



EVERYTHING MATTERS

# Global Investigations: Issue Spotting In A Case Study

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**Carolyn F. McNiven**

Partner

555 Mission Street, Suite 2400  
San Francisco, California 94105-2933

2000 University Avenue  
East Palo Alto, California 94303-2214

T: +1 415 836 2505 F: +1 415 659 7304  
carolyn.mcniven@dlapiper.com

- 13 years as prosecutor
- 6 years as health care fraud coordinator
- 5 years in white collar defense

- Describe how law enforcement is reacting to globalization of business
- Spot Key Legal Issues that Arise During Investigations
  - What are the questions you should be asking
  - Identify red flags
- Provide a Guide/Template for Conducting Investigation
- Apply Template to Case Study
  - Focus on Document Gathering and Witness Interviews

# IMPLICATIONS OF GLOBALIZATION

- Key Business Operations in Multiple Countries
- Actions subject to multiple countries' laws and regulations
- People (Witnesses) and documents in multiple jurisdictions
- Transactions/interactions may implicate a country's laws even where no physical nexus exists





# Law Makers and Law Enforcement Respond to Globalization

- Enact laws with expansive/aggressive extra-territorial reach
- Increased international cooperation in enforcement



# Consequences of Enforcement Responses

- Enforcement actions concerning global operations at an all-time high
  - FCPA/UK Bribery
  - Money Laundering
  - Anti-Trust
  - Tax etc, etc, etc
- Practical reality of gatekeeper roles of FDA and counterparts necessitates compliance regardless of actual reach of laws
  - New Drug trials
  - Good Manufacturing Practices
- Chauvinism/Nationalism/Protectionism
  - ... Enormous Headaches for GCs and Compliance

# GLOBAL INVESTIGATIONS TEMPLATE



- Step 1: Identify the laws/regulations under investigation
- Step 2: Identify where acts took place and where evidence – witnesses & documents – are
- Step 3: Create Investigative Plan
- Step 4: Identify countries whose laws may be implicated by Investigative Plan
  - Procedural (i.e., privacy and privilege protections)
- Step 5: Investigate
- Step 7: Respond
  - Report/recommend/document/produce/comply/redress
  - Identify protections covering affected employees

# THE CASE STUDY

Company “Big Pharma,” which produces “Cureall,” has global operations including manufacturing facilities in China, HQ in US, and business office in UK

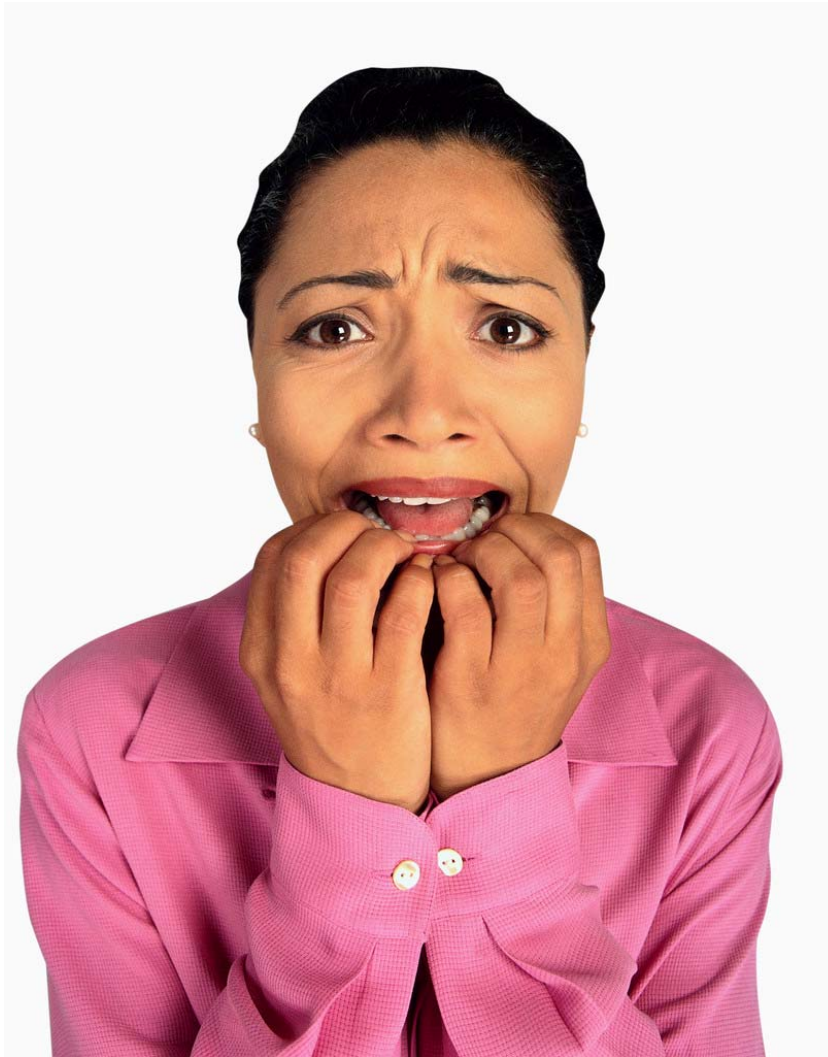
Company learns that whistleblower claims plant supervisor in China purchased low-cost contaminated ingredients for Cureall and lavishly entertained South Korean and Chinese government officials responsible for purchasing Cureall for state hospitals

Patients who took Cureall become ill in South Korea

SEC sends subpoena to US HQ requesting documents relating to Cureall marketing and distribution, with focus on entertainment of government officials; DoJ Crim Div sends subpoena requesting same documents; South Korean authorities have opened investigation on illnesses

Documents are in China, Europe and US

# Response?



APPLY TEMPLATE TO CASE STUDY



- Remember: Assess reporting obligations
  - Is Big Pharma publically traded? regulated? Where?
  - Does service of subpoena trigger reporting obligations
- Patient Health Risk
  - Parallel scientific investigation
- Other Voluntary steps
  - Board/Audit committee
  - Recall –voluntary etc
  - PR/Media
  - Investor Relations
- Identifying Team
  - Engaging outside legal counsel
- Establish Litigation Hold

# Step 1: Identify Underlying Offense

- Who is investigating?
  - US law enforcement – SEC, DOJ criminal prosecutors
  - South Korean health officials
- What are they Investigating?
  - Violation of US law relating to Cureall
  - Bribes/manufacturing issues/consequences
- Bases of liability/alleged offense?
  - FCPA
  - BMP
  - False Statements?
  - Books & Records?
- Identify other Countries whose laws may have been broken
  - UK
  - China
  - South Korea
  - Others?

# Step 2: Identify Locations Involved

- Where did the event(s) take place?
  - manufacturing: China
  - bribes & entertainment: China
  - drug purchasing: China & South Korea
  - Health effects: South Korea
  - Reporting/Books & Records: US and ?
- What are the relevant documents and where are they located?  
(Make sure lit hold is in place)
  - majority of hard documents: US, Europe & China
- Where are the witnesses?
  - China, US, and South Korea

# Step 3: Develop Investigative Plan

- Identify Goals of Investigation
  - Assess exposure/potential liability
  - Respond to document production
- Exposure Assessment
  - Start by examining allegations
    - (1) Bad manufacturing process that (2) caused harm to patients and (3) extravagant entertainment to (4) induce purchase of Cureall
  - Develop Plan targeted to uncovering facts relating to all allegations
    - Target 1: Bad Manufacturing
    - Target 2: Entertainment to Influence Purchases
  - For Each Target Identify:
    - What are the key facts
    - How am I likely to learn them

- Issue 1: Was there a Manufacturing Problem at Plant?
  - Review records relating to alleged contaminated goods
  - Interview plant manager and others on the ground at plant
  - Trace shipments of alleged contaminated goods
  - Interview supervisors in France
  - Gather information about illnesses in South Korea
- Issue 2: Were Officials Responsible for Drug Purchases Lavishly Entertained
  - Review expense reimbursement reports
  - Interview regional sales manager and sales staff on the ground
  - Examine sales reports



# Step 4: Identify Laws Implicated by Investigation Plan/Production

Conducting global investigations require sensitivity to regional laws and regulations. Broadly, those fall into four categories:

1.

2.

Interviews of  
Employees  
or  
Third-Parties

3.

Involvement  
of/  
Interactions  
with Local  
Authorities

4.

Remedial/  
Disciplinary  
Actions

Basic Concern: Where are the relevant documents/data and is dissemination/disclosure prohibited or otherwise protected in country where they reside?

Issue Spotting:

- Contain sensitive information (personal etc)?
- Are there any local laws controlling dissemination?
- Can production be compelled?
- What are the consequences for violating local law versus not responding to compelled production?
- If document is (voluntarily) produced, what if any consequences are there?
  - Is there a waiver of privilege
  - Are you bringing documents otherwise inaccessible to law enforcement and thereby exposing them to (1) us by that country's authorities; (2) use by other authorities

## China

No general data protection laws exist. Regulation on Management of the Administration of Internet Electronic Messaging Services requires the contents of particular databases be kept confidential, be security protected, and not be distributed. Article 12 arguably requires consents before personal information can be collected, obtaining consent is advised.

Articles 260, 265 and 266 of PRC Civil Procedure Law preclude a foreign court from seeking discovery from subsidiaries in the PRC, that would violate Chinese judicial sovereignty. See *Sugian Wahaha Bev. Co. Ltd., et al v. KPMG Guangzhou* (2008). Voluntary disclosure to parent is ok.



## Japan

Personal Information Protection Law (2003) governs databases of more than 5,000 individuals. Employees must be informed and they must opt out if they object. May not transfer data to third parties without first obtaining employee consent (exceptions exist).

## Singapore

Singapore constitution does not provide for privacy right. Common law protects personal data from being revealed and used without authorization. Optional Model Code (2002). No database registration required. No law requires consent to process or transfer data.



## Taiwan

Limited privacy rights in Taiwan's Constitution. Taiwan's Computer-Processed Personal Data Protection Law (1995) regulates computerized processing of data. No comprehensive data protection laws. Employees must register with government to process or transfer employee personal data. Subject to some restrictions, you may transfer data out of the country. You need written consent to collect and process employee data or you need: other contract agreement, data public, academic purpose or other law allows it.

## Thailand

Constitution (1997) establishes traditional privacy rights. No general data protection law. Data Protection and Privacy Bill (2001 proposed) awaits approval. No Registration required and no consent required. Advisable to obtain consent.

## Bad Manufacturing Prong:

- Documents: Documents relating to shipment of contaminated Cureall to South Korea are located in hands of third party but could be obtained by the company
- Presume: documents of a type covered by subpoena
- Issue Spotting
  - Should the Company obtain and produce to US Authorities?
  - Does it have to?
  - Should counsel seek to review them in hands of third party?
  - Will South Korean Authorities Obtain from US Authorities?
  - If legal counsel makes notes about contents of records are those notes subject to discovery if sent in an email



- Data: patient identifying information regarding adverse reactions
- Presume: covered by subpoena
- Issue spotting:
  - Is the patient information protected from production
  - What countries involved/laws apply?
  - Is production mandatory?
  - What are the consequences of production/non-production?

- Data Privacy
  - Inherent conflict between obligation to disclose and obligation to keep private information confidential.
  - Different jurisdictions resolve this conflict differently.
  - Possible sanctions for violation of law include: fines, cease and desist orders, criminal penalties.
- Hotlines/Anonymous Tip Collection
  - Required in some jurisdictions/Prohibited in others



## Pre Interview Issue Spotting:

- Is written consent required?
- Should a specific warning be given to the witness?
- What can company do if employee fails to cooperate?
- Do local laws give employees rights?
  - To know of allegations in advance
  - To have a representative (union/attorney) present
- Who should conduct the interview and how is it to be memorialized?
  - **BIG ISSUE:** Availability of Attorney Client Privilege & Attorney Work Product Protections are key

# Special Consideration: Privilege

- Not all countries recognize attorney client privilege at all
- Many do not recognize in-house counsel for purposes of asserting attorney/client privilege.
- Other jurisdictions which base privilege based on the attorney-client relationship define the term client narrowly and thus caution will need to be taken to ensure that any particular individual will be considered as client.
- Certain Asian countries, such as China and Japan, do not recognize the concept of “privilege” so as to enable an attorney to refuse to disclose information, but do recognize a more general concept of “confidential information.”
- In other counties where privilege is recognized it is not as clear whether such privilege will extend to in-house counsel

*See sample survey chart next slide for sample survey. Always check with local counsel.*

# Summary of Privilege Laws

Country	AC Priv?	In-House AC Priv?
▪ Belgium	Yes	It depends
▪ Brazil	Yes	Yes, if related to a/c
▪ Czech Rep.	No	No
▪ EU	No	No, not at EU
▪ Germany	Yes	It depends
▪ Hong Kong	Yes	Yes
▪ France	Yes	No
▪ Hungary	Yes	No
▪ Italy	It depends	It depends
▪ Japan	No	No
▪ Luxembg.	Yes	No
▪ Netherlands	Yes	yes, can depend
▪ China	No	No, except state secrets/comm. info.

Country	AC Priv?	In-House AC Priv?
▪ Poland	Yes	Yes
▪ Portugal	Yes	Yes
▪ Romania	Yes	Yes
▪ Russia	Yes	No
▪ Singapore	Yes	It depends
▪ Slovakia	Yes	No
▪ Spain	Yes	Yes
▪ Sweden	Yes	No
▪ Switzerland	Yes	No except for business confidentiality
▪ Thailand	Yes	Yes
▪ UK	Yes	Yes
▪ US	Yes	Yes, except for business advisory role



## Key Interviews:

- Plant Manager in China
- Regional Sales Manager who directed entertainment of government officials
- What Ifs:
  - Refuse to cooperate?
  - Confess?
  - Say they got approval from higher up?
  - Lie?
  - Deny?



- Report
  - Is it privileged?
  - Can it be discovered?
  - Does it matter?
- Produce Documents Pursuant to Subpoena (if exists)
- Take Action
  - Remediation
  - Revise SOP/Compliance Plan
  - Terminate wrong-doer

**NOTE:** Before you do any of the above, an assessment should be made of the probable consequences and a plan for dealing with them developed.

# Note About Remedial/Disciplinary Actions

In certain countries there may be limitations or obstacles Requirements for the involvement of trade union representative or Work Councils

- Evidence or level of proof required to “establish” wrong-doing
  - See, e.g., 2003 Act (Art. 158) in Indonesia which requires: (i) apprehending the worker red-handed; or (ii) an admission of guilt by the worker; or (iii) evidence to the act, and a confirmation of the evidence by at least two people.
- Requirement for phased termination e.g., oral warning, written warning, and termination.
- Requirement for outside determination
  - In Egypt, the employer is barred from directly dismissing the employee. The employer must first submit a request for dismissal to the appropriate labor committee, which is the only authority empowered to dismiss the employee.

## **PRACTICE POINTER**

*In certain countries, including many countries in Asia & the Middle East, there may be certain advantages to reaching a negotiated settlement with employees rather than “forcing” termination*

USE LOCAL COUNSEL

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