compliance and Policy Applications

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Today’s Session

**Agenda**

I. Compliance Overview
II. Case Study Review
III. Risks and Actions
IV. Due Diligence
V. Best Practices
Conclusion

**Activities**

Presentation
Reading
“Neighbor” discussions
Full group discussions
Technology supported exercises
Accessing Interactive Exercises

Access Conference Wi-fi  Turn off Pop-up Blockers  Access Workshop Portal

http://pcc2017.pharmacertify.com
Username: Compliance
Password: PCC2017
Workshop Portal

Login Page

Home Page

Welcome to the Portal
When instructed by the facilitators, click the icons below.
I. Compliance Overview

Sergio Alegre

Vice President, Global Compliance
Osmotica Pharmaceuticals
Build a Good Foundation

• Define your program
  • Your department (under your control)
  • Other department within company
  • Are there any gaps?

• Learn what laws, regulations and guidelines apply to you

• Keep up to date on changes
Define “Compliance”

• What is the scope of your organization’s Compliance Program?

Activities Possibly Within Scope

- Auditing & Monitoring
- Training
- Interactions w/HCPs
- Promotional Review
- Investigations
- Aggregate Spend
- Pricing
- Ethics
- State Licensing
- Contracts Approval
- FMV Analysis
- Publications
- Clinical & Research
- Managed Care
- Vendor Credentialing

- Grants/Charitable Contributions
- Social Media
- Privacy
- Specialty Pharmacy
- Medical Information
- GMP
- Pharmacovigilance
Federal Laws

• Food, Drug & Cosmetic Act (FDCA)
• Food and Drug Administration Modernization Act (FDAMA)
• False Claims Act
• Federal Anti-Kickback Statute
• Prescription Drug Marketing Act (PDMA)
• Physician Payments Sunshine Act (PPACA § 6002)
• Health Insurance Portability and Accountability Act (HIPAA)
Federal Government Guidance Documents and Enforcement Actions

- Untitled Letters, Warning Letters
- Corporate Integrity Agreements
- Federal Sentencing Guidelines
- OIG Compliance Program Guidance
- FDA Guidance for Industry
- OIG Workplan
- HCCA-OIG Compliance Effectiveness Guide
State/Local Laws and Organizational Requirements

• Restrictions on promotional activities (MN, VT, MA)
• Transparency statutes and ordinances (VT, MA, CT, DC, Chicago)
• Sales rep registration requirements (Chicago, Dade Cty, DC, LA)
• Compliance program certifications (CA, NV, MA)
• Access requirements ("Vendor Credentialing") – DOD/VA; Hospitals, ASCs
• Hospital Conflict of Interest prohibitions
Voluntary Industry Guidelines

• PhRMA Code on Interactions with HCPs

Code’s “intention [is] that our interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine” and is “based on the principle that a HCP’s care of patients should be based ... solely on each patient’s medical needs and the HCPs medical knowledge and experience.”

• AdvaMed Code of Ethics

An HCPs “first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with HCPs. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance.
Case Law (e.g. First Amendment Cases)

- Washington Legal Foundation cases
- Sorrell vs IMS Health
- Caronia
- Amarin
- Pacira
- Vascular Solutions
International Laws

• U.S. Foreign Corrupt Practices Act
• U.K. Anti-Bribery Act
• EFPIA Code on Disclosure of Transfers of Value
• ISO Anti-Bribery Standard
• EU: Data Protection Directive - General Data Protection Regulation
Seven Elements of an Effective Compliance Program

• Implementing written policies and procedures
• Designating a compliance officer and compliance committee
• Conducting effective training and education
• Developing effective lines of communication
• Conducting internal monitoring and auditing
• Enforcing standards through well-publicized disciplinary guidelines
• Responding promptly to detected problems and undertaking corrective action
II: Case Study

Steve Vincze
Interim Chief Compliance Officer
Kastle Therapeutics/Trestle Compliance, LLC
Case Study: The Commercial/Compliance Evolution of Rare Disease Pharma, LLC

• Click on the Case Study icon on the Portal
• Take 5 minutes to review the case study and consider the questions on page 3 of the document
Your first day on the job...

- What do you do?
- Where do you start?
- What are your top risks/priorities and why?
- What is your timeline to implement the program?
- How do you advise the Executive, Commercial and Medical/Regulatory teams regarding coordinating with patient assistance not-for-profit organizations?
- How do you educate and convince your Executive Team to spend precious resources on compliance? How should you scale-up and measure credible progress?
III. Risks and Actions

Pam Hrubey
Managing Director,
Crowe Horwath LLP
Prioritize your RISKS

1. Click on the **Exercises** link on Workshop Portal
2. Discuss RISK areas with your neighbors
3. Individually or with neighbors, move what you believe are the **Top 5 Risks** into the box on the right

Stay on the page for Debrief/Discussion
Risk Areas To Consider

- First commercial product for company
- Private equity funded, high pressure to perform
- Targeted to treat a population that includes minor children
- Small number of patients could raise pressure to expand beyond approved indication
- Clinical/regulatory issues (study in Ukraine, small patient population, questionable clinical situation)
- Significant safety signals may raise product liability
- Executive pharma experience
- Pressure from advocacy groups (parents of patients)
- Potential high reimbursement rate
- Contract sales force
- Leveraging NFP patient assistance foundations
- General Counsel has no pharma/regulatory/commercialization experience
- No compliance program thus far (likely means no organized training programs, no Code of conduct, no hotline, etc.)
- Culture
- Other risks?
Prioritize your ACTIONS

1. Click on the Exercise screen
2. Discuss ACTION AREAS with your neighbors
3. Individually or with neighbors, move what you believe are the TOP 5 ACTIONS into the box on the right

Stay on the page for Debrief/Discussion
Possible Actions...

- Build an E&C strategy, game plan, and key deliverables model
- Establish roles and responsibilities (one person can’t do everything)
- Learn about the business
- Create a Code of Conduct with associated training
- Identify key policy statements and develop associated procedures, or support efforts of senior leaders to do so
- Launch an executive education program around E&C risks
- Establish a compliance hotline and educate employees regarding the purpose and use of the hotline; establish and provide education around a no-retaliation policy
- Build the visibility of the E&C function with employees
- Prepare sales force training regarding: on-label promotion, scientific exchange, etc.
- Develop standby statements regarding clinical, regulatory and product safety issues
- Prepare CEO and other execs to communicate proactively internally and externally regarding values and E&C standards
- Support legal in building a product liability mitigation strategy with education, communications, etc.
- Establish a monitoring program to track performance key risk areas
- Others...
IV. Due Diligence

Brian Van Hoy
Vice President
G&M Health, LLC
Case Study: The Commercial/Compliance Evolution of Rare Disease Pharma, LLC

Part 2: RDP prepares to get acquired by Big Pharm Co.

• What diligence can/should RDP do from a compliance perspective?
• What diligence can/should Big Pharm Co. do from a compliance perspective?
V: Best Practices

Pam Hrubey
Managing Director,
Crowe Horwath LLP
Part 3: Institution of Best Practices in Ethics and Compliance

• M&A-related due diligence is proceeding well, albeit slow as a snail

• As CCO, you receive counsel from your external advisors that you should begin focusing on institutionalization of ethics and compliance best practices to address potential concerns that could arise from potential acquiring parties

• While no specific gaps have been raised, you decide to undertake three specific initiatives…

Case Study: The Commercial/Compliance Evolution of Rare Disease Pharma, LLC
Case Study: The Commercial/Compliance Evolution of Rare Disease Pharma, LLC

Three best practices...

1. Conduct a robust ethics and compliance program effectiveness review
2. Enhance corrective action-related processes and associated information management
3. Collaborate with internal assurance functions on risk assessment-related activities
Best Practices

Conduct a robust ethics and compliance program effectiveness review

• Leverage the internal audit team
• Leverage an external consultancy
• If necessary, based on your specific situation, limit focus to specific elements (policies and procedures, training, for example) – but be careful to paint the results using the appropriately sized brush (effective policies and procedures do not equal effectiveness across all 7 elements)
• Consider implementing a regularly scheduled effectiveness review – measuring effectiveness is a behavior not an event
• Document results be sure to follow up on the deficiencies
Best Practices

Enhance corrective action-related processes and associated information management

Goal – Determine if something systemic led to non-compliance:

- Policies and procedures weren’t clear
- Management pressed for results – “do whatever it takes”
- Training was non-specific or failed to engage
- Tone at the top described a culture of compliance but demonstrated a desire for results at any cost
Best Practices

Collaborate with internal assurance functions on risk assessment-related activities

• Transition the timing of risk assessment activities to match times in the year when senior leaders are already formally thinking about risk (strategic planning, business planning, preparing for board meetings, etc.)

• Leverage a database of risk-related information that all internal assurance functions can access for their specific purposes

• Consider coordinating questions (avoid asking the same question in different ways unless you are purposefully testing)
Conclusion

Sergio Alegre
Vice President, Global Compliance
Osmotica Pharmaceuticals
Good news!

RDP has been acquired for 10 Gazillion dollars, and as CCO, you are now in a position financially to purchase your own island and move to the beach!

However, before you pack up your office, you must summarize the key lessons you learned during your tenure as RDP’s CCO so that your replacement is able to maintain a robust program.
Passing on your wisdom...

Three tips/reminders you plan to leave behind for your replacement, addressing these considerations:

• What is the most important thing for them to remember about the ethics and compliance program?
• What item/idea is likely to be most surprising to your replacement?
• Based on what has transpired in the case study, what lesson(s) might be transferred to your replacement to ensure their success?