# The Second Annual Pharmaceutical and Industry Regulatory & Compliance Summit

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# Document Retention and Destruction: Implementing a Document Management Policy


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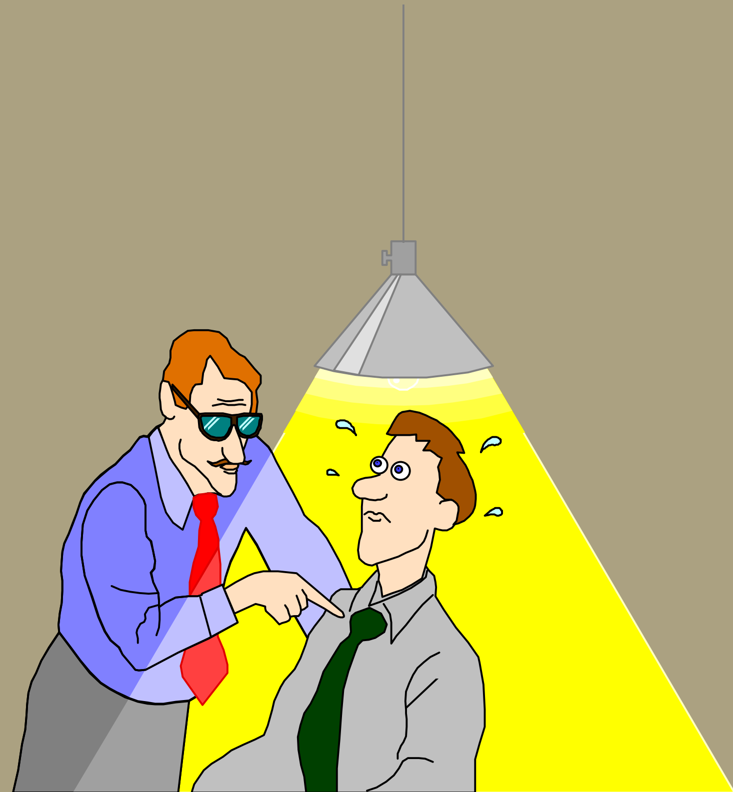
# The written records of your business:

Some can help

Some can hurt



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# Overview

- Elements of a document management policy

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# Document Management Policy

- To minimize litigation risks and to reduce expenses of document retention, a company should implement a document management and destruction policy
- Keeping documents, both in hard copy and electronically, posses special risks for subsequent litigation and investigations

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# Document Management Policy

- A routine document management and destruction policy is lawful as long as it is not keyed to actual or threatened litigation
- The policy should be in writing, issued in the same manner as other company policies and made a part of company policy manuals maintained in the normal course of business

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# Document Management Policy

- The document management program should be based solely upon the company's legitimate business needs
- The applicable regulatory framework must be carefully analyzed to assure compliance with applicable rules and regulations

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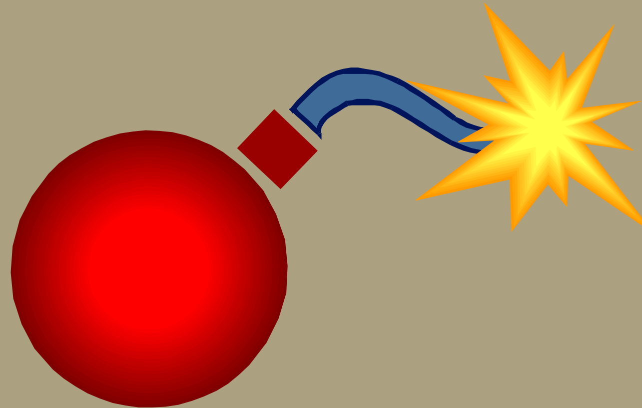
# Document Management Policy

- The policy should emphasize that selective destruction of potentially relevant and damaging documents is prohibited



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# Document Management Policy

Policy should include:

- Limiting distribution of privileged and confidential documents
- Marking documents as "Attorney-Client Privileged" or "Attorney Work Product"
- Affirmatively stating that documents are for purpose of seeking, obtaining, or providing legal advice

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# Document Management Policy

- Limiting distribution (only to those who "need to know")
- Maintaining in separate, secure files marked "Privileged & Confidential"
- Physically separating privileged from non-privileged files

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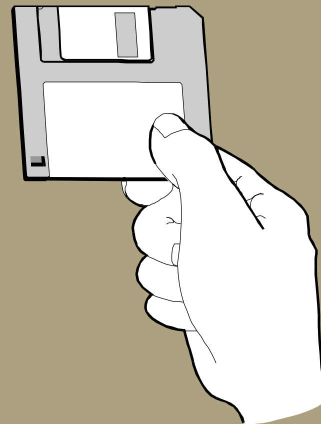
# Document Management Policy

- Explicitly requiring corporate confidentiality agreement so that corporate records are not to be disseminated outside of the company absent management permission



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# Document Management Policy

Other considerations:

- Categorize Documents
- Some maintained indefinitely (corporate bylaws)
- Others slated for routine, regular destruction after appropriate time periods

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# Document Management Policy

- Drafts followed by final may be appropriate for regular destruction as soon as a final report on topic prepared
- The policy should make explicit who has authority to produce documents in response to subpoenas in order to assure control over the process

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# Document Management Policy

Some examples from the caselaw:

- *In re Comair Air Crash Litigation* (E.D.Ky. Dec. 8, 1986) (Document retention policy adopted in bad faith. Sanctions imposed.)
- *Carlucci v. Piper Aircraft Corp.* (S.D. Fla. 1984) (No evidence that company personnel had ever routinely complied with any policies of document management program. True purpose was to eliminate unfavorable documents in litigation. Default judgment entered.)

# Document Management Policy

- *Levy v. Remington Arms Co., Inc.* (8th Cir. 1988) (Even a routine document destruction program did not preclude a finding that certain documents should have been retained notwithstanding the policy.)

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## "Knock, Knock . . . Who's There?"

## A Primer on Search Warrant Responses


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# Search Warrants

- Increasing reliance on search warrants as a tool in business crimes investigations (vs. Subpoenas)
- Businesses beware:
    - Search warrants are not just for “traditional” crimes and hardcore criminals anymore
- Government’s key advantages: “SURPRISE” & CONTROL

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# Search Warrants

- All searches and seizures are governed by the 4th Amendment's:
  1) Prohibition against **unreasonable** searches and seizures; and
  2) Requirement the warrants to conduct searches be supported by **"probable cause"**

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# Search Warrant

- A search warrant is **NOT** a license to conduct employee interviews
- Rule 41(a) limits a search warrant to:
  - "1) Property that constitutes evidence of the commission of a criminal offense; or
  - 2) Contraband, the fruits of crime, or things otherwise criminally possessed; or
  - 3) Property designed or intended for use or which is or has been used as the means of committing a criminal offense."

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# Search Warrants

- Process for Obtaining Warrant

1) Rule 41 - Fed.R.Crim.P

2) Federal law enforcement officer requests warrant from Magistrate Judge - usually with sworn affidavit with supporting grounds

3) Key Inquiry = **"Probable Cause"**

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# Search Warrants

- "Probable Cause" =

  - "A fair probability that contraband or evidence of a crime will be found in a particular place."

  - A "fluid concept" that is not easily translated into "a neat set of rules," but rather turns on the **"totality of the circumstances."**

See Illinois v. Gates, 462 U.S. 213, 238 (1983).

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# Search Warrants

- Search warrant can be completely based upon **hearsay** evidence
- Company does not even have to be a "Target" to be searched
- Warrant must describe "with particularity"--
  - places to be searched
  - items to be seized

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# Search Warrants

- Search must occur within 10 days of the warrant being issued
- Warrant shall be served In the daytime (6AM - 10PM) unless other times are specifically requested and authorized

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# Search Warrants

- Government has strong legal leverage during execution of search
- Number of agents varies (2-50)
- No need for "Cowboy" mentality:

  Be professional & courteous
- Best Advice:
  - Advance planning & organized response
  - Establish internal procedures & search response plan

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# Overall Goals of SW Response

- Improve “Crisis” Management:
  1) Demystify “searches” and prevent panic
  2) Prepare company representatives
- Protect legal interests of company and personnel/employees
- Minimize disruptive impact of search to on-going business operations

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# Overall Goals of SW Response

- Convey "good corporate" image
- Respond appropriately & legally --

  Not doing whatever the government requests
- Get the government what they are entitled to take or review as quickly as possible --- and get them out

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# Overall Goals of SW Response

- Make certain company operations can proceed after search completed
- Maintain integrity of privileged and proprietary information and documents
- Gain valuable insight into allegations & government investigation

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# Action Steps <u>During</u> Search

- Immediately contact management & counsel
- Request agents' credentials & copy of the warrant (and supporting affidavit - if unsealed)
- Provide agents with company memorandum re: search and privilege
- Request meeting with agents to discuss ways to minimize disruption with on-going operations (i.e. floor plans, organizational charts, etc.).

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# Company Search Memo

- Company's search memorandum should clearly state that company:

  1) Objects & does not consent to search;

  2) BUT - Company is willing to cooperate;

  3) Is represented by counsel;

  4) Requests opportunity to confer with counsel prior to search; and

  5) Requests all inquiries during search be directed to company search coordinators - not random employees.

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# Action Steps During Search

- Carefully review warrant for:
  1) Accuracy of information;
  2) Particularity of search limits; and
  3) Nature of alleged violations
- Typical “Defects”:
  1) Name of company;
  2) Facility address;
  3) Beyond deadline.

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# Action Steps During Search

- Pay close attention to scope of warrant
  - places to be searched
  - items to be seized
- Limit search to those areas specifically designated in warrant
- Do not consent to or allow agents to exceed limits and conduct an "expanded" search

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# Action Steps During Search

- Identify legally protected/privileged Files

  ** If dispute arises - segregate & submit to Magistrate "In Camera."

- Accompany agents & carefully monitor and record all aspects of search (conduct, statements, questions, requests, attitude)
- If agents refuse to allow company to accompany them -- seek order from Magistrate

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# Handling Employees During Search

- Alert employees (by e-mail or memo)
- Consider wending employees home
- Provide employees with an overview of rights (Gov't Usually Does Not)
- Advise employees not to interfere with or obstruct search
- Do Not instruct employees not to speak with the government agents
- Ask employees to direct questions from agents to company's representatives (search coordinator or legal counsel)

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# Employees' Rights During Search

- Employees are under no legal obligation to talk to the agents - However, they can if they choose
- Employees have a right to consult with an attorney
- Company will provide counsel (if applicable)

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# Employees' Rights During Search

- In many circumstances, employees should be sent home (after being advised of their rights)
- Where employees consent to be interviewed, try to be present during the interview and take detailed notes on both:
  1) Questions asked; and
  2) Answers given.

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# After the Smoke Clears

- Information is Power
- Gather all facts surrounding the allegations/investigation
- The Good, the Bad, and the Ugly

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# Post-Search Activities

- Request copy of search receipt / inventory (list of items taken)
- Request copies of all items seized.

  ** If request is refused - file Rule 41 motion
- Obtain copy of “Return” filed with court.

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# Post-Search Activities

- Immediately and thoroughly debrief or interview all employees who consented to government interview (if you were not present)
- Summarize all interviews into written memos

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# Post-Search Activities

- Since a search is “News,” prepare company’s media response/press release emphasizing:
  1) Preliminary nature of investigation
  2) Company’s willingness to cooperate (if applicable)
  3) Company’s own efforts to investigate facts
  4) Other positive / accurate facts

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# Post-Search Activities

- Channel all media inquiries to counsel
- Counsel should communicate with federal prosecutor to gather additional information (i.e., nature of investigation, targets, etc.).

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# Post-Search Activities

- Most Important Task:

  Initiate Privileged Internal Investigation

  1) Interviews

  2) Document Review & Summary

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# Government Subpoenas and Grand Jury Representation


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# Subpoenas, Audits, and Information Requests

- Government agencies and enforcement lawyers typically use subpoenas, audits, and information requests to obtain information
- Each form of legal process must be based on statutes or regulations authorizing such process
- For example, HHS Office of the Inspector General ("OIG") has authority to subpoena information, documents, reports, records, and accounts of any provider participating in the Medicare or Medicaid programs

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# Failure to Comply May Be Violation of Regulatory Requirements

- Failure to comply with a regulatory agency request may subject the subpoena recipient to sanctions, civil penalties or exclusion from federal programs
  - For ex., non-compliance with HHS OIG subpoena or other request for access to records can result in exclusion from the Medicare or Medicaid programs
- And federal law typically permits agencies to force compliance through court orders

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# Department of Justice Subpoenas

- DOJ may issue a subpoena duces tecum (requiring record production) in the name of a Grand Jury, or based on federal statutes
- We represent a hospital in a federal qui tam action, involving both a civil investigation (handled by the DOJ Fraud Division and HHS), and a criminal GJ investigation
  - Subpoenas are issued: (a) for witnesses using Grand Jury authority; & (b) for documents, using authority given DOJ under federal health care laws (Section 248 of the Health Insurance Portability and AccountabilityAct, 18 U.S.C. 3486)

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# Subpoenas Must Be Reasonable

- Courts may limit unreasonable or oppressive Grand Jury subpoenas
  - F.R.Crim.P. 17(c), and
  - United States v. R. Enterprises, 498 U.S. 292, 299 (1991)
- Same true for civil subpoenas
  - United States v. Powell, 379 U.S. 48 (1964);
  - United States v. Morton Salt Co., 338 U.S. 632, 652 (1950);
  - Oklahoma Press Pub. Co. v. Walling, 327 U.S. 186 (1946)

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# Subpoena Checklist

- Determine when production required, what efforts necessary to comply, and possibility of privilege assertion
- Confer with counsel about law enforcement or regulatory agency involved, scope of subpoena and potential need to seek narrowing agreement or clarification
- Confer with counsel concerning whether subpoena is part of a broader investigation; why did agency issue subpoena?

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# Subpoena May Mean Serious Enforcement Investigation is Likely

- Each subpoena is issued in a unique factual context: some subpoenas should make obvious a company is in serious trouble and a criminal or civil fraud investigation is actively underway
- The circumstances should be considered and reviewed with counsel to ensure an appropriate strategy is developed

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# Decide Company Strategy to Respond to Gov't Investigation

- Absent prompt response at sign of government investigation, particularly criminal investigation, may subject company and personnel to greater risk of prosecution
- Absent prompt involvement of counsel, employees may make ill informed decisions, such as destruction of documents or incriminating statements, which can make investigations worse

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# Grand Jury Investigations

- When investigators are serving subpoenas and interviewing witnesses, companies must decide how they are going to approach an investigation
- Historically, counsel would (1) advise employees of their Fifth Amendment rights, (2) arrange private counsel for employees issued subpoenas (who would then assert their Fifth Amendment rights), and (3) enter into Joint Defense Agreements to cooperatively defend against government investigations

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# Changes In Criminal Enforcement Process

- Government policies re voluntary disclosure and corporate cooperation have changed the way corporations must respond to government investigations
- How to respond, to maximize (1) defense opportunities or (2) arguments for lenity, is a major policy decision and a company should focus on that policy issue in advance, before company begins an internal investigation

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# DOJ Policy re Voluntary Disclosure and Corporate Cooperation

- DOJ policy (“Holder Memo”) sets out general principles prosecutors consider in deciding whether to bring federal criminal charges against corporation
- Policy states that prosecutors may abstain from prosecuting based upon corporation's cooperation in an investigation and prosecutions arising from an investigation

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# DOJ Policy States:

"A corporation's ***timely*** and voluntary disclosure of its wrongdoing and its willingness to cooperate . . . ***may*** be relevant factors. In gauging the extent of the corporation's cooperation, the prosecutor ***may*** consider the corporation's willingness to identify the culprits within the corporation . . . , to make witnesses available, to disclose the complete results of its internal investigation, and to waive the attorney-client and work product privileges." (Emphasis added.)

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# Prosecutors' Likely Cynicism

- Prosecutors consider whether voluntary disclosure occurred at a time when prosecutors would have otherwise learned of alleged misconduct
- Prosecutor likely cynical about, and give little credit for, "voluntary disclosure" if already been allegations of wrongdoing and subpoenas issued
- Prosecution likely despite disclosure if company controls are inadequate

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# Policy Is Discretionary

- DOJ policy does not bind federal prosecutor, regardless of any voluntary disclosure
- Rarely can forecast whether client will receive benefit from disclosure, unless disclosure occurs before government has any hint of wrongdoing and there is no whistleblower clearly headed in government’s direction
- In such cases, prosecutors have declined; particularly if company had good controls, audit policy, policy requiring compliance, and bad actor is “rogue”

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# Personal Experience

- Prosecution despite disclosure and cooperation probable unless disclosure made prior to government discovery of violation and discovery pursuant to audit (not intercepted whistleblower)
- Little credit is given companies that cooperate after investigation begun; opportunity to comment on press release and some willingness to charge bargain

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# Federal Sentencing Guidelines:

- Are federal Sentencing Guidelines applicable to corporate offenses
- Guidelines supposed to take guesswork out of federal sentencing
- In reality, judges make discretionary decisions in key areas
- Guidelines suggest possible reward for voluntary disclosure, but also unpredictable

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# “Culpability Score”

- Under Sentencing Guidelines, criminal fine depends upon organization's "culpability score," in addition to other things like the total amount of loss caused.
- Is language in USSG § 8C2.5(g), section of guidelines relating to “culpability score,” that discusses voluntary disclosure

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# USSG § 8C2.5(g) provides:

- If an organization
  - (A) ***prior*** to an imminent threat of disclosure or government investigation and
  - (B) within a reasonably prompt time after becoming aware of the offense,
- reports offense to . . . authorities, fully cooperates in investigation, and clearly demonstrates recognition and affirmative acceptance of responsibility for criminal conduct, it ***may*** be eligible for favorable treatment (reduction by five points in culpability score) (emphasis added).
- Five points may mean major $ difference in fine

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# Key here:

- Must evaluate risk that sentencing court (if any charges filed) will consider voluntary disclosure to have occurred at a time when there already was an imminent threat of disclosure, if there are already allegations being made
- If disclosure not ***prior*** to threat of disclosure, theoretically no reward
- Decision is discretionary and unpredictable

# No Cooperation, No Plea

- In many cases in the past three years, DOJ offices have been telling corporations in settlement negotiations: no cooperation/privilege waiver, no plea deal
- DOJ may want full cooperation, including producing investigation files (privilege waiver)

# Practical Consequences

- Can’t predict in advance what necessary in disposition of government investigation (may have to cooperate)
- When do corporate internal investigations, must assume may later become equal to government agent
- If entity counsel writes it, may give it up; write it, may testify it
- Testify or disclose it, entity counsel may get sued unless clear in interviews that only represent entity

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# Possible Confusion re Client Relationship

- Issue makes very poignant need to ensure clarity as to who corporate counsel represents
- Entity client representatives may think corporate counsel represents them, in addition to entity
- If employees become targets, may seek to block or challenge any sharing of information with government; examples White Pass and BP cases in Alaska

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# Ethics Pointers for Corporate Counsel in Internal Investigations:

- Identify self and status as counsel representing the company -- clarify that corporate counsel does not represent employees personally
- Company has asked counsel to provide legal advice -- requires thorough fact-gathering
- Company has requested employee cooperation
- Interview is privileged & confidential -- privilege belongs to the company (and the company will choose if to assert the privilege)
- Request employee to maintain interview as confidential

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# Other Government Policy Developments

- Government does not want entities to provide counsel for targets of government investigations
- Government does not want entities to enter into Joint Defense Agreements; DOJ lawyers have claimed if do so, more likely to insist on privilege waiver and production of internal investigations

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# Practical Meaning of DOJ Policies

- Must assess pros and cons of disclosure and voluntary cooperation very early on when case turns criminal:
  - Is this a case where credit may be given for disclosure and cooperation? If yes, conduct investigation accordingly
  - Is this a case where credit never will be given? If yes, conduct investigation to maximize privilege and ability to defend corporation, officers, and employees

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# Communication With Employees Re Rights

- It is important and appropriate to advise employees of their rights during a pending criminal investigation
- These communications must be made assuming the government will learn of them later, and employees may provide inaccurate versions
- Accordingly, these communications should be either written or carefully scripted, to avoid obstruction of justice

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# Advice of Rights to Employees

- Employees may be contacted by investigators on or off work site
- Employees may choose to talk or not to talk, to consult with an attorney before determining whether to submit to interview, and to have counsel present during an interview
- If employees choose to submit to interview, it is critical they tell truth
- Employees should not discuss investigation subject matter amongst themselves absent counsel

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# Communications With Employees Re Engagement of Personal Counsel

- Company needs to decide its policy in individual cases; is there a need for counsel?
- Corporate counsel joint representation creates conflicts which may result in disqualification
- Company should steer employee to competent, experienced counsel

# Strategies to Explain Need for Separate Counsel

- Criminal investigation is serious matter; most people benefit from some personal advice
- Is difficult to look out for your personal interests at the same time as looking out for the interests of other clients; such joint representation creates conflicts
- Doesn't mean do not wish to work together toward common goal, should your personal counsel wish to

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# Should You Fish or Cut Bait? Pointers for an Effective Settlement Strategy

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# Trial or Settlement ?

- Can You Afford to Try the Case?
  - What are the strengths of the case
  - Access publicity impact
  - Assess impact of Corporate Integrity Agreement
- False Claims Act: Treble Damages and over $11k per claim

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# Pharmacy Hypothetical

- $.07 overpayment per claim/100,000 claims
- Potential Liability:

  $21,000 damages

  $1,100,000,000 penalties
- GNP of Mongolia:  $1,006,000,000 (1997 UN data)
- Conclusion for Most Providers: Settlement Posture from the Outset

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# Settlement Pointers

- Make your case
- Conduct your own investigation
- Estimate Liability - Don’t rely on Government numbers

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# Settlement Pointers

- Make sure everyone is at the table
- DOJ cannot settle Medicare Exclusion issues (DOJ handles the $$$)
- HHS/OIG has 16 counsel assigned to FCA cases
- Negotiate Corporate Integrity Issues as part of the settlement process
- Watch out for MFCU's!

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# Settlement Pointers

- National Initiatives: "A foolish consistency is the hobgoblin of little minds"… BUT
- If more than $1 M is involved, Main Justice will be looking

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# Settlement Pointers

- Get a release but don’t be greedy (No release of issues without investigation)
- Rarely get release from criminal prosecution, *unless*
- Separate release from relator
- Make sure relevant time periods are covered