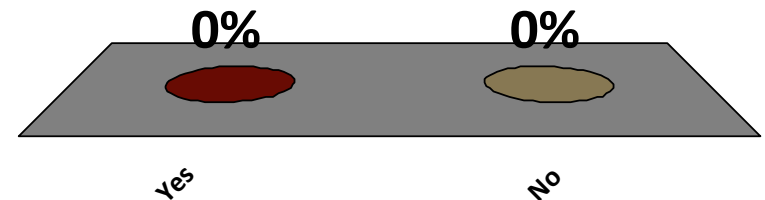


HAVE YOU EVER HAD FCPA-RELATED JOB RESPONSIBILITIES? ¹

A. Yes

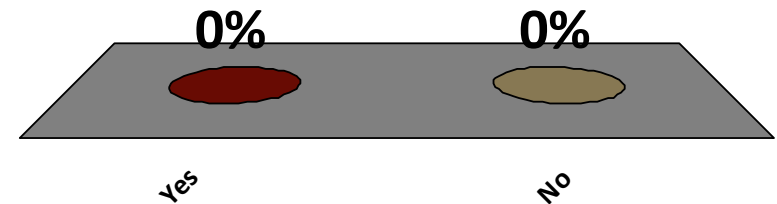
B. No



HAS YOUR COMPANY EVER HAD SIGNIFICANT FCPA ISSUES?

A. Yes

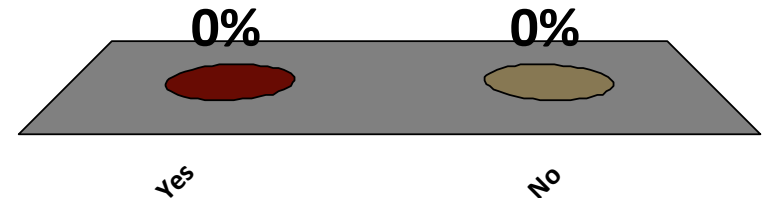
B. No



HAS YOUR COMPANY HAD FCPA ISSUES WITH THE GOVERNMENT?

A. Yes

B. No



***FCPA ANTICORRUPTION: EXAMINING A
HYPOTHETICAL CASE FROM ALL SIDES: DOJ, SEC, AND CCO***

Sixteenth Annual Pharmaceutical Regulatory and Compliance Congress

Washington, DC
October 21, 2015



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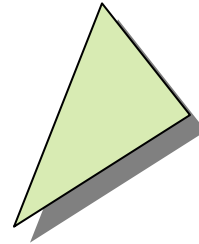
INTRODUCTION

- Panelists
 - Gary Giampetruzzi, Paul Hastings LLP
 - Jeffrey Knox, Simpson Thacher
 - Cheryl Scarboro, Simpson Thacher
 - Ashley Watson, Merck & Co

- Workshop Format
 - Hypothetical compliance crisis / internal investigation
 - Questions to prompt discussion throughout
(and the questions are for the audience as well)

HYPOTHETICAL FCPA SITUATION

- GOOD Pharma Co. is a publically traded, multinational pharmaceutical company that engages in research, manufacturing, and sales of pharmaceutical products



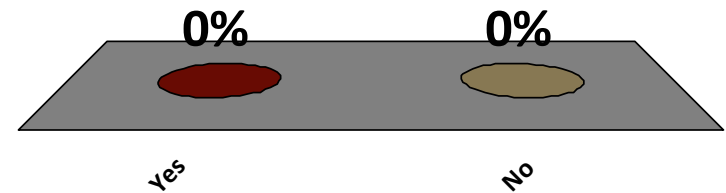
GOOD Pharma Co.

- GOOD Pharma Co. has \$15 billion in annual sales
- In early 2010, it had a “modest” kickback settlement with the Boston U.S. Attorney’s Office for \$75M, and a 5-year Corporate Integrity Agreement (CIA)
- Due to the CIA, the company developed a robust global compliance program
- The HHS-OIG forced GOOD Pharma Co. to separate its compliance and legal departments, with the CCO reporting directly to the CEO (rather than GC)
- The CIA expired approximately six months ago
- Brimming with confidence and relief that the CIA has expired, GOOD Pharma is in the midst of returning to the pre-CIA compliance organization structure, with the CCO positioned under GC, a very prominent figure in the company

**WAS IT A GOOD IDEA FOR GOOD PHARMA TO RETURN TO THE
'NEW' COMPLIANCE / LEGAL STRUCTURE FOLLOWING THE
EXPIRATION OF THE CIA?**

A. Yes

B. No



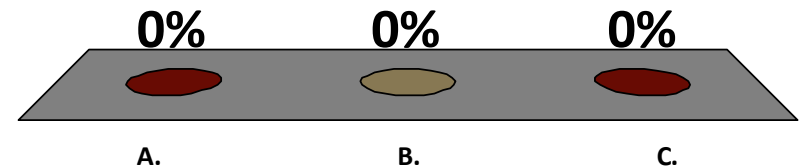
FRANK THE WHISTLEBLOWER

- Frank Dodd works at GOOD Pharma Co
- He is a Chinese citizen, who has been working at the U.S. affiliate
- Frank has made compliance allegations in the past that, following investigation, have been found to have been unsubstantiated
- The Company has expended considerable resources conducting investigations into the various allegations that he has made
- He witnesses misconduct surrounding the launch of GOOD Pharma Co.'s new product, Vieva, including off-label promotion and kickbacks in the U.S.
- Being a friendly guy, and spending quite a bit of time around the water cooler, Frank has good reason to believe that the same activity is happening in GOOD Pharma Co.'s offices in China, and perhaps other markets
- Having seen compliance brochures almost everywhere he seems to look, touting the company's compliance program and encouraging reporting, Frank decides to call the GOOD Pharma hotline to report the misconduct
- But the hotline doesn't work!

- To Frank's distress, the misconduct continues
- Three months pass from Frank's failed hotline call, and he contemplates leaving the company to protest the ongoing misconduct, and join a family business.
- Instead, he decides to report the misconduct again
- The Board, GC and CEO receive an email, laying out the alleged wrongdoing in great detail, as if written by an outside lawyer. It's anonymous.
- The email indicates that if the Company doesn't do the right thing in the 120 days, the information would be shared with the US Attorney's Office in Boston, the U.S. DOJ and SEC in Washington DC, and the Chinese authorities
- Upon a careful reading of the email complaint, however, it appears that some of the language used resembles language used in Frank's past claims

IN LIGHT OF THEIR SIMILARITY TO FRANK'S PAST UNSUBSTANTIATED CLAIMS, THE COMPANY SHOULD DO WHICH OF THE FOLLOWING WITH THESE NEWEST CLAIMS?

- A. Conduct a full investigation
- B. Narrow the scope of any investigation
- C. Potentially disregard the newest claims as frivolous

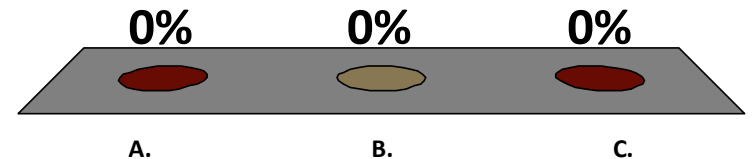


THE LEADERSHIP MEETING

- Gary G., the GC, Ashley W., the CCO, and Sir Henry Leaks, the CEO, meet to discuss Frank's email, and what to do about this sudden mess
- The whistleblower allegations are the first major legal and compliance issue GOOD Pharma Co. has experienced since the CIA expired six months ago
- Ashley thinks the Compliance team should lead the investigation and report the results. Gary thinks that's absurd, and the Legal team should handle it
- Sir Henry asks what support outside counsel can provide
- With budgets slashed quite a bit since the CIA expired, the investigation team needs to be cost efficient because there is no budget for any of this
- The internal team agrees that there needs to be an investigation

WHICH FUNCTION – COMPLIANCE OR LEGAL – SHOULD LEAD THIS REVIEW? IF COMPLIANCE WERE TO LEAD IT, COULD THE REVIEW BE CONSIDERED LEGALLY PRIVILEGED?

- A. Legal, and it's privileged
- B. Compliance, and it's privileged
- C. Compliance, and it's not privileged



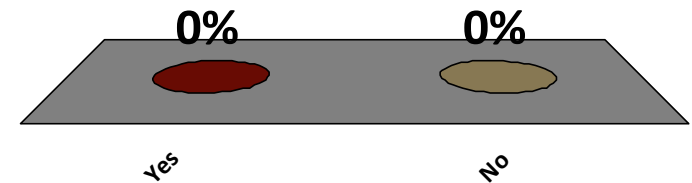
THE LEADERSHIP MEETING CONTINUED

- The team hires outside counsel to handle the investigation
- Ashley and Gary disagree on what to do about the threat to contact the various government authorities, and whether to make a voluntary disclosure
- Ashley, incredibly worried about all of this, wants to make an immediate disclosure to the various government authorities, one and all, citing the credit GOOD Pharma Co. will get for being forthright and cooperative
- Gary, does not think GOOD Pharma will get any credit by disclosing at this stage and instead risks engaging the government unnecessarily, before GOOD Pharma has investigated the allegations. He has no idea why Ashley, as the CCO, should even be offering her opinion on a strictly 'legal' matter
- Sir Henry isn't sure what to do, and is not happy that his two direct reports haven't gotten aligned. But he tends to agree with his General Counsel, and doesn't think that companies really receive a benefit for making disclosures

ARE SIR HENRY AND GARY RIGHT THAT THE COMPANY SHOULD NOT REACH OUT TO THE AUTHORITIES AT THIS TIME BECAUSE THERE WOULD BE NO BENEFIT?

A. Yes

B. No



- Sir Henry chimes in that, in addition to thinking about informing the government, Pharma Co. needs to consider what to say to its Board of Directors and Audit Committee, neither of which have really been asking a lot of questions about compliance since the expiration of the CIA.
- He also asks Ashley and Gary what, as a publically traded company, they need to be thinking about in terms of making any sort of public disclosures?
- And what about the outside auditors, who are always seemingly giving them a hard time about stuff as unimportant as routine t&e matters?
- Things seem to be happening quickly is there anyone they are missing?

QUESTION: Which of these stakeholders needs to be briefed at this point?

THE INVESTIGATION

- The investigation team discusses the scope of the investigation and raises a lot of questions. They finally know that they need to get started on this.
- What GOOD Pharma Co. offices should the team investigate: China, as mentioned in Frank's email, or any other markets? Or GOOD Pharma Co. globally? Do they do this by product? By business line? By geography?
- From whom should the team collect documents, and what search terms should they use? Should they just focus on the server? Actual laptops?
- What about preserving all of this information?
- What do they tell their employees about what to do and what not to do?
- And who should do all of this? Gary's team? Outside counsel?

QUESTION: What rules of thumb should the investigation team use as they determine the scope of the investigation?

WITNESS INTERVIEWS

- The investigation team runs into trouble as they begin witness interviews
- One witness wants his own lawyer present during the interview
- One wants to record the interview
- One refuses to cooperate at all
- With there being much to do, GOOD Pharma hired two law firms in order to try to get done as much as possible within the threatened 120 days
- Unfortunately, though, the two firms have been conducting their witness interviews differently. One is providing Upjohn warnings, and noting the government investigations. The other is taking a more 'cautious' approach.

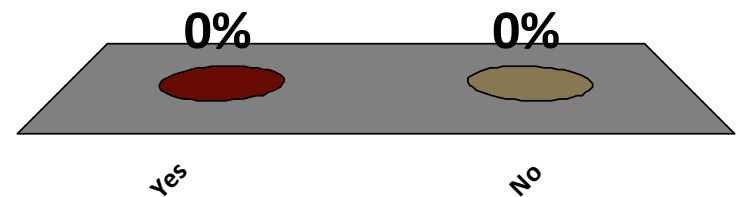
QUESTION: How should the investigation team handle these issues?

- The investigation team finally finishes the investigation and has prepared a summary report. It's long, and full of detailed, adverse findings
- The draft report, prepared by outside counsel, also names individuals within the company, some of whom were involved in serious FCPA violations
- Ashley wants to send the report to the government, in the spirit of cooperation and full disclosure, and argues that the company can selectively waive privilege with the government, and still protect it vis-à-vis others
- It is no surprise that Gary wants to keep the report internal in order to maintain legal privilege around the matter. This is a legal matter after all.
- He suggests sharing some underlying documents instead of a formal report

**QUESTION: In what manner should the investigation be reported internally?
What are the positives /negatives of providing the report to the
government?**

WOULD YOU MAKE A DISCLOSURE OF THIS MATTER TO THE GOVERNMENT?

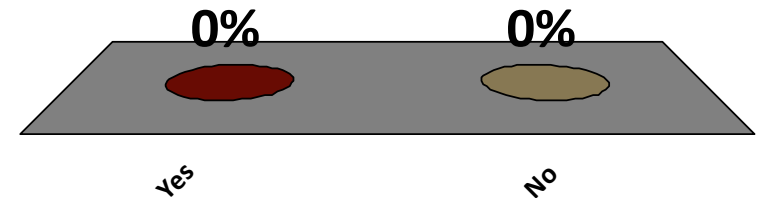
- A. Yes
- B. No



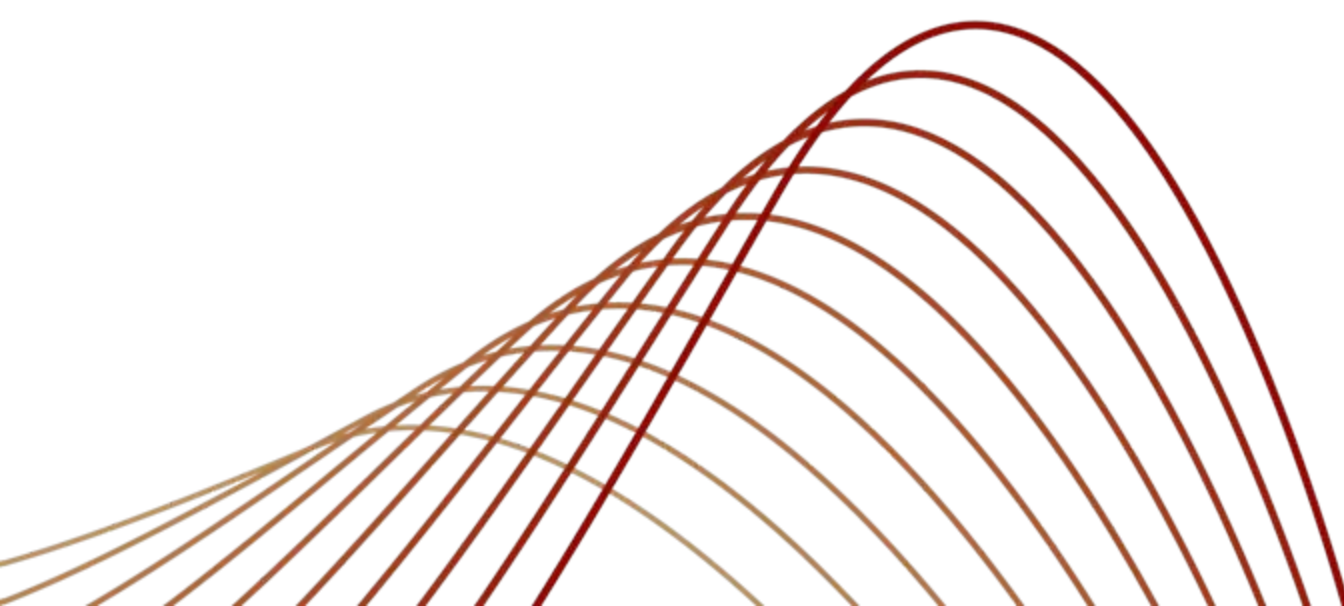
- Sir Henry reads the draft report and has serious concerns
- Two mid-level managers, whom he knew well as he rose through the ranks, are directly implicated in the likely FCPA violations
- Outside counsel has advised that, in light of the government's *Yates* memo, that the Company must produce all evidence against them
- In addition, the report mentions two members of Sir Henry's leadership team who are good friends and longtime colleagues
- The evidence against them is more mixed, but outside counsel again advises that in order for the Company to gain cooperation credit, the Company must also produce all evidence against them

WHAT SHOULD SIR HENRY, ASHLEY AND GARY DO? WOULD YOU TURN OVER ALL OF THE EVIDENCE AGAINST YOUR COLLEAGUES?

- A. Yes
- B. No



COMMENTS AND QUESTIONS



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