

20
23

09 MAY – 11 MAY

LIFE SCIENCES CONFERENCE

Future-Ready Resilience: Preparing to
Face Challenges in the Uncertain Future

ACC Association of
Corporate Counsel
SAN FRANCISCO BAY AREA

Virtual CLE &
Live Social Event

**WILSON
SONSINI**

Life Sciences and the FCPA – What Are Your Risks and How Can You Manage Them in the Face of New DOJ and SEC Enforcement Priorities?

Tarek Helou and Nicole Kim

May 11, 2023

Agenda

Identify key anti-corruption compliance issues for life sciences companies

Share best practices for how to approach compliance and how to handle investigations

Agenda:

- How does the FCPA apply to you?
 - Who is a “foreign official” under the FCPA?
- What are your biggest FCPA risks?
- How should you respond to aggressive enforcement by the DOJ and SEC?
- How do the DOJ’s new policies affect compliance and investigations?

How does the FCPA apply to you?

The FCPA prohibits bribing non-U.S. government officials to gain any business advantage

■ Elements of an FCPA violation:



How does the FCPA apply to you?

The anti-bribery provisions of the FCPA apply to your company if:

- Its shares trade on a U.S. exchange
- It is incorporated in the United States or has its principal place of business here
- An employee (or agent) bribes a foreign official while in the United States

How does the FCPA apply to you?

The FCPA's accounting provisions apply only to companies with securities that trade on a U.S. exchange

■ Issuers must:

- Maintain accurate books and records
 - Applies to spending and use of assets
 - Standard is reasonableness
- Implement a system of effective internal accounting controls
 - Ensure that money is spent as authorized by management
 - Standard is reasonableness

■ Civil corporate violations: strict liability

■ Criminal corporate violations: wrongful conduct

Who is as a “foreign official?”

Any employee or person acting on behalf of any:

- Foreign governments
- State-owned or state-controlled enterprises
 - Public hospitals (doctors and nurses)
 - Public pharmacies (pharmacists)
 - Public universities (researchers)
- Royal families (including royal family members)
- Public international organizations (the World Health Organization, the U.N.)
- Political parties (including party officials)
- Candidates for political office
- Family members of “foreign officials”

What are your biggest FCPA risks?

In the life sciences industry, many business advantages involve “foreign officials”

- Selling to or through public health institutions
- Promoting products through health care providers
- Operating clinical trials
- Obtaining regulatory approval, licenses, or permits
- Responding to market research studies
- Conducting research studies
- Affecting price controls
- Advancing or impeding legislation
- Influencing court proceedings
- Using consultants to navigate complex regulatory regimes

In recent years, many pharmaceutical companies have been investigated and prosecuted for bribing foreign HCPs to promote and boost sales.

These bribes were often through gifts, entertainment, travel, and conference support, rather than cash.

What are your biggest FCPA risks: Third parties

Using third parties significantly increases your risk FCPA risk

- Third parties include business partners, finders, sales agents, travel agencies, and consultants
- Third parties may fund bribes using success fees, retainers, consulting fees, or discounts
- Bribes are illegal whether they are paid directly or through a third party
 - The DOJ and SEC must show that you *knew* a bribe would be paid
 - Knowledge:
 - Actual knowledge
 - Belief a in “high probability” that something will happen
 - Conscious disregard or “willful blindness”

What are your biggest FCPA risks: Third parties

Take reasonable protective measures (such as those listed on this slide) to ensure that business partners and other third parties comply with anti-corruption laws

- Consult with the Compliance Department to assess operational, corruption, compliance, and reputational risks from potential investments or business partners
- Document due diligence conducted and anti-corruption analysis
- Obtain internal approvals
- Regularly monitor third parties

What are your biggest FCPA risks: Third parties

Third parties are involved in half of all FCPA cases

■ Why are you using a third party?

■ Effective due diligence

- Should not take months
- Risk-based (use your data to determine your risk)
- Obtain corporate background information on potential targets and partners
- Order independent reputational due diligence report
- Discuss compliance-related issues and expectations with the third party's management
- Assess corruption risks presented by the country and the industry
- Follow up on any red flags
- Document everything (including exceptions)

What are your biggest FCPA risks: Third parties

Third parties are involved in half of all FCPA cases

■ Onboarding

- Meet them at their office
- Contract provisions
 - Comply with law
 - Appropriate payment terms
 - Clear explanation of services with work product requirements
 - Clear protocols for interacting with foreign officials
 - Audit rights and duty to cooperate with investigations
 - Disclose violations
 - Certifications
 - Subcontractor provisions

What are your biggest FCPA risks: Third parties

Third parties are involved in half of all FCPA cases

■ Continuous monitoring

- Controls over payments
- Exercise your audit rights
- Train the third party's employees
- Certifications
- Refresh due diligence

Hypothetical

- You are conducting due diligence on a potential distributor in India.
- Through your due diligence, you learn that the distributor's manager is the son of an Indian politician who runs a regional government agency that oversees licensing and permitting for businesses, including the distributor.
- The partner's proposed fees seem to be in line with market rates.
- The partner also certifies during diligence that it will comply with applicable anti-corruption laws.

What should you do?

- A. Pull out of the proposed arrangement.
- B. Escalate this issue to your Compliance Department.
- C. Conduct additional diligence on the supplier.

What are your biggest FCPA risks: Joint ventures

- Joint ventures can create FCPA risk
 - Depends on the degree of control and knowledge of the JV's conduct
- Often required
 - Extra attention to JVs with state-owned companies
- Due diligence, establishment, and monitoring
- Pre-deal
 - Identify risks and possible existing misconduct
 - Due diligence on JV partners
 - Screen directors and ultimate beneficial owners
 - Third parties, customers, existing contracts, and licenses
- Control of JV and liability
 - Majority owner or minority stake
 - JV could be your agent
 - Willful blindness



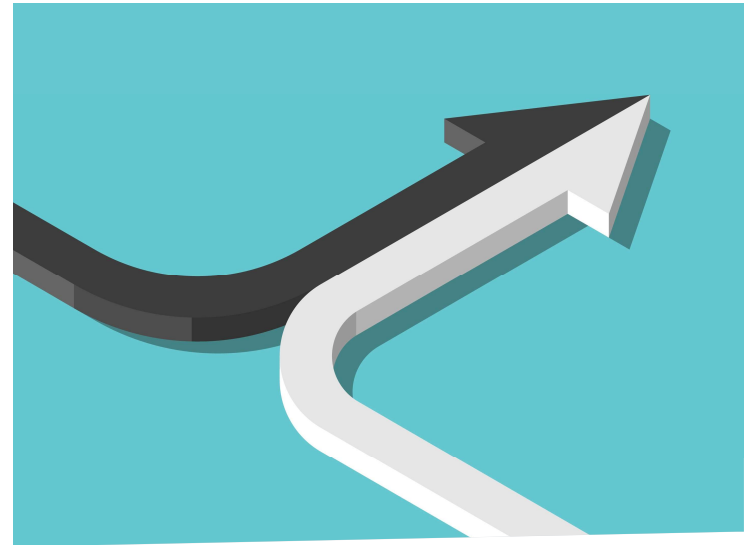
Risk Areas: Joint Ventures (cont'd)

■ Agreement and governance to consider

- Provisions to address and minimize corruption risk
 - Even if you own a minority stake
- Include a CCO and compliance program
 - Apply your compliance program if you control the JV
- Forward-looking and retrospective representations
- Audit requirements
- Termination clause
- Who do you want to select: CEO? CCO? CFO? Head of HR?

■ Operations

- Continue to assess risk and address it
- Certifications
- Train individuals who interact with foreign officials



Hypothetical

- A Brazilian agent comes to you with an opportunity to invest in a Brazilian pharmaceutical company that sells directly into Brazil's state-run healthcare system.
- The agent seeks a commission for connecting you with this company and for providing local knowledge and contacts.
- The commission is higher than would be expected in the United States, but the agent insists that the proposed commission is consistent with industry standards in Brazil.
- In addition to making these connections, the agent also will arrange meetings with the Brazilian government so that you can better understand the company's growth potential.

What should you do?

- A. Approve the commission since it seems to be reasonable in Brazil.
- B. Reject the proposed commission and flag the agent as a suspicious third party that you should avoid.
- C. Carry out more diligence on the agent to better understand the agent's background, the services that the agent would provide in this deal, and whether the proposed commission is reasonable in Brazil.

How should you respond to aggressive enforcement by the DOJ and SEC?

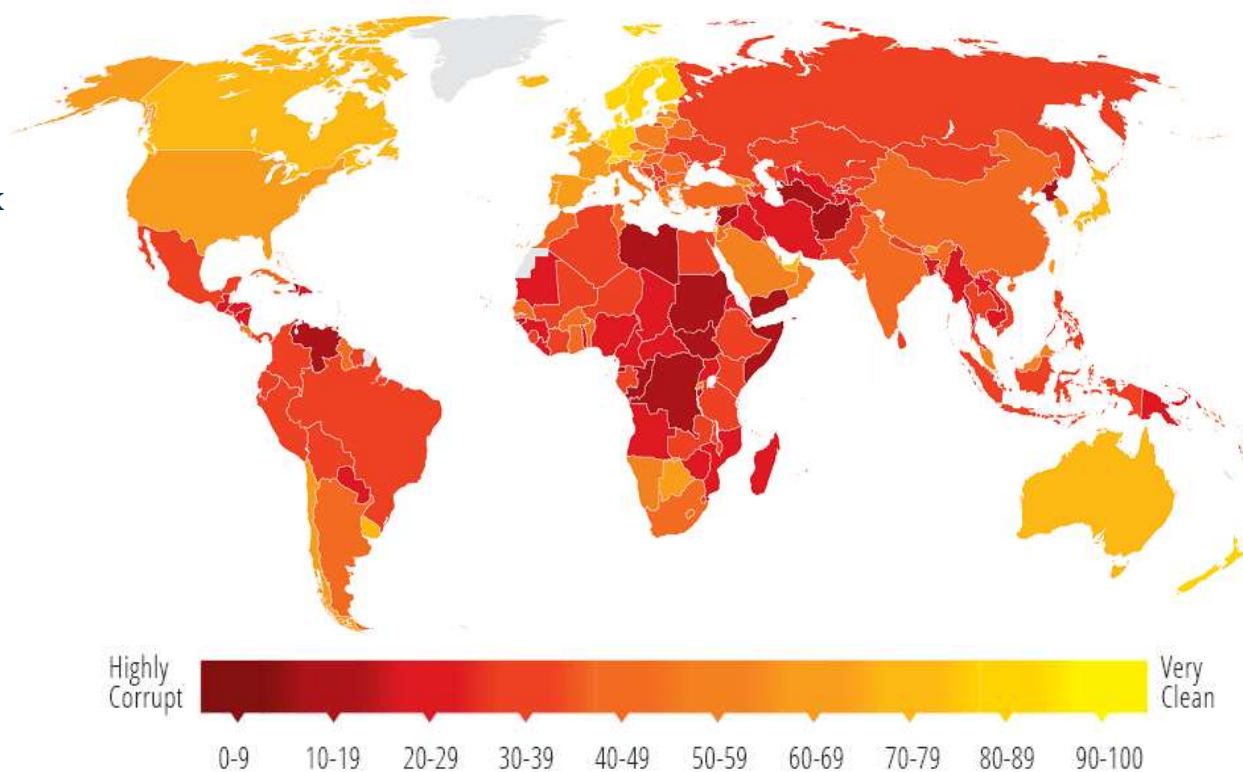
Get ahead of them: an ounce of prevention is worth a pound of cure

- Your compliance program should have adequate controls and processes for reviewing and approving high-risk expenses
- DOJ and SEC expect companies to use their own data to detect suspicious expenses
- Keep an eye out for:
 - Speaker fees or conference fees for HCPs
 - Gift, travel, or entertainment for foreign officials
 - Payments for research grants or regulatory inspections
 - Inflated invoices to customers or distributors
 - Misused or falsified marketing expenses

How should you respond to aggressive enforcement by the DOJ and SEC?

Make your program risk-based

- Be extra vigilant when operating in high-risk countries
- Transparency International publishes the annual Corruption Perception Index
- Geography should be a factor
 - Not the only factor



How should you respond to aggressive enforcement by the DOJ and SEC?

When prevention fails, remediation must succeed

- Determine whether to disclose violations and cooperate with government
 - Often the most important decision a company must make
 - DOJ has recently offered more guidance that changes this calculus
- Review and improve your compliance program
- Discipline culpable employees
 - Have a range of options
 - Factors
 - Violation of law?
 - How culpable?
 - Did they cooperate?
 - Seniority?

How do the DOJ's new policies affect compliance and investigations?

Revisions to how the DOJ evaluates corporate compliance programs

■ New guidance addressing off-channel messaging apps (like WhatsApp, WeChat, and iMessage)

- The DOJ's focus is fact-intensive and looks at company-specific issues, such as:
 - Do you preserve business-related electronic data and communications?
 - Do you have a policy for using off-channel communications?
 - Is it tailored to your risk profile and business needs?
 - Is it integrated with other policies (BYOD policy, IT policies)?
 - Do you train your employees?

■ Provide financial incentives tied to compliance

- Compensation structures that reward ethical behavior
- Compensation structures that punish unethical behavior
- Apply to all titles and positions

How do the DOJ's new policies affect compliance and investigations?

Revisions to how the DOJ evaluates corporate compliance programs

■ New guidance addressing off-channel messaging apps (like WhatsApp, WeChat, and iMessage)

- Considerations for evaluating your own compliance program:
 - Do you want to permit messaging apps?
 - What messaging apps are your employees currently using?
 - Do they use personal devices or company-issued devices?
 - What preservations and deletion settings do you use?
 - Do your policies require employees to retain substantive communications?
 - Are your policies enforced?
 - How do you train employees?

How do the DOJ's new policies affect compliance and investigations?

Revisions to how the DOJ evaluates corporate compliance programs

- New guidance addressing the company's culture of compliance
 - DOJ expects companies to value and invest in compliance, including by:
 - Empowering compliance officers
 - Having discipline procedures that are clearly communicated and *actually enforced*
 - Rewarding ethical behavior through compensation structures
 - Punishing unethical behavior swiftly and without regard to title or position

“Our goal is to ensure that the company uses compliance-related criteria to reward ethical behavior and punish and deter misconduct.”

- Assistant Attorney General Kenneth Polite

How do the DOJ's new policies affect compliance and investigations?

New incentives for companies to self-disclose and cooperate with the DOJ

- The original standard for getting a declination—a company's best outcome—has not changed.
- Absent aggravating circumstances, the DOJ will decline to prosecute a company when it meets three factors:
 - 1) Voluntary self-disclosure
 - 2) Full cooperation
 - 3) Timely remediation

Aggravating circumstances include (but are not limited to):

- Involvement by executive management
- Significant profit from the misconduct
- Egregiousness or pervasiveness
- Criminal recidivism

How do the DOJ's new policies affect compliance and investigations?

New incentives for companies to self-disclose and cooperate with the DOJ

- The DOJ created a higher standard with additional opportunities to achieve a declination
- Even with aggravating circumstances, the DOJ will decline to prosecute a company when it meets ***four*** factors:
 - 1) ***Immediate*** voluntary self-disclosure
 - 2) ***Extraordinary*** cooperation
 - 3) ***Extraordinary*** remediation
 - 4) ***Had an effective compliance program that detected the misconduct***

How do the DOJ's new policies affect compliance and investigations?

New incentives for companies to self-disclose and cooperate with the DOJ

- Companies with aggravating circumstances that meet the lower standard but not the higher standard:
 - 50-75% reduction in penalty
- Companies that did not voluntarily report the potential violation—but still cooperated and remediated:
 - Up to 50% reduction in penalty

How do the DOJ's new policies affect compliance and investigations?

DOJ is prioritizing individual accountability

- Prosecutors are being encouraged to *quickly* prosecute individuals who commit and profit from white collar crime
- New requirement for full cooperation credit
 - Company must come forward “more quickly” with evidence and information relating to individual culpability

How do the DOJ's new policies affect compliance and investigations?

DOJ is prioritizing individual accountability

■ Pilot Program on Compensation Initiatives and Clawbacks

- Three-year test period
- Applies to companies with DOJ resolutions
- Must incorporate compliance criteria into compensation structures
 - Might include withholding bonus for employees who do not satisfy compliance requirements
- Company's fine will be reduced by 100% of the money it claws back from culpable individuals
 - Company's fine may still be reduced 25% even if good-faith clawback efforts fail.

“Our goal is simple: to shift the burden of corporate wrongdoing away from shareholders, who frequently play no role in the misconduct, onto those directly responsible.”

- Deputy Attorney General Lisa Monaco

Presenters



Tarek Helou
Partner
Litigation Department
thelou@wsgr.com
D: 202-973-8863

Nicole Kim
Vice President of Litigation
Cardinal Health
nicole.kim@cardinalhealth.com