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A Case Study: How to Conduct an Effective and Compliant Internal Investigation

CareSource **STRADLEY RONON ATTORNEYS AT LAW**

Speakers

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HYPOTHETICAL FACT PATTERN

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Hypothetical Fact Pattern

Scientific Drug Company of Columbus, Ohio, is excited to announce today it has received FDA approval for a breakthrough lung cancer drug called Freedom. Dr. Frank Johnson, Medical Director and PhD, has worked on the development of Freedom for 15 years. Dr. Johnson intended Freedom to be used for dementia and not lung cancer. Despite Dr. Johnson's work for the past 15 years, the FDA would not approve dementia as a permitted use for Freedom.



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Hypothetical Fact Pattern

Once the FDA approved Freedom for lung cancer, the Scientific Drug Company's Compliance Department began training the Marketing Teams throughout the United States on the appropriate uses of the drug, Freedom. Compliance Trainer, Jack Paul, put together extensive training materials for the Marketing Department for the appropriate use of Freedom. Jack conducted training for all marketing employees. Jack specifically trained all marketing employees not to sell the drug, Freedom, for dementia despite Dr. Johnson's clear dissatisfaction with Jack's training materials.



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Hypothetical Fact Pattern

CHICAGO BULLS



In January Jack took a training trip to the Chicago office to train the Marketing staff on the appropriate uses of the new drug, Freedom. While in Chicago, Jack took his two nephews, ages eight and nine, to the Bulls game and expensed three Bulls' tickets as a Scientific Drug Company Marketing Compliance Teambuilding Activity. Jack also posted pictures of the Bulls game on Facebook.



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Hypothetical Fact Pattern

In April, Jack went to visit his primary care physician for his routine physical. Jack's primary care physician commented that Freedom was having a dramatic effect on two of his patients who are suffering from dementia. At Jack's primary care physician's comment as to the remarkable results that he was seeing, Jack inquired as to how it came about that the primary care physician was using Freedom for dementia. Jack's doctor explained that the Marketing Team from Scientific Drug Company had been in the office in February to explain the dementia use of the drug, Freedom.



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Hypothetical Fact Pattern

Jack immediately reported this to the Chief Compliance Officer of Scientific Drug Company, Brett Bender. Jack reviewed with Brett that he had instructed all Marketing Departments to sell Freedom only for lung cancer and never for dementia. Brett decided to hire outside counsel in order to conduct an Internal Investigation.



Outside counsel, Joe Jackson, began interviews and interviewed the Vice President of Marketing, Tom Smith, regarding the Marketing Department's sales activity regarding the drug, Freedom. Mr. Jackson gave Mr. Smith an Upjohn Warning. Mr. Smith indicated he was willing to cooperate with Scientific's investigation of this matter; however, he wanted personal counsel paid for by the company and wanted an Indemnification Agreement for discussing any matters.



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Hypothetical Fact Pattern

A Finance Department employee, who was a friend of Jack, was processing the expenses for Jack's Chicago trip and had seen on Facebook that Jack had taken his two nephews to the Bulls game. The date of the post on Facebook corresponded with the same expense for a Marketing Compliance Teambuilding Activity. The Finance Department employee reported this to the Chief Compliance Officer.



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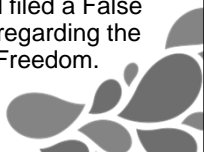
Hypothetical Fact Pattern



Jack became disillusioned as the Internal Investigation dragged on and no direct order was issued to stop the Marketing Department from marketing Freedom as a dementia drug. Jack sought outside counsel and filed a False Claim Act Complaint under seal regarding the off-label marketing and sales of Freedom.



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Hypothetical Fact Pattern

The Chief Compliance Officer confronted Jack regarding his expense account of the Bulls game. Jack refused to answer any questions until Jack received answers as to the progress of the Internal Investigation. Jack indicated he would answer all questions if Scientific Drug Company paid for counsel to represent him regarding this matter and provided him an Indemnification Agreement. Scientific terminated Jack for falsification of the expense report and failing to cooperate with an Internal Investigation.



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Hypothetical Fact Pattern

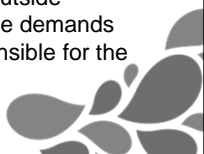
Jack immediately file an Amended Complaint alleging retaliation in his False Claim Act filed under seal.



The Department of Justice subpoenaed scientific drug company and requested the internal investigation report from outside counsel. The Department of Justice demands the names of all employees responsible for the off label marketing of Freedom.



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WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

Directors

Committee Representation	Individual Representation
<ul style="list-style-type: none"> • Special Litigation Committee • Compliance Committee 	<ul style="list-style-type: none"> • Potential Caremark Issues • Potential Breaches of Other Fiduciary Duties <ul style="list-style-type: none"> • Duty of Care • Duty of Loyalty

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WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

RESPONSIBLE CORPORATE OFFICER DOCTRINE

- AKA the "Park Doctrine" – *United States v. Park*, 421 U.S. 658 (1975)
- Concept – officer stood in "responsible relation" to the underlying violative act or omission
- Origins
- Statutory Bases
 - Food Drug & Cosmetic Act
 - Has since expanded
- Bottom Line: Essentially Strict Liability Based Solely on Being in a Position of Control

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WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

- THE "YATES MEMO"
 - Issued in September 2015 by the now famous (or infamous) former Acting Attorney General, Sally Yates, when she served as Deputy AG under Eric Holder. [insert video clip from "The Apprentice" of Donald Trump saying, "You're fired."]
 - DOJ Response to political and public outcry out of lack of individual accountability for the 2008-2009 "Great Recession"
 - Gist: Any corporate entity hoping to obtain cooperation credit from DOJ had better be prepared to throw one or more individual wrong-doers under the bus.
 - Result: Along with RCO, heightened emphasis by DOJ on holding individuals accountable for corporate wrongs.

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WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

- WHO PAYS LEGAL FEES AND COSTS?
 - ADVANCEMENT
 - INDEMNIFICATION
 - D&O INSURANCE
- SOURCES OF AUTHORITY
 - State general corporation law
 - Company Articles of Incorporation and By-Laws
 - Contracts (e.g., Indemnification Agreements)
- See Johnston, McFadden, et al. *Indemnification and Insurance for Directors and Officers*, BNA Bloomberg Corporate Practice Portfolio Series, No. 54-3rd.



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WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

- DECISION IS NOT ENTIRELY WITHIN CONTROL OF CORPORATE ENTITY AND ITS COUNSEL
 - Irrespective of Company's decision, certain individuals may insist on separate counsel.
 - Typically the genesis of the biggest fights over advancement, indemnification, and insurance.



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WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

- FORGING ALLIANCES – JOINT DEFENSE AND COMMON INTEREST AGREEMENTS
 - CONCEPT: US v. Them => Privileged Communications
 - The Bane of Every Prosecutor or Plaintiff's Attorney
 - Written or Unwritten?
 - What happens when one member decides to that the best course is to save his/her own skin?
 - Navigating Conflicts




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PLANNING THE INVESTIGATION

- STEP 1: ISSUE IDENTIFICATION AND POTENTIAL EXPOSURE ASSESSMENT
 - What is at stake here? What is the worst-case scenario?
 - Administrative exposure – Exclusion
 - Civil exposure
 - False Claims Act
 - Shareholder's Derivative Suit
 - Criminal exposure
 - Kickbacks
 - Fraud
 - Statutory violations
 - RCO


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PLANNING THE INVESTIGATION

- Step 2: Collecting Documents
 - Legal Hold Notice
 - Identification of Custodians
 - Development of Keyword Search Protocols
 - E-mails are the nail that seals the coffin
 - E-discovery Plan and Process
 - Creation of a searchable database
 - What are the inputs?
 - Backup tapes? Other media?


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PLANNING THE INVESTIGATION



- Step 3: Witness Interviews
 - Identification of Key Witnesses
 - Document Review
 - High-Level Discussions with Control Group
 - Preparation of Witness Binders
 - Resolution of Representation Issues
 - Resolution of Privilege Issues
 - Former Employees

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PLANNING THE INVESTIGATION

- FORM OF REPORT
 - Oral v. Written
 - Level of Detail
- THE KEY CONSIDERATION: DISCOVERABILITY

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PLANNING THE INVESTIGATION

- ASSESSING THE PROS AND CONS OF SELF-DISCLOSURE AND "COOPERATION CREDIT"
 - Regulatory Self-Disclosure Requirements
 - Yates memo revisited
 - Sentencing Guidelines

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CONDUCT OF THE INVESTIGATION

- DETERMINATION OF THE CONTROL GROUP, POINTS OF CONTACT, AND LIMITATIONS ON COMMUNICATION
 - Maintaining independence as the internal investigator, and the importance of being able to demonstrate it later.

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CONDUCT OF THE INVESTIGATION

- WITNESS INTERVIEWS
 - Upjohn Warnings - Upjohn Company v. United States, 449 U.S. 383 (1981)
 - Gist
 - This conversation is covered by the attorney-client privilege
 - That privilege belongs to one entity and one entity only: the Company
 - WE DO NOT REPRESENT YOU
 - The Company, and only the Company, can decide whether to waive or maintain the privilege



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CONDUCT OF THE INVESTIGATION

- A REPRESENTATIVE UPJOHN Warning
 - Identify yourself as an attorney; identify your client
 - Make clear that you represent NO ONE OTHER THAN THE CLIENT: "I do not represent you."
 - State the purpose of the interview
 - Obtain facts, in confidence, in furtherance of providing legal advice to the client = the Company. Classic elements of the attorney/client privilege
 - Make clear to whom the privilege belongs and who can waive it.



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CONDUCT OF THE INVESTIGATION

- A CLASSIC QUESTION FROM THE WITNESS: "Do I need my own lawyer?"
- THE NECESSARY AND ONLY RESPONSE.
- ORDER OF INTERVIEWS (typically bottom to top)



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The Yates Memo: Background

"In the most basic ways, though, corporate misconduct isn't all that different from everything else DOJ investigates and prosecutes.

[Crime is crime.]

And it is our obligation at the Justice Department to ensure that we are holding lawbreakers accountable regardless of whether they commit their crimes on the street corner or in the boardroom. In the white-collar context, that means pursuing not just corporate entities, but also the individuals through which these corporations act."

Sally Quillian Yates, Deputy Attorney General, September 10, 2015



The Yates Memo: Background

Issued:
September 9, 2015

Recipients:
All DOJ Attorneys

Goal:

Consistency across all DOJ departments in holding individuals accountable for illegal corporate conduct.



Author:
Sally Quillian Yates,
Deputy AG

Subject:
"Individual Accountability for Corporate Wrongdoing"

Content:
Six "key steps" to "strengthen our pursuit of individual corporate wrongdoing"



The Yates Memo: Significance



Continuing Evolution of Principles of Federal Prosecution of Business Organizations (U.S. Attorney's Manual 9-28.000)



Principles revised to reflect Yates Memo expanded focus on individuals



Prosecutors rely on Principles in determining whether and what charges to bring



Principles provide important guidance to corporations regarding compliance programs and cooperation during investigations



The Yates Memo: 6 Key Steps

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graph LR; 1[1] --> 2[2]; 2 --> 3[3];
```

1

- Eligibility for any cooperation credit requires corporations to **provide DOJ with all relevant facts** about the individuals involved in the misconduct.

2

- Both criminal and civil corporate investigations should focus on **individuals from the investigation's inception.**

3

- Criminal and civil DOJ attorneys handling investigations should be in **routine communication** with one another.

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The Yates Memo: 6 Key Steps

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graph LR; 4[4] --> 5[5]; 5 --> 6[6];
```

4

- No corporate resolution will **provide protection** from criminal or civil liability for individuals, except in "extraordinary circumstances."

5

- Corporate cases should not be resolved without a **"clear plan" to resolve related individual cases** before the statute of limitations expires, and declinations as to individuals in such cases must be memorialized.

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- Civil attorneys should consistently focus on individuals and evaluate whether to **bring suit against an individual based on considerations** beyond the ability to pay.

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The Yates Memo: Implications

- Increased pressure on prosecutors to pursue individuals
- Possible increases in civil actions due to the increased communication requirement
- More cooperation deals with lower level executives in order to reach highest level leaders
- Chilling effect on corporate cooperation with federal prosecutors due to "all or nothing" approach

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The Yates Memo: Implications

- Chilling effect on self-reporting by corporations
- Chilling effect on personal cooperation with internal compliance investigations
- Conflicts of interest:
 - Legal representation (personal/corporate)
 - Involvement of personal stakeholders in internal corporate investigation
- Waivers of attorney-client privilege?

The Yates Memo: Action Items

Proactive

- Review and enhance compliance program
- Make leadership aware of Yates Memo
- Document efforts to remain compliant

Reactive

- Retain counsel experienced in criminal investigations (particularly in dealing with DOJ)
- Promptly deal with conflicts of interest


DRAFTING THE REPORT




DRAFTING THE REPORT

Case Information

- Investigative Team Details (names, position/roles, contact information)
- Name of Legal Counsel (if involved)
- Complainant/Referral Source Details (names, position/roles, contact information, date report or complaint was submitted, manner in which report was made (hotline, in-person meeting with CCO, exit interview, etc.))
- Summary of Allegations (description, seriousness, type, dates of alleged violation(s), names of parties involved)





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DRAFTING THE REPORT

Scope of Investigation

- Succinctly state the scope of the investigation
- Summarize the objective of the investigation




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Investigation Plan

- List of documents to be collected
- Litigation holds
- List of referral source(s) and witnesses to be interviewed
- Order of interviews




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DRAFTING THE REPORT

- Communication plan and outline for interviews
 - Upjohn warnings
 - Introduction/case overview
 - Investigator's role
 - Overview of non-retaliation policy
 - List of general and specific questions
 - Concluding Messages: reiterate confidentiality, non-retaliation policy, preserve all documents and abide by litigation holds, call investigator with further information
- List of legal issues to be researched
- List of applicable company policy and/or legal authorities


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DRAFTING THE REPORT

Documentation of Interviews

- Promptly and accurately memorialize interviews
- Be complete
- Document all parties who were present during interview
- Be consistent in format and organization of interview notes
- Summarize how key concepts were explained (see previous slide)
- Include "word-for-word" quotes, especially on important points




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Document Investigator Impression of Interviews (separate from summaries of interviews)

- Credibility assessments
- Interviewer's notes/ impressions section



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Document Evidence

- Attach key documents
- Attach interview summaries
- Attach key company policies, code of ethics provisions, or legal authorities



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Factual Findings

- Summarize the facts that decision makers need to know
- Business units and functions, individuals involved
- Dismiss facts that are irrelevant
- If 2 or more positions are at issue, discuss both sides
- Weigh the facts
- Finance related findings



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DRAFTING THE REPORT

Example of Factual Findings

- “Mr. X logged onto a government web portal with another employee’s log-in credentials.”
- “Mr. X’s supervisor was aware that Mr. X logged onto a government web portal with another employee’s log-in credentials.”
- “There is no company policy or procedure for the use of log-on credentials on government web portals.”



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DRAFTING THE REPORT

Examples of Conclusions (note how conclusions and recommendations track factual findings.

- “Mr. X violated ___ CFR Section ___ and may have violated 18 U.S.C. § 1001
- “Mr. X’s supervisor failed to supervise Mr. X’s adherence to the company’s log-in policies”
- “The company’s internal controls regarding use of log-on credentials is in adequate.”



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Examples of Recommendations

- “Mr. X should be disciplined or terminated.”
- “Mr. X’s supervisor should be disciplined or moved to a non-supervisory position.”
- “The company should develop internal IT controls and retain an outside IT security consultant to assist it in doing so.”
-



DRAFTING THE REPORT

- Summarize follow-up steps
- Corrective Action/Process Improvement
- Determine if voluntary disclosure should be made
- Determine if overpayments were made and must be repaid
- Determine if fines are to be paid
- Determine if licensing bodies or regulators must be notified
- Notify complainant that appropriate action is being taken



PRESENTING THE REPORT



- Status reports (how frequent and audience)
- Reports to management
- Reports to audit and compliance committees
- Reports to governing boards

LIPJOHN WARNING

We are conducting an investigation for the _____ (Company) into certain events related to _____. We believe that you may have facts and/or documents that may be relevant to our investigation and we appreciate you meeting with us.

To be clear, we serve as counsel to the Company. We are not your personal counsel and cannot give you legal advice.

In addition, your communications with us, as part of this investigation, are confidential and protected by, among other things, the attorney-client privilege. As the Company is our client, the attorney-client privilege belongs solely to the Company. Accordingly, the Company, in its sole discretion, may elect to waive the privilege and reveal your communications with us to third parties, including the government.

As part of this investigation, we are interviewing a number of employees to gain a better understanding of the relevant issues. The fact that we are conducting this investigation does not mean the Company believes that any current or former employee has engaged in improper or illegal conduct. It simply is the process through which the Company ensures that it maintains the highest standards of corporate integrity. Your candor and honesty are critical to our ability to conduct effective our investigation. To maintain the integrity of this investigation, we request that you keep our conversations today confidential. We appreciate your cooperation.

Employee _____
 Print Employee Name _____
 Date: _____
 I acknowledge receipt of a copy of this Lipjohn Warning.
 Employee _____
 Date: _____

LIPJOHN WARNING

I am a lawyer for _____ and I do not represent you personally. I represent only _____.

I am conducting this interview to gather facts in order to provide legal advice for _____.

This interview is part of an investigation to determine the facts and circumstances in order to advise _____ how best to proceed.

Your communications with me are protected by the attorney-client privilege. But the attorney-client privilege belongs solely to _____ and you. That means your communications with me are protected by the attorney-client privilege and reveal our discussion to third parties alone may elect to waive the attorney-client privilege and reveal our discussion to third parties. I alone may decide to waive the privilege and disclose this discussion to such third parties as federal or state agencies, at its sole discretion and without notifying you.

In order for this discussion to be subject to the privilege, it must be kept in confidence. In other words, with the exception of your own attorney, you may not disclose the substance of this interview to any third party, including other employees or anyone outside of the company.

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ACKNOWLEDGEMENT

I acknowledge receipt of an "Lipjohn Warning" which was given to me on this date by _____ in connection with an interview of me to gather facts for the purpose of rendering confidential legal advice to _____. I understand that _____ does not represent me and only represent _____. I understand that any communication between me and _____ is protected by the attorney-client privilege and the attorney work product doctrine, each of which belong solely to _____ and which _____ may waive if it so chooses.

I agree that this interview is confidential and that I will not disclose the substance of this interview to any other _____ employee or to anyone outside of the company. The only exception is that I may disclose this information to my own attorney.

I acknowledge that I proceeded with the interview under the terms contained within the "Lipjohn Warning" given to me.

Signature _____
 Date _____
 Witness _____

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ATTORNEY-CLIENT PRIVILEGE **ATTORNEY-WORK PRODUCT - CONFIDENTIAL**

General Instructions

Please read this entire litigation hold notice. Please take sufficient time to read over and thoroughly understand the litigation hold notice and your obligations thereunder. Preserving evidence for potential or current litigation matters is an important legal duty both for you as an employee and as a caregiver. Failure to follow the instructions contained in this notice may have very serious consequences for you.

Once you have read the entire litigation hold notice, please respond to the questions you find fit in the provided fields.

Litigation Hold

[Insert brief description of the potential lawsuit or current lawsuit]

This notice does not mean that you are necessarily involved in the lawsuit, however electronic files that might become relevant or potentially relevant to the lawsuit. Some of the information may be relevant to the lawsuit, and as an employee, you have a legal duty to preserve that information. During this litigation hold period, you must:

- 1. Preserve all electronic files that are or may be relevant to the lawsuit, including but not limited to: outgoing electronic mail and attachments, incoming electronic mail and attachments, calendar entries, contact lists, voicemail messages, text messages, instant messages, videos, photographs, information on your mobile phone, back-up tapes, discs and any other data stored in any medium from which information may be obtained. The information must be preserved in its original electronic form, without changing any related metadata, so that all information contained within a selected email or text, is also available for responsive use. It is not sufficient to make a hard copy of electronic communication.
- 2. Immediately, your government litigation data extends to the preservation of relevant data on external media, including hard drives, DVD, CD, USB, personal home computers, laptops and mobile devices, including PDAs, cell phones and tablets.
- 3. Preserve any non-electronic information that is generated after you receive this notice that could be considered relevant to this litigation matter; and
- 4. Preserve any hard paper copies under your control, which may include written correspondence, handwritten notes, litigation logs, calendars and other business records.

If any individuals working with you or under your supervision, direction or control are, or have been, involved in this litigation, including but not limited to reviewing documents and data created by this notice, or any of the subject matter of this litigation matter, you must notify those names in the government information and answer that they create with it. Additionally, if you have of any other current or former employees who may have relevant materials and information, but did not receive a copy of this litigation hold notice, please forward the names of those individuals to the person named below and provide those names on the government information and answer.

If there is any doubt as to whether a document or ESI is subject to the litigation hold, please contact [redacted] and do not destroy the document or ESI until written permission to destroy is granted by [redacted].

The legal department is available to meet with you to further explain your obligations or to respond to any questions you might have about this litigation hold notice. It is important that you keep this information confidential and do not talk about it with any other employee, unless it is necessary to comply with this litigation hold. Additionally, unless otherwise permitted or required by law, you are prohibited from disclosing any information relating to this litigation matter to anyone outside the company without the express authorization of [redacted]. This prohibition includes publications and disclosures made on consumer or electronic social media websites, such as Facebook, Instagram, LinkedIn, Pinterest, Tumblr and Twitter.

Thank you for your cooperation.

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CONFIDENTIAL AGREEMENT

This document sets forth the terms and conditions for the use of the information that you are providing to the undersigned. This information is confidential and may be used for purposes other than those stated in this document. You agree to keep this information confidential and not to disclose it to any other person, firm, or organization, without the prior written consent of the undersigned. This agreement shall be binding on you and your heirs, assigns, and estate, and shall survive the termination or expiration of your employment with the undersigned.

The undersigned agrees to use the information provided to the undersigned solely for the purposes stated in this document and to keep this information confidential. The undersigned shall not disclose this information to any other person, firm, or organization, without the prior written consent of the undersigned. This agreement shall be binding on you and your heirs, assigns, and estate, and shall survive the termination or expiration of your employment with the undersigned.

WHEREFORE I AGREE

I, the undersigned, agree to the terms and conditions set forth in this document and to keep this information confidential. I understand that this information is confidential and may be used for purposes other than those stated in this document. I agree to keep this information confidential and not to disclose it to any other person, firm, or organization, without the prior written consent of the undersigned. This agreement shall be binding on me and my heirs, assigns, and estate, and shall survive the termination or expiration of my employment with the undersigned.

I have read and understand the terms and conditions set forth in this document and I agree to be bound by these terms and conditions. I understand that this information is confidential and may be used for purposes other than those stated in this document. I agree to keep this information confidential and not to disclose it to any other person, firm, or organization, without the prior written consent of the undersigned. This agreement shall be binding on me and my heirs, assigns, and estate, and shall survive the termination or expiration of my employment with the undersigned.

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QUESTIONS

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