



Practical Approaches to Handling Investigations: Case Studies



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Case Study #1

QUESTION 1



Wayne Enterprises is a pharmaceutical company that has created an innovative specialty drug for a rare disease known as Bat Flu. Wayne Enterprises has a relationship with Arkham Assistance, a 501(c)(3) charitable foundation, that provides co-pay assistance exclusively to Medicare patients with Bat Flu. Company policy does not allow Medicare patients with Bat Flu to participate in the Company's free drug program for those in financial need, and instead requires employees to refer those patients to Arkham Assistance for financial help. Most of the charitable contributions from the Company to Arkham Assistance are paid in cash.

Wayne Enterprises also has a concierge service agreement with specialty pharmacies in which nurse practitioners visit patients in their home and administer the Bat Flu drug. The Company's agreements with specialty pharmacies require that the nurse practitioners visit the patient at least once a week. Company policy states that any home visits that include up-titration of Bat Flu drugs will result in a bonus payment to the specialty pharmacy. The same incentive is offered to Wayne Enterprises employees in the Company's reimbursement HUB: those employees get an additional bonus for each reimbursement obtained.

***Do these practices present any compliance-related issues for the Company?
If so, what risk areas are implicated?***

Case Study #1



QUESTION 2

Harvey Dent, an employee in the Medical Affairs department at Wayne Enterprises, observes the Company's relationships with Arkham Assistance and the specialty pharmacies. After receiving training on Compliance last week, Harvey grows concerned that these practices pose risk to Wayne Enterprises.

Harvey shares his concerns with his line supervisor. His line supervisor reassures him that all of the Company's practices are legal, and "not to worry about it."

What should Harvey do? Does he have a further obligation to report? If so, to whom?

Case Study #1



QUESTION 3

After a few weeks, Harvey's line supervisor hasn't mentioned Arkham Assistance or the concierge program. Worried that his concerns will not be investigated, Harvey calls the Wayne Enterprises compliance hotline and submits an anonymous report.

Bruce Wayne, the Chief Compliance Officer, is alerted to the intake report submitted by Harvey.

What should Bruce Wayne do? How should he run this investigation?

Case Study #1



QUESTION 4

During the course of his internal investigation, Bruce Wayne receives a Civil Investigative Demand from the Department of Justice related to the concerns raised in Harvey Dent's hotline complaint.

How should Bruce Wayne handle this? What steps should Bruce take?

Case Study #2



Oscorp is an international pharmaceutical company that operates in 70 different countries and has a blockbuster drug, Marvel XR, that was just approved and has quickly become the standard of care for heart disease. As part of the Marvel XR launch program, Oscorp has employed an array of HCP speakers. Oscorp is rumored to pay its speakers the highest fees in the industry. In connection with its ongoing development program, the Company has also encouraged many of its high prescribers to conduct independent studies. There is a tacit understanding among HCP speakers that they will receive further incentives for participating in independent studies.

Most of the development work for Marvel XR takes place at a clinical trial hub in Vietnam. Similar practices are rumored to be occurring with regard to payments clinical investigators there. For example, the fees paid by Oscorp to the Vietnamese clinical investigators are rumored to be the highest in the industry.

The data from the clinical trials indicates that Marvel XR shows promise for treating critical limb ischemia (CLI). Although the drug has not yet been approved for that use, Oscorp organized (and covered the costs of) a conference for cardiologists where several thought leaders in cardiology talked about their experience with the drug. Some of them talked about their success in using it to treat CLI, and those presentations were videotaped.

Case Study #2



Peter Parker, a compliance officer for Oscorp, receives a whistleblower complaint through the Company’s anonymous compliance hotline that, after the cardiology conference, Oscorp sales people were given videos of those CLI-related speaker presentations to use in sales pitches.

When Peter reports the complaint to the Chief Compliance Officer, he is told that the hotline complaint is probably unfounded. The CCO also assures Peter that all sales materials are vetted by Compliance. Although Peter trusts the CCO, he does some investigating of his own. Peter Parker digs deeper into the HCP engagement process in place at Oscorp and discovers that many of the physicians in the speaker program have received free samples of the drug to use with their patients, and a few early adopters, including Dr. Octopus, were given shares in Oscorp at a time when shares had only a nominal value.

He also discovers that some clinical investigators in Vietnam have extra line items in their invoices. Specifically, some Vietnamese investigators receive a payment that is consistent with FMV in addition to a line description that simply states “Additional Services.”

Case Study #2



Norman Osborn, the president of Oscorp, returns home from traveling abroad and turns on the evening news. A special edition of “60 Minutes” is about to begin.

The host begins to talk about a scandal in the pharmaceutical industry in which a major drug company is accused of paying off doctors to promote a new drug and to fudge the data in clinical trials to obtain favorable results. As soon as Norman realizes that the media exposè is about Oscorp, his phone starts ringing. It's the Company's Chief Compliance Officer.

***Discuss your questions with your team
and prepare to report out!***

Case Study # 2



QUESTION 1 – ISSUE SPOTTING

What issues do the various activities described in the fact pattern present for the Company?

- Which compliance-related concerns?***
- Which legal concerns?***

Case Study # 2



QUESTION 2 – UPWARD ESCALATION; REPORTING ROLES & RESPONSIBILITIES

What actions should Peter Parker take?

- *Does he have an obligation to report to someone other than the CCO?*
- *If so, to whom?*

To whom should the CCO report?

- *When should the Board of Directors get involved?*
- *Who else, if anyone, should be involved?*

Case Study # 2



QUESTION 3 – CONDUCTING THE INVESTIGATION

How should the Compliance department at Oscorp run the investigation into the hotline complaint?

- What actions should be taken internally?***
- What actions should be taken with regard to regulators?***

Case Study # 2



QUESTION 4 – CRISIS MANAGEMENT

How should Norman Osborn delegate tasks to address this potential crisis? What are the roles of:

- Board of Directors*
- Outside counsel*
- Senior management*

How should the Company handle:

- Media*
- Disclosure management*

Thank You!



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