
**Advanced Issues
and
Best Practices in Investigations**

HOW IT STARTS

- You are chief compliance officer. You start your day every day by listening to the hot line calls. Here is what you hear today, a female voice:

Hi. I can't talk to my boss, he is such a jerk. If you don't play golf and you didn't know him all your life, there is no hope to get ahead. I can't believe what he just asked me to do. It's like selling information, I mean buying information from our customers. Oh shoot ..."
- Just before the dial tone, you hear a male voice that sounds familiar: "Hey, Gertrude, can I see you in my office?"
- A quick check of the company directory shows one Gertrude in sales.
 - **What do you do?**

LEGAL GETTING INVOLVED

- You are General Counsel and the Chief Compliance officer gives you a call:

"Hey, just a heads up, there was a hotline call that we got that we are looking into. Not sure if there is anything you need to worry about, we about have the investigation wrapped up. It only involves one employee."
- After probing, you determine that the issue concerns whether a sales rep in a particular region was peddling information between doctors and may have been getting paid by doctors for the information. It is unclear whether other current reps are involved; all of the other potentially involved reps are ex-employees. She and her boss are pointing fingers at each other.
- While not squarely within the parameters of your search terms, you stumble across emails raising concerns about payments outside the U.S.
 - **Next steps?**

ELBOWING COMPLIANCE ASIDE

- Legal takes over the investigation, and determines to re-interview some of the same employee witnesses. Because lawyers can't help themselves, there is now a second set of interview memos for the same witnesses. During the course of these interviews, some of the employees contradict what is written in the memos.
 - **What do you do about this?**
 - **Are all the notes privileged?**

INVESTIGATING ON THE QT

- An email review conducted quietly by the legal department uncovers an employee who has sent many emails, including with company documents, to a YAHOO email account. The name on the email address is “fuzzy”: it is not clearly associated with the name of the employee. While the company has a policy against using non-company email accounts for transacting company business, you know that this policy is violated by everyone, including you in Legal.
 - **What does this mean?**
 - **What action can, do you take?**

TEXTING

- You determine to interview the employee; in the course of the interview, he claims he is aware of bad conduct by some employees, but after some probing, you determine that he has the law wrong, but he is pretty adamant about it.
 - **What do you do? What action do you take?**
- He also says that he “is not a dinosaur and texts all the time.”
 - **What do you do about the text messages?**
 - **Is your company a “bring your own device” company? What is your company's policy on use of text messaging for conducting business and retention of text messages? If there is a policy against texting for business, how often is the policy violated? Does that matter, that the policies are pretty routinely violated all up and down the chain of command?**

FDA RULES VIOLATION

- While dealing with the text message issue, you discover that this same employee has failed to follow the law on the proper handling of samples for a J code drug-- he gave samples to a physician but reported them as lost, so there is no accurate sample signature card reflecting the distribution of the samples.
- You also get a lead that suggests employees were buying services from a specialty pharmacy and that there “might be” some “loose connection” between the payment for services and sales targets for the SP.
 - **What do you do about these things?**

THE COMPETITION

- General Counsel at your competitor calls you and says:
 - "Hi, sucks to be you. Not only are we whipping your butt in the marketplace, but we have stolen away many of your best employees for our just completed and **wildly** successful product launch. The only thing bumming me out just a little, but only a little, the FBI hit the homes of four of our employees last night, not asking questions about our stuff, but asking them about what they did when they worked over at your unethical shop. Do you want the names?"
 - "Hey, while I have you on the phone, some of our other folks are telling me the vaccine tenders you guys just won in Brazil and Argentina, well, how shall I say this, it wasn't on the basis of your better price, but your better green, you get what I am saying?"
- **What do you do? What do you conclude from the fact of the interviews?**

A STRONG LEAD

- You determine that all four employees were asked questions about the wining and dining of physicians and that there were lots of questions asked about the logistics of setting up physician speaking engagements, in the US and in abroad. Many of the questions that the ex-employees can remember focus on the southeast US, where the company has a regional headquarters and processing center in Birmingham, Alabama, and where the meeting and planning department is located.
 - **How do you handle this?**
 - **Concerns you should have?**
 - **Steps you should take?**

THE DAWN RAID

- Your effort to get outside counsel retained and employees interviewed swiftly to see what the problem is, if there is one, is still working its glacial way up the chain of financial command. Your cell phone rings early in the morning, and the head of security for the Birmingham building tells you there are 40 agents from the FBI milling around outside, that he hasn't let them in, but that they are screaming about having a warrant and threatening to arrest him. Not only that, he says, but the agents are stopping everyone who is coming into work, right out in the parking lot, and interviewing them. Looking for the Latin America head. "Oh, and by the way, did I mention the CBS news truck?"
 - **What do you do? What do you tell him to do? What steps do you need to take in the next hour? Day? Week?**

THE GOVERNMENT

- Outside counsel has finally been retained and you are it. The search is still going on, and you have to decide whether you go to the location. The FBI is also still interviewing employees. You call the AUSA, who agrees to meet but also tells you the investigation is fast moving and "there are going to be indictments by the end of the year."
- You also find out from the AUSA that they searched offices used by the legal department, but not clearly marked as such, and it is not clear that the government team did any planning for the potential seizure of privileged materials.
 - **What do you do?**

ADVICE OF COUNSEL

- You do some digging around on the issue, and you find that a prior firm provided advice on the issue of inviting doctors to speak, and that the advice might be helpful to negate criminal intent. You are evaluating whether to raise the advice of counsel defense.
- After some preliminary investigation, you find out that the company used several firms, sometimes at the same time, and all provided advice on kickback issues and that the advice is not all uniform.
 - **What are the investigative considerations?**
 - **What are the legal considerations?**
 - **What happens if a memo or an email has multiple topics on which lawyers gave advice, all presenting varying risk?**

PARALLEL INQUIRIES

- The government starts issuing grand jury subpoenas to current and past employees. You work to retain counsel for them.
- While that criminal process is pending, the Civil Division of the USAO also issues CIDs for some of the same witnesses. You don't, as General Counsel, think that any employee, or the company, has criminal exposure, and you are also getting pressure from management to move the investigation along, for one business reason or another. Some of the lawyers retained for employees on the criminal side start to advise their clients to “take 5.”
 - **What do you do?**
 - **What should you be thinking about?**
 - **Is it in the company's interest that the employees go in and testify to the CIDs?**
 - **Do you fire those who assert their fifth amendment privilege? What do you tell their lawyers?**
 - **Does it matter that there has been no mention of Latin America?**

BEST PRACTICES

- Investigation issues and context vary; your investigation must match both and must be flexible
- There is no “single list” of best practices to follow in every investigation; there are *smart* things to do:
 - Listen well and follow the evidence
 - Trust what you hear but verify
 - Catch up to the government and try to stay ahead
 - Be cognizant of the potential land mines and road blocks that litter the investigative path
 - Communicate clearly on developments within your own team and with the business teams that are impacted and *always* with senior management
 - Communicate clearly on risks as they surface
 - Maintain strong credibility with the government team
 - Identify an effective solution