

General Counsel's Decision Tree

Internal Investigations



Life Sciences

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Building on last year’s initial edition of the *General Counsel’s Decision Tree*, we have designed this year’s resource to enable in-house teams to understand what factors to consider in internal investigations and to address challenges that may arise in conducting them, including addressing unique and developing considerations that have been introduced by the COVID-19 pandemic.





A well-planned and executed internal investigation keeps the exercise focused and organized, as well as paving the way for smoother resolution of issues internally (e.g., remediation) and, if needed, externally (e.g., later resolution with government authorities or regulators).

Manufacturers and distributors of health care products, including pharmaceuticals, biologics, medical devices and diagnostics regularly face challenges that may require an internal investigation to determine the root cause of an issue in order to evaluate how best to remediate and guard against future occurrences of a potentially harmful event. These range from industry-specific concerns, such as those related to quality and safety, product labeling and promotion in compliance with the Food, Drug and Cosmetic Act, federal and state healthcare program reimbursement, whistleblower and False Claims Act (FCA) matters, HIPAA protections, supply chain compliance, to more general corporate concerns equally applicable to the entire life sciences industry, such as import/export controls, Foreign Corrupt Practices Act (FCPA) compliance, product liability issues, data breaches, environmental catastrophes and human resource issues. While having a robust compliance program can help avoid many issues, not all issues can be foreseen or avoided. This internal investigations playbook has been designed to facilitate the identification and remediation of issues and is an important complement to a well-designed and functioning compliance program. It also will facilitate the in-house team's communications with outside counsel, who have a range of experience guiding companies through these precarious situations. In addition, adherence to a well-crafted playbook helps companies meet the expectations of enforcement authorities, such as the Department of Justice (DOJ), the Department of Health and Human Services Office of Inspector General (OIG), the Food and Drug Administration (FDA), the Securities and Exchange Commission (SEC) and state attorneys general (as well as others), which can materially mitigate potential enforcement efforts and sanctions.

When a developing situation requires an internal investigation, a general counsel may be required to make a series of decisions, sometimes in rapid succession. Beyond first protecting the integrity and quality of patient care and safety and public health, many constituents must stay top of mind as the situation moves forward, including some or all of the following:

- the board of directors
- board committees
- board committee chairs
- senior officers/partners
- employees
- internal auditors

And while this decision tree is focused on recommended practices for conducting an *internal* investigation, external constituents – like the ones listed below – must also be kept in mind as the investigation is launched and progresses. The following external

stakeholders may, for example, require updates and/or document productions, should an internal investigation be conducted in response to a subpoena or regulatory inquiry:

- local, state and federal governmental authorities
- self-regulatory organizations
- independent auditors
- listing exchanges
- shareholders or debtholders
- insurers and health plans
- vendors, suppliers and business partners
- customers and prescribers
- patients and caregivers
- consultants and contractors
- the public
- media outlets (including social media)

Each constituent has unique information needs, and all constituents must remain in the general counsel's focus.

This work-flow document is designed to help companies navigate the myriad decisions and twists and turns of an internal investigation without losing focus on the various constituents and how best to emerge from the investigation. This document should be used in conjunction with communications with outside counsel and existing company policies – it is not a complete legal or strategic analysis on any topic. Although no one document can anticipate everything, this document is intended to provide an efficient, easy reference for what can be a difficult process.



While this decision tree is focused on recommended practices for conducting an internal investigation, keep external constituents in mind as the investigation is planned, launched and concluded.

Quick Reference Guide

Each is described in greater detail below.

Policy

Should relevant company policies apply, those should be carefully considered – and any deviations documented – before an investigation is launched.

Scope and Purpose

Time periods, relevant business units and employees, and goals for the internal investigation should be determined at the outset. While such scope often expands or changes based on the facts identified, it may be counterproductive and unduly burdensome on a company for an investigation to take on a “clear the (compliance) decks” exercise.

Data Preservation

Whether an investigation stems from a subpoena or other legal process, steps should be taken immediately to preserve all potentially relevant data and documents. In short, you rarely know at the outset what information the investigation will need to consider and review, and you can rarely “undo” data deletion. Recommended steps often include communicating preservation obligations to employees and relevant parties (e.g., board members) and suspending routine document retention and/or deletion policies.

Who should be directing, conducting and/or receiving updates about investigation findings are critical decision points for any matter. This includes identifying whether key stakeholders may be witnesses to relevant facts, whether independence of the investigation will receive scrutiny, and relatedly, whether outside counsel should be retained, whether the internal investigation will be conducted under privilege and what company personnel will need to assist with fact gathering.

Document and Data Review

While often essential, comprehensive document processing and review can take time, and an initial assessment should be made as to whether there are key documents and/or data sets available that should be collected and reviewed – is there electronic correspondence about the specific topic of the allegations, are certain systems or records referenced in the complaint, is contextual data on parties involved

(sales numbers, contracts) available, are minutes from key meetings available, etc.?

Employee Interviews

Once key players are identified (whether through document/data review or some other source), direct engagement and questioning to gather individual perspectives on matters subject to review are key parts of any internal investigation and can often (as is discussed below) be the most complicated step.

A decision should be made early on as to whether and how the factual findings and – if outside counsel is involved – the legal conclusions stemming from an internal investigation will be memorialized and reported. In some cases, oral briefings/presentations to key stakeholders may be enough, and in others, formal, written reports can facilitate information sharing with key stakeholders. Such decisions may depend on the privileged nature of such reports and external pressures, with regulators, auditors and/or the public.

Public companies and their officers have regular obligations to certify to independent auditors that they have notified the auditors of all information important to the audit. In the event of an internal investigation, careful consideration must be given to communicating to the independent auditor information about the investigation and the related obligations imposed on auditors once they are notified of an investigation.

While this decision tree focuses on the steps involved in an internal investigation, it is critical to bear in mind the issues that will surface should a government or regulatory body examine the issues involved in the internal investigation. Companies that evaluate how to involve the compliance department early in its investigation, position itself to cooperate with a government investigation and treat whistleblowers are better positioned to respond to a subsequent or parallel government investigation should one arise.

Getting Started

POLICY

Reference the existing policies, procedures, guidelines or other governing documents that address how an internal investigation should be conducted. To the extent governing documents differ from the suggestions in this document, be sure to reconcile any differences, ensure authority for any changes and keep records of steps taken that go beyond the company's documented plans.



COVID-19 Consideration:

As the company's operations likely have changed during the pandemic – perhaps permanently – consider evaluating how to update policies, procedures or other governing documents to account for such changes. These may include things like how to preserve and collect data from employees who are working from home and may more regularly save data on local devices, how to comply with industry code requirements (such as regarding meals, samples, and interactions with health care professionals generally), and protocols for conducting interviews virtually. However, for temporary policy or process changes during the pandemic, consider documenting that an exception is in place for the duration of the emergency situation so that the process taken does not appear to deviate from the established policy.

SCOPE AND PURPOSE

Internal investigations may be required due to questions or information arising from internal sources (e.g., hotlines, employee complaints, audits) or external sources (e.g., government agencies, self-regulatory organizations, media reports, competitors). When an internal investigation is necessary, consider the following:

Determine Initial Scope and Purpose

Thoughtfully and quickly identify the relevant time period, potential witnesses, internal and external stakeholders, and subject matters. Decisions related to investigation scope can have lasting consequences that will affect the entire investigation. Including key stakeholders in the scoping decision early can save significant costs and time later. Defining the purpose of the investigation and/or goals at the outset can be beneficial to avoid “mission creep” and avoid too much being taken on relative to the concerns or issues initially raised.

Expect Changes

Recognize each decision as to scope could change as investigators (internal or external) learn more during the process.

Expand if Needed, but Be Wary of Scope Creep

It is important for internal investigators to be able to confirm that no one hindered them from expanding or shifting the scope of the investigation in response to information learned during the investigation. For example, if the internal investigation involves potential False Claims Act issues, it is likely the Department of Justice will expect that those conducting the investigation believed they (or someone else) adequately followed up on what they learned during the investigation.

- Internal investigations can spin out of control, leading to unnecessary legal spend and the diversion of critical resources. Focus the inquiry on the root cause and contributing factors. Do not, however, ignore noncompliance concerns that could increase the company's exposure and that are within “plain view” simply because they fall outside the agreed-upon scope. If new and unrelated issues surface during the internal investigation, as they inevitably will, evaluate priorities and consider addressing these issues separately and on a parallel track, as necessary.

INSURANCE COVERAGE

Applicable insurance policies should be reviewed at an early stage to determine if, and to what extent, coverage is available in order to ensure that coverage is not waived. Where coverage is available, notice should be provided to the insurance carrier per the requirements of the policy. Experienced outside counsel may be particularly valuable in evaluating what coverage is available and making sure that appropriate steps are taken to comply with the notice requirements in the policy.



DATA PRESERVATION

Immediately upon determining that an investigation is needed, consider preserving potentially relevant data for the relevant time period, potential witnesses and subject matters.

Evaluate Requirements

Determine whether your organization is subject to requirements or restrictions with respect to certain categories of electronically stored information, such as, for example, HIPAA, the EU's General Data Protection Regulation (GDPR) or laws limiting the distribution of company data (e.g., China's state secrecy law and blocking statute).

Identify Data Sources and Locations

Evaluate where information likely to be relevant to the investigation is stored, such as paper files, data servers, hard drives, laptops, shared drives, off-site storage, home offices, personal devices, etc. Any prior data mapping exercises by the company can prove invaluable. Consider how potential subjects or witnesses of the investigation communicate and store materials using different types of devices and where key information is likely to be stored, including at personal/private locations, such as a home office or personal device. It may be prudent to conduct so-called custodian interviews to verify that relevant data and sources are captured.



Stop Destruction/Automatic Deletion

Involve an information technology (IT) resource, within the company if possible, who can stop any ongoing, routine document and data destruction or recycling of potentially relevant information and devices. This is particularly important for popular (and quick-to-delete) instant messaging systems like Slack, Microsoft Teams, Google Chat, etc.

Document Retention Memo

Consider sending a document retention memorandum from the general counsel's office to relevant employees, and potentially directors, to advise them to preserve and retain specified categories of potentially relevant documents. While issuing document retention memos may seem fairly mechanical, consider carefully whether a memo is being issued in the context of a confidential government investigation or as part of an investigation initiated by a whistleblower complaint. These special circumstances, among others, may call for adjustments in how the document retention memo is crafted and distributed.

**COVID-19 Consideration:**

During a period when many employees are working from home, the company may face unique challenges in collecting or preserving data from company-issued laptops and mobile devices that are in the possession of these employees at their homes. Under the right circumstances, remote collection strategies, during which the employees back up their data under the close supervision of e-Discovery professionals working with the investigation team, can help bridge this gap. To the extent these measures are different from the company's normal practice, the COVID-19-based reasons for the alternate procedures should be documented as part of the collection process.

COVID-19 Consideration:

In the coming years, companies conducting internal investigations will need to consider whether relevant data may have been stored or maintained in an unconventional manner or in a way that departed from policies due to unique conditions during the pandemic. Companies mapping out strategies for collecting data that may have been created or maintained during this time, should consider conducting preliminary custodian interviews to learn how they stored data during this time. Document retention memos should also require employees to consider their data management practices during the pandemic, if relevant to the investigation.

Forensic Experts

Depending on the nature of the investigation and the company's in-house IT capacity, it may be prudent to have counsel retain third-party forensic experts to capture and preserve data and be in a position to testify, if necessary, to the reasonableness of the company's efforts to discharge its obligations to preserve relevant evidence.

Secure Essential Data Quickly

Repositories of electronic documents that are centrally monitored or maintained may be the easiest to secure. These can include email and instant message systems, shared servers and archived sources. Investigators – potentially assisted by experts with experience collecting data in a forensically sound way – should work with internal stakeholders at the company to identify and preserve the most relevant essential data. In many cases, it will be prudent to preserve this centrally maintained data before informing the relevant custodians that an investigation is being conducted or issuing them a document preservation notice. This not only shores up the integrity of the investigation, but also may help protect the individual custodians from facing questions about whether they improperly deleted documents after learning an investigation was in progress.

Devices**▪ Laptops and individually controlled storage devices**

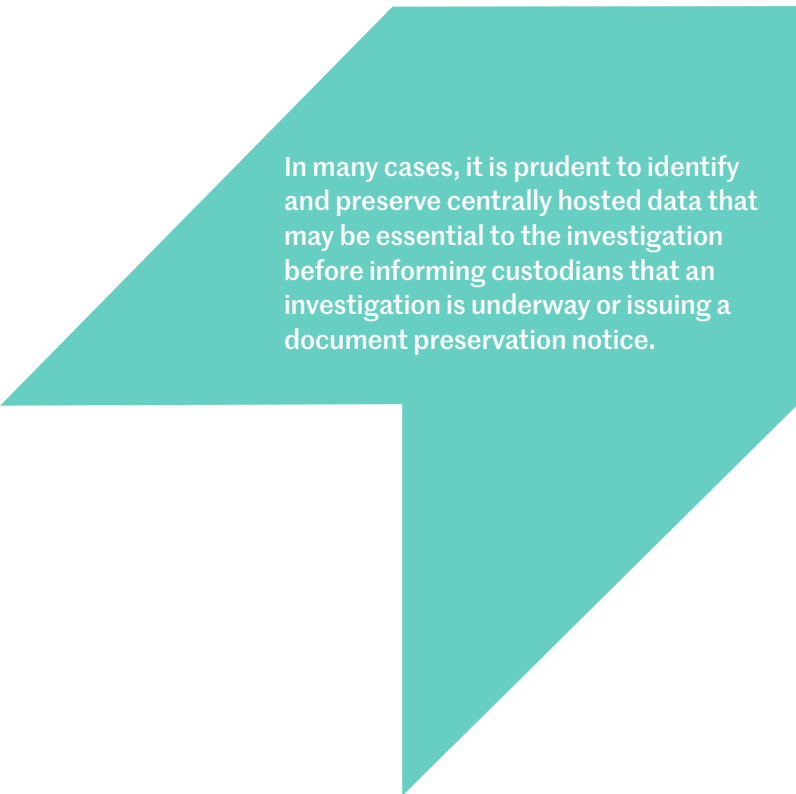
- Consider capturing and preserving relevant data on laptops and individually controlled storage devices, including imaging, where appropriate, depending upon the nature of the investigation or enforcement concern.
- If imaging is not done, consider ensuring that laptops are preserved in their current state (e.g., by swapping out an employee laptop for a new one and placing the old one on hold).

▪ Mobile Devices

- Consider if the relevant witnesses:
 - Conduct business-related communications using company devices, personal devices, or both.
 - Communicate using means that are not centrally stored by the company (e.g., SMS, iMessage, WhatsApp, Zoom, GoToMeeting, BlueJeans, and other video-conferencing applications with recording features).
- Identify ownership of the content on the personal device
 - Seek permission from relevant personnel for imaging of their personal devices if permission is not already granted by a company bring-your-own-device policy.
 - Determine whether the contents of personally owned devices are company property or the company pays for data services for those devices such that there may be a claim that the data is company property.

Keep Records

Be ready to describe the retention activity and to evaluate whether to expand it as you learn more.



In many cases, it is prudent to identify and preserve centrally hosted data that may be essential to the investigation before informing custodians that an investigation is underway or issuing a document preservation notice.

Define Roles/Structure

DESCRIPTION OF ROLES DURING AN INVESTIGATION

Oversee

A board committee, a legal department representative or another senior employee whose conduct is not at issue typically would oversee the investigation that is being led by someone else.

Lead

The voice of the company for purposes of directing the investigation; this could be a board committee, someone in the legal department, or someone in internal audit or compliance, but one individual or group needs to be on point and authorized to lead the investigation. If a board committee is leading the investigation, additional oversight typically is not necessary, although for efficiency's sake it may be prudent to designate one member of that committee as the lead with authority to make decisions concerning routine day-to-day matters. Moreover, in the event some function other than legal is identified as lead, consider creating a foundational document that states the purpose of the investigation in way that preserves attorney-client privilege and work product protections if a privileged investigation is deemed necessary.

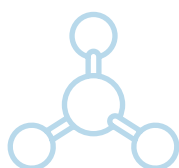
Conduct

Typically outside counsel, inside counsel, or employees in internal audit, compliance, corporate security, or investigation functions conduct the investigation, in coordination with whoever is serving as lead.

Support

Internally, the compliance department, accounting/finance, internal audit, IT/data security or other subject matter experts may aid the investigation, provided that the individuals providing assistance are not under scrutiny in the investigation. Externally, often one or more vendors are used, typically engaged by outside counsel if attorney-client privilege must be maintained. These may include:

- document vendors for gathering, processing, hosting and reviewing documents;
- subject matter experts such as forensic accountants, information technology experts or others;
- data analysis consultant;
- clinicians, researchers or engineers needed to analyze product functions, patient related care and clinical interactions;
- industry consultants with the ability to perform data and benchmarking analyses; and/or
- company employees with unique expertise who could be assigned to the investigation and reporting to the legal department for this limited purpose.



STRUCTURE

Who oversees, leads and conducts the investigation given the specific circumstances should be considered carefully at the outset. Companies often have procedures that provide a guide for this appointment. Check there first. Critically, once this is decided, make sure stakeholders have a good understanding of the reporting structure, especially if the investigation is subject to a legal privilege. This clarifies expectations about communication channels and decision-making authority and will also improve the likelihood of available privileges and protections being maintained.

When is independence Required?

An independent investigation is likely required if the allegations potentially implicate senior management or suggest widespread or recurring systemic concerns. Independence adds credibility to the findings (especially where the findings may need to be shared with enforcement authorities or disclosed to shareholders) and typically provides an additional layer of trust when an agency is reviewing any disclosure or deciding whether to close out an investigation. Additionally, if a company is publicly held and is facing derivative litigation, an independent investigation will also likely be required.

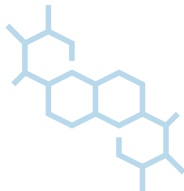
What is the Measure of Independence for an Internal Investigation?

From a traditional corporate perspective, an analysis of independence under Delaware law focuses on whether the individuals leading the investigation are free of economic ties to the persons or subject matter being investigated, as well as on noneconomic factors, all designed to ensure the impartiality and objectivity of those making decisions on behalf of the entity. Whether a law firm and the investigation team are independent depends on a variety of factors, including the extent to which the law firm and members of the investigation team previously have worked for the company or any of the individuals under scrutiny. Inspectors general and agencies generally accept the independence of an investigation if it is conducted by outside counsel, which reviews and presents the relevant facts (as verified) and proposes solutions.

Who Oversees and Who Leads?

- Consider having a board committee or independent member oversee or lead the investigation if it involves corporate-level issues including:
 - accounting, financial reporting, disclosure or compensation issues involving conduct by senior management;
 - systemic or recurring compliance issues, such as payments to health care professionals or off-label marketing, that may involve conduct by senior management;
 - issues involving noncompliance with regulatory standards;
 - any matters that could have criminal implications;
 - integrity, “Me Too,” racial insensitivity or other conduct issues involving conduct by senior management;
 - allegations that, if true, could significantly harm the company and/or its constituents; or
 - a derivative lawsuit.
- Alternatively, consider not having a board committee oversee or lead the investigation if the matter does not directly implicate disclosure controls and procedures or if the matter would otherwise be more efficiently addressed at the company level. Board control over an investigation can be counterproductive in concerns that are far afield from the expertise of the board and too attenuated.

When identifying an investigation lead, consider the availability and desirability of attorney-client privilege. If desired, how should the legal department and/or outside counsel be involved?



Increased and unnecessary bureaucracy, competing interests, and the perception of micromanagement can also exacerbate pre-existing tensions between the board and the company and can adversely impact investigative fact-finding and the free flow of information.

- If the conduct of independent board members is at issue and/or none of the independent directors are free of conflict regarding the issues under investigation, consider adding one or more directors to the board and having those new directors lead the investigation.
- If the conduct of the general counsel or chief legal officer is at issue, it may be appropriate for a board committee to lead the investigation, and for independent outside counsel to conduct it (i.e., representing the board committee, not the company).
- If a board committee is overseeing the investigation and the general counsel is leading it, consider creating a reporting line for the legal department to report directly to that board committee for purposes of the investigation (to protect those leading the investigation from being fired if bad facts regarding senior management are discovered).
- If internal audit or compliance functions lead the investigation, consider whether attorney-client privilege is available and desirable, and if so, whether the legal department and/or outside counsel also needs to be involved in an effort to limit the company's exposure or to appropriately maintain the privilege. In such a situation, the fact that internal auditors or other nonlawyers are acting at the direction of counsel should be documented in order to clearly establish the basis for preserving privilege and work product protection.
- Be prepared to adjust leadership of an investigation if it is initially overseen by internal audit or the compliance department outside the protections of the attorney-client privilege. For example, facts or issues may be discovered that could potentially result in findings of violations of law or regulation, in which case leadership should be immediately transitioned to in-house or outside counsel in an effort to establish and preserve attorney-client privilege and attorney work product protections.

Who Conducts? Will the Investigation be Privileged?

If legal advice is needed regarding the investigation or its findings (i.e., there is any meaningful chance that the investigation may lead to a decision about compliance with laws) or if litigation or regulatory investigations are anticipated, steps must be taken to establish and protect the attorney-client privilege and attorney work product. The choice of whether to rely on in-house lawyers or outside counsel will be driven to some extent by who is leading the investigation. For example:

- Any investigation that needs to be "independent" should be led by independent board members and conducted by independent outside counsel.
- Any investigation led by a board committee should be conducted by outside counsel.
- Any investigation overseen by a board committee should be conducted by counsel, which probably will be outside counsel (even if that outside counsel is led by the legal department under a protected reporting line to the board committee).

- Any investigation led by the legal department could be conducted by in-house or outside counsel. The decision whether to have in-house or outside counsel conduct the investigation is driven by:
 - whether the greater resources available to outside counsel are needed to handle the investigation quickly and efficiently;
 - whether the experience of outside counsel (e.g., ongoing interactions and feedback from government regulatory authorities, or the ability to benchmark industry behaviors) is valued to provide attorneys familiar with certain areas of the law or with particular government agencies, regulators or prosecutors who already are, or who reasonably could be expected to be, involved;
 - whether the experience of outside counsel would be useful in making complex judgment calls;
 - whether the relative independence of outside counsel would be an advantage, particularly as remediation steps following the investigation are considered and implemented; and
 - whether establishment and preservation of the attorney-client privilege and attorney work product protections could be better achieved by using outside counsel.

Who Supports?

- Identify internal functions and subject matter experts (internal or external) who may need to be called on to support the investigation, and determine what support will be needed and whether internal experts' usual, ongoing responsibilities allow them to support the investigation.
- Those who are conducting the investigation typically would engage necessary consultants, using a special engagement letter (even for internal personnel in some cases) describing how attorney-client privilege will be handled.
- In the event that internal support functions are engaged, a clear chain of command should be established and instructions should be provided, if applicable, about how to maintain any attorney-client privilege or attorney work product.

How Can Costs be Controlled?

Costs can add up quickly, and typically the company will request a budget from outside counsel that includes third-party support, even if the company is paying the supporting entity directly.



Fact Gathering

DOCUMENT AND DATA REVIEW

Document and data collection, processing, and review regularly serves as the foundation for internal investigation findings and related legal conclusions, and is often required in response to a regulatory subpoena or request. As subpoenas and regulatory requests often call for production of broad document date ranges and implicate numerous substantive areas and custodians, outside counsel can often help narrow the materials to be reviewed and produced, and assist with assessments of applicable privileges and protect confidential business information, to the extent possible. External data processing and document review vendors can also be brought in to make these efforts more cost-efficient and organized, and can do so under protections of privilege, provided sufficient contractual and process protections are in place. If intensive review and production are not necessarily warranted, given the nature of the allegations or concerns at play in the investigation or review, internal company resources (such as IT personnel) may be used to assist with identification of pertinent, key documents or data to assist with factual findings and/or preparation for employee interviews.



EMPLOYEE INTERVIEWS

Employee Interview Status

During an internal investigation, company employees typically are interviewed. Special considerations apply to the employee witness interviews depending on the employee's role in the conduct being investigated and the investigation topic.

- If the employee is the subject of the investigation and could potentially face employment action as a result of the investigation, careful attention must be paid to company policies and procedures when talking with the employee. The investigation should attempt to confirm as much information as possible about the employee's knowledge of those policies and the potential violations. If the subject employee is a member of a union, then that employee likely has a right to have union representation at the interview. Subject employees also need to be counseled about the company's prohibitions on retaliation to the extent complaining, reporting or whistleblowing witnesses are involved as well.
- As for the complaining, reporting or whistleblowing employee witnesses, careful respect needs to be paid to their unique role in the investigation. These employees need to be assured of the company's serious approach to the issue, the prohibition on retaliation and the general process for the investigation. Investigators should steer clear, however, of absolute promises of confidentiality, as often these are impossible to maintain, and of agreements to report back fully on the outcome of the investigation, which also may not be possible. While it is often appropriate and encouraged to share internal investigation conclusions with the complaining, reporting or whistleblowing employee, at times this is not possible depending on the investigation's conclusions and the necessary remedial measures.



**COVID-19 Consideration:**

Internal policies designed to protect the health and welfare of employees must be considered during the pandemic. Insisting on in-person interviews could present legal risks to the company and is unlikely to generate the kind of rapport with the witness that encourages free information flow. As with other situations where ordinary investigations practices cannot be observed in full, be sure to document the circumstances and reasons for following an alternate process. Finally, while the health and safety of employees is paramount, external stakeholders are unlikely to be persuaded that interviews could not take place at all – e.g., by telephone or video-conference – during the pandemic, absent some other compelling reason to delay.

When?

Different investigations require different strategies. In some investigations, it is important to talk with witnesses quickly, before any documents have been reviewed, and then perhaps speak to them again with a set of documents once those conducting the investigation know more. In other situations, reviewing the documents before interviewing witnesses is essential to an orderly and efficient process. Another consideration is the order in which interviews are conducted. In some cases, it is prudent to start with the lowest-level employee and work up the management chain. In other cases, it is prudent to start with upper management and work down the chain.

Where?

Under normal circumstances, the interviews occur in a conference room or convenient location within the company's offices, preferably in an area that allows the process to remain as confidential as possible. Often, the lawyers conducting the investigation travel to the office location for each witness. Some interviews may be conducted by video conference or telephone, although neither of those situations is ideal. Independent investigators often are able to gather the most information and best impressions when conducting interviews in person, and in-person interviews tend to have the most credibility when evaluated by third parties, such as enforcement authorities.

Who Participates?

- In general, witness interviews should be as streamlined as possible by limiting the interview to a single witness and only those interviewers who are most essential to the investigation.
 - Consider whether the witness is likely to provide more candid and accurate information if the interviewer is independent or at least not a company employee.
- Those conducting the investigation typically would lead the interviews.
- When board members or management are overseeing or leading the investigation, they might want to attend the witness interviews and perhaps even question the witnesses. This certainly is not required and should be addressed on a case-by-case basis, because in some circumstances it may even be ill-advised.
- In-house counsel, compliance or internal audit personnel sometimes attend witness interviews that are being conducted by outside counsel. Depending on the circumstances, their presence can make witnesses more or less comfortable. It is important to ensure that witnesses feel free to provide accurate information and frank views.
- Supporting consultants may also attend and participate in interviews, depending on the circumstances. It may prove necessary in certain circumstances to include consultants in interviews involving highly technical concerns.
- It is advisable to have at least two participants from the investigation team to later corroborate statements should there be a disagreement with the interviewee.



Interviews do not transform facts into privileged information – privilege covers the communications during the interview and follow-up that might occur.

Should Witnesses have their own Counsel?

- Companies typically are not required to provide counsel to employees during internal investigations, and witnesses often are not represented during internal investigations. This is particularly true when the investigation is being conducted by company employees (internal audit, compliance, corporate security, investigations, or legal department). It also is often the case when outside counsel is asking the questions. Companies should be prepared, however, for employees; to inquire about the need for their own counsel as part of any investigation plan.
- Counsel representing the company or a board committee in the investigation typically cannot advise witnesses as to whether they need their own lawyers, even if the witnesses request that advice.
- One potential benefit of a witness having counsel is that it can give the employee the opportunity to think through the conduct at issue in the investigation and to be more precise in the information the witness delivers during the interview.
- When companies decide to make counsel available to employees, companies sometimes engage “pool counsel” who would be available to represent multiple employees during the internal investigation in an economical and efficient manner, while also appropriately protecting the employees. Pool counsel must ensure that they can ethically conduct a joint representation without encountering insurmountable conflicts of interest or revealing confidential information. Pool counsel arrangements usually are set up so that the company pays the bills, but the attorney-client privilege would be between the employees and pool counsel and not include the company. Pool counsel may share information with the company, as appropriate, under a common interest understanding between the individuals and the company.
- Senior officers may request counsel of their own, and companies often honor this request even if a short delay occurs while the officer selects an attorney. Legal departments and outside counsel may have recommendations tailored to the specific subject matter, potential government interest or other factors. It is often useful to select counsel that both has the necessary experience and can work collaboratively with the company’s own counsel.
- Officers and employees likely will want the company to pay the bills for their individual counsel. Whether the company is obligated to do so often turns on provisions in employment agreements, corporate governance documents such as bylaws and charters, and relevant state law. Companies often “indemnify” officers, which usually entails reimbursing fees at the end of a process once it is determined that the officer is entitled to indemnification (e.g., they acted in good faith) and also “advance” indemnification payments along the way so the officer does not bear the legal fees out of pocket. Companies typically require officers to sign an “undertaking” in which they agree to repay any advanced amounts if it is determined that the officer is not entitled to indemnification.
- The cost of legal fees and expenses may be covered by director and officer insurance, although coverage is less likely if no litigation has been filed. Determinations about whether coverage exists and the extent of any coverage will be governed by the policy and direct negotiations with the insurance carriers.
 - When the company is subject to a government investigation, but not active litigation, it will be further necessary to review the specific terms of applicable policies to determine whether coverage exists.
- Sometimes, witnesses want to bring their own individual counsel to the internal investigation interview. There generally is no requirement to allow this. Companies typically evaluate whether to proceed with interviews with such counsel based on the relevant circumstances at the time.

“Upjohn Warnings”

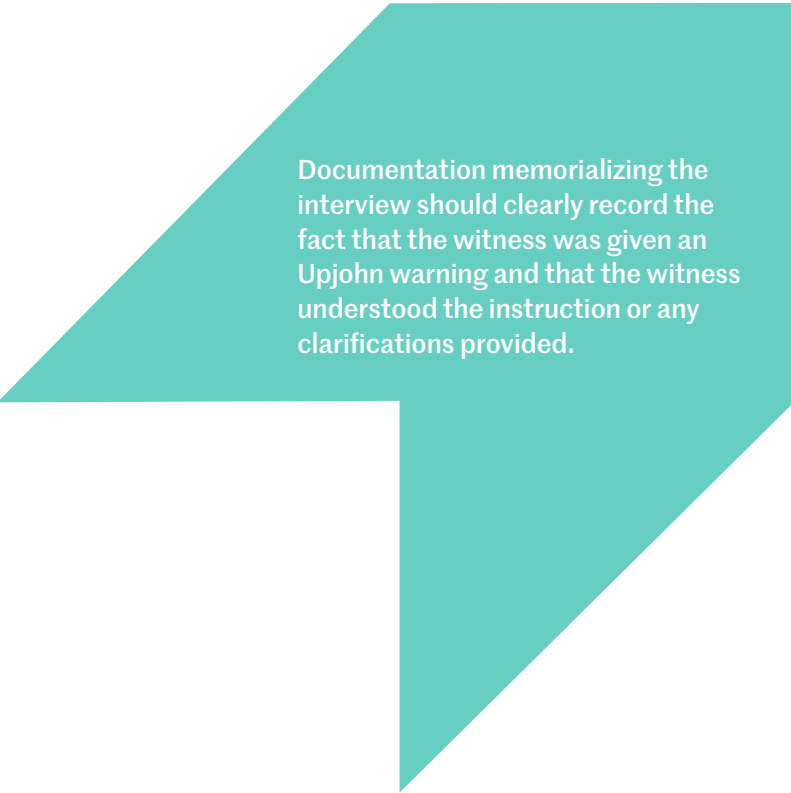
At the outset of employee interviews conducted by counsel for the company, it is important that the witness understand as much about the investigation background as can be shared without impacting the integrity of the investigation. Do not, for example, impart facts to the employee that the employee would not ordinarily have or that would otherwise shape his or her testimony. Witnesses should be informed of how the attorney-client privilege applies to the interview and of their obligation to

maintain the confidentiality of the statements made during the interview. It is also essential that the witness understand that the investigators (including in-house and external counsel, if attending) represent only the company (or the board committee) and do not represent the witness or have an attorney-client relationship with the witness.

- The concept of Upjohn warnings comes from *Upjohn Company v. United States* (449 U.S. 383 (1981)), in which the United States Supreme Court held that a company's attorney-client privilege is preserved when the company's attorney communicates with the company's employees. Beyond the Court's holding, Upjohn warnings are short-hand for providing clarity to the employee about the existence of attorney-client privilege between the company and its lawyers, what the "client" is in the investigation (the company, the board or a committee of the board), how the privilege is maintained, and that information from the interview may be shared with others later should the client decide to do so.
- The warning typically clarifies that:
 - the lawyers represent the company (or the board or board committee) and not the employee;
 - communication occurring during the interview is protected by the company's attorney-client privilege; and
 - the company alone controls whether to provide information learned through the interview to anyone outside the company, including a government agency.
- It is important to note that the interview does not transform existing information into privileged information – it only covers the communication during the interview and any follow-up that might occur. And it does not prevent the witness from talking separately to the government about information the witness knows. It just protects the privileged communication.

Documentation of the Witness Interviews

- Interviewers often take notes during the interviews to document witnesses' responses to questions. Practices differ as to whether interview notes are in the form of a transcript (Q&A) or – when an attorney conducts the interview – include the attorney's inferences, shorthand and mental impressions. The latter, however, are more easily protected from discovery as attorney work product if the interviewer is legal counsel.
- Interview memoranda are more formal records of the communication during the interview.
 - These often are created by one of the individuals who attended the interview, and then may be edited by others on the investigation team.
 - If a lawyer is involved in the interview, interview memoranda typically would be protected from third-party access by the company's attorney-client privilege and, depending on the circumstances, by the attorney work product doctrine.
 - Creation and completion of interview memoranda is time-consuming and expensive, and it is important to determine whether that expense is necessary under the specific circumstances of the investigation. A middle ground is to prepare a summary of key points from the interview shortly after it is completed and events are fresh in the investigators' minds, and to prepare a detailed interview memorandum later if necessary based on the particular circumstances of the investigation.
- Either notes or formal interview memoranda should clearly memorialize the fact that the witness was given an Upjohn warning and that the witness understood the instruction or any clarifications provided.

A large teal geometric shape, resembling a stylized arrow or a corner bracket, pointing towards the bottom right. It is composed of several rectangular and triangular sections.

Documentation memorializing the interview should clearly record the fact that the witness was given an Upjohn warning and that the witness understood the instruction or any clarifications provided.

Memorializing the Investigation

CONTENTS

Investigation findings may include not only a summary of the relevant facts, but also conclusions regarding whether:

- the company and/or individuals violated the law, rules or regulations (but only if the investigation is being led by attorneys under the attorney-client privilege);
- the company and/or individuals violated company policy or procedure;
- there was a root cause of any determined noncompliance;
- any potential noncompliance could have been prevented;
- any potential noncompliance has been remediated and/or whether corrective measures have been put in place to prevent similar future noncompliance;
- any affirmative defenses might be available;
- given their conduct as determined by the investigation, company officers and employees can be relied upon by various outside third parties, such as governmental authorities and regulators or, as applicable, the company's independent auditors;
- senior management's representations were accurate;
- the company's certifications were accurate;
- the company's representations to regulators during examinations/audits or in required filings were accurate;
- the company's representations to lenders, analysts and shareholders were accurate;
- the tone they set at the company was sufficiently supportive of ethical conduct by employees (a good "tone at the top"); and
- there was any attempt to retaliate or actual retaliation against a whistleblower.

Special Requirements to Document

- whether, for companies that are subject to regulatory filing requirements, applicable regulatory filings need to be revised, amended or updated
- whether, for companies that are subject to a corporate integrity agreement (CIA), the findings trigger "reportable event" obligations
- whether, as a result of the findings, the company has triggered any applicable regulatory reporting requirements or may be required to refund overpayments to federal health care programs (i.e., in the case where the company submits claims to government health programs, such as Medicare or Medicaid)

Additional Considerations for Publicly Held Companies

- Whether the company's public filings remain reliable and accurate in light of the information learned, and if not, whether restatement is required (using, among other things, an SAB 99 materiality analysis.)
- Whether the investigation revealed material weaknesses or significant deficiencies in the company's internal controls.

FORM AND DISTRIBUTION

Should there be a Formal Written Report?

Deciding whether and how to document the results of the investigation requires a complex analysis. Drafting a formal report of the investigation is time-consuming and expensive. Many constituents would prefer a full, detailed report of the information gathered during the investigation and the findings, which ultimately is made public. In some cases, such as where the investigation results may require regulatory reporting, complete documentation may be required. In other situations, companies may prefer only oral reports and no public disclosure at all. Whether the ultimate report is protected by the attorney-client privilege depends on:

- the facts and circumstances of the specific investigation (including whether the object of the investigation related to legal compliance/litigation risk versus company policy violations/business risks);
- the company's obligations to its board or shareholders;
- whether an active government or third-party investigation exists or may occur;
- whether the report is being prepared for disclosure to regulatory authorities; and
- whether a shareholder lawsuit exists or is likely.

How Should Results be Shared?

Regardless of form, findings from an investigation that reveal weaknesses in a compliance program or other company functions should be shared in the appropriate manner with other internal stakeholders in order to prevent recurrence. Not only does providing this feedback help prevent future misconduct, but it aligns with DOJ's expectations outlined in its recent compliance program guidance and the guidance outlines in the U.S. federal sentencing guidelines.¹



Special Obligations of Public Companies and Independent Auditors

PROCEDURES

Alerting the Auditors

Public companies and their officers must certify regularly to independent auditors that they have notified the auditors of all information important to the audit. Information requiring investigation often may impact a company's financial reporting and documentation, internal controls, and other compliance systems, especially if the subject of the information is a senior officer, someone in a financial reporting or control function, or another employee or director on whom the auditor may rely. Knowing when and how to alert auditors is an important component of handling internal investigations responsibly. Knowing what the auditors will be required to do upon receiving that notification also can help company personnel anticipate needs and ensure completeness.

Section 10A Procedures

Securities Exchange Act of 1934 Section 10A (15 U.S.C. § 78j-1) requires a public company's independent auditor to work through a set of detailed procedures if the audit firm "detects or otherwise becomes aware of information indicating that an illegal act (whether or not perceived to have a material effect on the financial statements of the issuer) has or may have occurred." The term "illegal act" is very broad, defined as "an act or omission that violates any law, or any rule or regulation having the force of law."

When Triggered

When an issue arises at a nonpublic subsidiary of a public company, these procedures may be triggered where the conduct at issue at the nonpublic subsidiary has a material impact on the public company's reported financial results, and where those involved in the conduct at issue at the nonpublic subsidiary also have senior positions/responsibilities at the public company.

What Auditors are Required to Do

The procedures set forth in Section 10A include:

- determining whether it is "likely" that an illegal act has occurred;
- determining and considering "the possible effect of the illegal act on the financial statements of the issuer";

- informing "the appropriate level of the management of the issuer and assur[ing] that the audit committee of the issuer, or the board of directors of the issuer in the absence of such a committee, is adequately informed with respect to illegal acts that have been detected or have otherwise come" to the firm's attention "unless the illegal act is clearly inconsequential";
- determining whether the illegal act has a material effect on the issuer's financial statements; and
- determining whether senior management (or the board) has taken timely and appropriate remedial actions.

Why the Auditors Hold the Cards

Special – and more serious – procedures are triggered if the audit firm concludes that the company's actions have not been sufficient. Under that circumstance, Section 10A requires that the audit firm determine whether that failure "is reasonably expected to warrant a departure from a standard report of the auditor, when made, or warrant resignation from the audit engagement."

- If so, the auditor must report the results of this determination to the board of directors.
- If this report is made to the board, the issuer must notify the SEC within one business day and provide a copy of this notice to the auditor.
- If the auditor does not receive a copy within one business day, the auditor must resign or furnish a copy of its own report to the SEC within one business day.
- If the auditor resigns under this provision, it must furnish a copy of its own report to the SEC within one business day after resigning.

Investigation findings that reveal weaknesses in a compliance program or other company functions should be shared with internal stakeholders that can prevent recurrence.

ADDITIONAL CONSIDERATIONS

The Challenging Dynamic

If these procedures are underway but are not yet complete, the auditor may not be able to complete its quarterly review or its annual audit. And, as the independent auditor, the firm cannot advise the company of the company's obligations – it can only react to what the company does and reach a view as to whether that is sufficient. This can set up a challenging dynamic in which experienced outside counsel may be especially valuable, particularly when navigating issues related to conveying information and conclusions from an investigation that might be protected by the attorney-client privilege.

Forensic Support for the Audit Team

When a company conducts an internal investigation that could trigger the auditor's Section 10A obligations, the auditor typically involves individuals from its forensic practice and/or its office of general counsel to advise the audit team. The auditor's forensic team may ask to review documents or data gathered in connection with the investigation, and experienced outside counsel can assist the company in balancing the auditor's needs with the need to maintain any attorney-client privilege or work product protections associated with the investigation.



Government and Regulatory Investigations



Whether as a result of the government's own information sources or as a result of the company's "self-report," government or regulatory entities may conduct investigations at the same time as the company's own internal investigation.

WHO

The investigating entities could include civil or criminal authorities at federal, state, local or international levels. They also could include "quasi-government" authorities such as self-regulatory organizations (e.g., stock exchange) or government contractors with delegated authority. More than one government or regulatory inquiry could occur simultaneously, particularly in high-profile matters that have cross-border aspects or have generated media coverage.

How to Address Multiple Fronts and Media

Navigating this multi-front process is challenging, as the company's existing regulatory or reporting obligations continue to apply, even as the government's requests and demands roll in. Experienced outside counsel will be invaluable during this process. As to media interest, while it may be tempting for management to assure customers, the public, and the press that matters under review are minor, are under control, or otherwise, such statements can often prove to be inaccurate, potentially causing additional issues and complications. A good rule of thumb for dealing with such inquiries, particularly at an early stage, is to minimize what is disclosed and to keep things factual (e.g., "the board/company is [conducting an internal review, cooperating with a governmental investigation, etc.]").

INVOLVE COMPLIANCE EARLY

It is often important to engage the organization's compliance department early on in a government investigation. The compliance department can provide important background information on the overall compliance program, as well as information about specific compliance controls. The DOJ's guidance *Evaluation of Corporate Compliance Programs* (updated June 2020) underscores the important role this information serves with respect to prosecutorial decisions.

"COOPERATION CREDIT"

The extent to which the government or regulatory investigators offer "cooperation credit" for an entity promptly sharing information gathered during the internal investigation differs between agencies and organizations, and sometimes even between teams within the same agency.

- For example, the DOJ issued guidance to its FCA litigators on May 7, 2019, regarding the incentives the DOJ offers to companies that provide "voluntary disclosure," "cooperate" with the investigation, "share" information gleaned from an internal investigation and take remedial steps through new or improved compliance programs.¹ In the FCA context, the DOJ is authorized to depart down to single damages in the case of full cooperation. The DOJ has also issued cooperation credit guidance in the FCPA context, and the DOJ Antitrust Division's Corporate Leniency Policy offers amnesty and other leniency based on cooperation and other conditions.
- DOJ has also recently promoted its professed willingness to provide credit to companies that self-report conduct identified in the course of mergers and acquisitions. As issues identified in the course of due diligence can result in post-deal internal investigations, it is important to consider the potential benefits and drawbacks associated with disclosing such conduct.
- The degree of a company's cooperation in an investigation may have an impact on whether the OIG would require a CIA following any ultimate resolution of the matter.
- The SEC's cooperation program is rooted in its *Report of Investigation* from October 2001 that is commonly known as the *Seaboard Report*.² The SEC has provided updated guidance through the years, including a formal cooperation program launched in January 2010 and multiple references in speeches and enforcement settlements.
- With some limited exceptions, the credit a company will get for cooperating is uncertain and difficult to quantify, and the cost of cooperation is high. But the cost of not cooperating may be higher.

GUARDRAILS

A company and its counsel can potentially become so intertwined with a government that a company's internal or independent investigation can be found to be "attributable" to the government, creating subsequent evidentiary risks for the government.

- In such instances, the Fifth Amendment rights of employees – who may be facing the difficult decision of whether to provide statements to counsel conducting an investigation or face potential termination – can potentially be violated.
- In 2019, the U.S. District Court for the Southern District of New York issued a decision that reviewed at length the factors suggesting counsel's internal investigation had essentially become the government's investigation.³ The factors cited by the court included:
 - The government directed the company and its counsel whom to interview and when.
 - The key witness was compelled, upon pain of losing his job, to sit for multiple interviews with the company's counsel.
 - The company's counsel provided the government with timely, detailed information from interviews.
 - The government did not appear to have undertaken any investigative steps involving witnesses outside of counsel's investigation.
 - The government directed the company's counsel over an extended period and did not make its own governmental investigation known to interview subjects.
 - The government ultimately constructed its own subsequent investigative plan based almost entirely on the information provided by the company's counsel.
- To protect the integrity of investigations conducted by the government and the company, counsel for the company should, as appropriate, document that significant investigative decisions are based on independent reasons for the benefit of the company and not taken at the direction of the government. Counsel should also consider providing language in communications with the government to make it clear that the company and its counsel are conducting their own investigation and exercising their own, independent discretion with respect to investigative steps and decisions.

WHISTLEBLOWERS

Whistleblowers may complicate both the internal investigation and government investigations, often without the company having any knowledge that a whistleblower has contacted the government.

- SEC and FCA whistleblowers are entitled to certain confidentiality and non-retaliation protections and have clear monetary incentives for bringing matters to the attention of federal authorities.
 - Companies are prohibited from "retaliating" against an SEC or FCA whistleblower, with retaliation potentially including discharging, demoting, suspending, threatening, harassing or discriminating (directly or indirectly) against the relator or whistleblower.
 - In this context, additional regulations prohibit against "impeding" employees from reporting misconduct to the government, which can include severance or confidentiality agreement provisions that could be read to prevent, or potentially even discourage, whistleblowers from reporting.
- A well-established part of the legal industry focuses on cultivating and promoting whistleblower actions.
- Whistleblowers can include current employees who provide information to the government in real time. Given the significant penalties for retaliating against whistleblowers and the many ways retaliation can be alleged, companies often decide not to engage in any effort to identify whistleblowers who have, or may have, reported potential violations.
- If the company is in communication with the whistleblower, whether because the whistleblower has not chosen to remain anonymous or because the company's systems allow for an anonymous communication with the whistleblower, consider developing a communication strategy to provide appropriate updates to the whistleblower, consistent with preserving attorney-client privilege and workproduct protection. Here again, experienced counsel can be very helpful.

As communication is established with the whistleblower, bear in mind that some whistleblowers may have been advised to record (in one-party states) communications that relate to the alleged misconduct, including correspondence with the company counsel.

Even in instances where the DOJ declines to intervene, it may be appropriate for the organization to conduct a further investigation of the allegations to comply with its obligations under the 60-day overpayment rule.

Interests of Various Constituents

During the course of an internal investigation, it may be helpful to pause and consider whether the interests of the various constituents are being addressed. While it may not be possible to address all of these interests, and while this list is not exhaustive, keeping these various interests top of mind will help general counsels serve their companies more effectively during the course of the investigation.

Internal Constituents and Their Interests

Constituent	Interests in the Internal Investigation Include:
Board of directors	▪ Clear understanding of process, schedule ▪ Updates as needed and appropriate ▪ Appropriate documentation of process including minutes, resolutions ▪ Integrity of process, findings, remedial measures ▪ Ability to rely on committees, experts, management
Board committees	<i>(in addition to interests as board members)</i> ▪ Timely understanding of allegations involving subject matters overseen by their committees ▪ Timely understanding of role in investigation (oversee, lead, receive reports, ensure appropriate documentation, provide information, preserve documents)
Board committee chairs	<i>(in addition to interests as board and committee members)</i> ▪ Audit or oversight committee chair needs to understand information being provided to independent auditors ▪ Audit or oversight committee chair needs to understand whether timeliness of public filings is at risk ▪ Other chairs may need early focus of upcoming needs in their areas (e.g., nomination and governance, compensation)
Senior officers	▪ Doing their jobs, and leading the workforce to continue doing their jobs, despite the distraction of the investigation ▪ Potential personal liability
Compliance department	▪ Ensuring coordination with ongoing compliance efforts, such as audits and risk assessments ▪ Receiving sufficient information to help ensure that any needed enhancements to compliance program and controls are implemented
Communications team	▪ To the extent that the results of an investigation may become public or are related to a public complaint or issue, the company's communications team may need to be prepared for eventual press inquiries or releases ▪ Provide appropriate updates
Employees	▪ Information flow ▪ Confidence in fairness of process and integrity of management ▪ Job security

External Constituents and Their Interests

Constituent	Interests in the Internal Investigation Include:
Government entities	- Compliance with laws, rules, regulations - Early alerts of potential illegal acts, including possible self-reports - Confidence in those overseeing, leading, conducting and supporting the investigation - Timely and accurate updates regarding investigation process, findings, remedial measures - Thoroughness of investigation - Cooperation by sharing of detailed factual information and key documents, and making witnesses available - Dissemination of lessons learned in process safety and other accident investigations
Independent auditors	- Early alerts of potential illegal acts - Confidence in those overseeing, leading, conducting and supporting the investigation - Timely and accurate updates regarding investigation process, information learned during investigation, findings and remedial measures - Thoroughness of investigation - Confirmation of reliability of senior officers - Briefing regarding all remedial action by management and/or the board of directors - Understanding of management's view, in light of information learned in the investigation, of the adequacy of its internal controls
Patients and the public	- Prevention of any increased risk of harm or reduced quality of care to current or prospective patients - Individualized or public notice or updates as needed and appropriate - Confidence in the company and its products
Lenders and debtholders	- Timely disclosures per any provisions in applicable agreements, including covenant breaches - Timely filings/reporting if at all possible
Listing exchange	- Timely disclosures - Compliance with listing standards
Other relevant legal counsel (e.g., securities or bond counsel, other pending litigation)	- Early alerts of potential illegal acts - Timely and accurate updates regarding investigation process, information learned during counsel in investigation, findings and remedial measures - Confirmation of reliability of senior officers - Briefing regarding all remedial action
Shareholders	- Clear and accurate financial statements and disclosures - Timely filings if at all possible
Suppliers, vendors and business partners	- Complete and timely restitution where warranted - Timely delivery of any required notices - Respect for company's integrity
Suppliers, vendors and business partners	- Confidence in the company and its products - Compliance with applicable industry and customer standards and requirements - Compliance with contractual commitments - Supply chain assurances

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Colleagues throughout King & Spalding contributed to this Decision Tree.

About the Practice

King & Spalding combines its government-facing practices into one Government Matters group, enabling a cross-discipline and multiple skillset-approach to serving our clients. Our teams include 104 former government officials from more than 27 different government departments, agencies, and offices, as well as scores of lawyers who have devoted their careers to helping clients navigate internal and government investigations.



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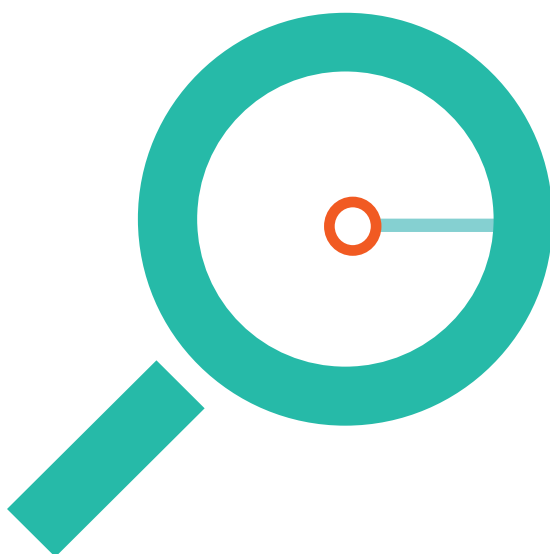


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¹ U.S. Dep't of Justice, Evaluation of Corporate Compliance Programs, June 2020, p. 16 ("Response to Investigations – Have the company's investigations been used to identify root causes, system vulnerabilities, and accountability lapses, including among supervisory managers and senior executives? What has been the process for responding to investigative findings? How high up in the company do investigative findings go?"); Federal Sentencing Guidelines Manual §8B2.1 (U.S. Sentencing Comm'n 2018) ("After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.").

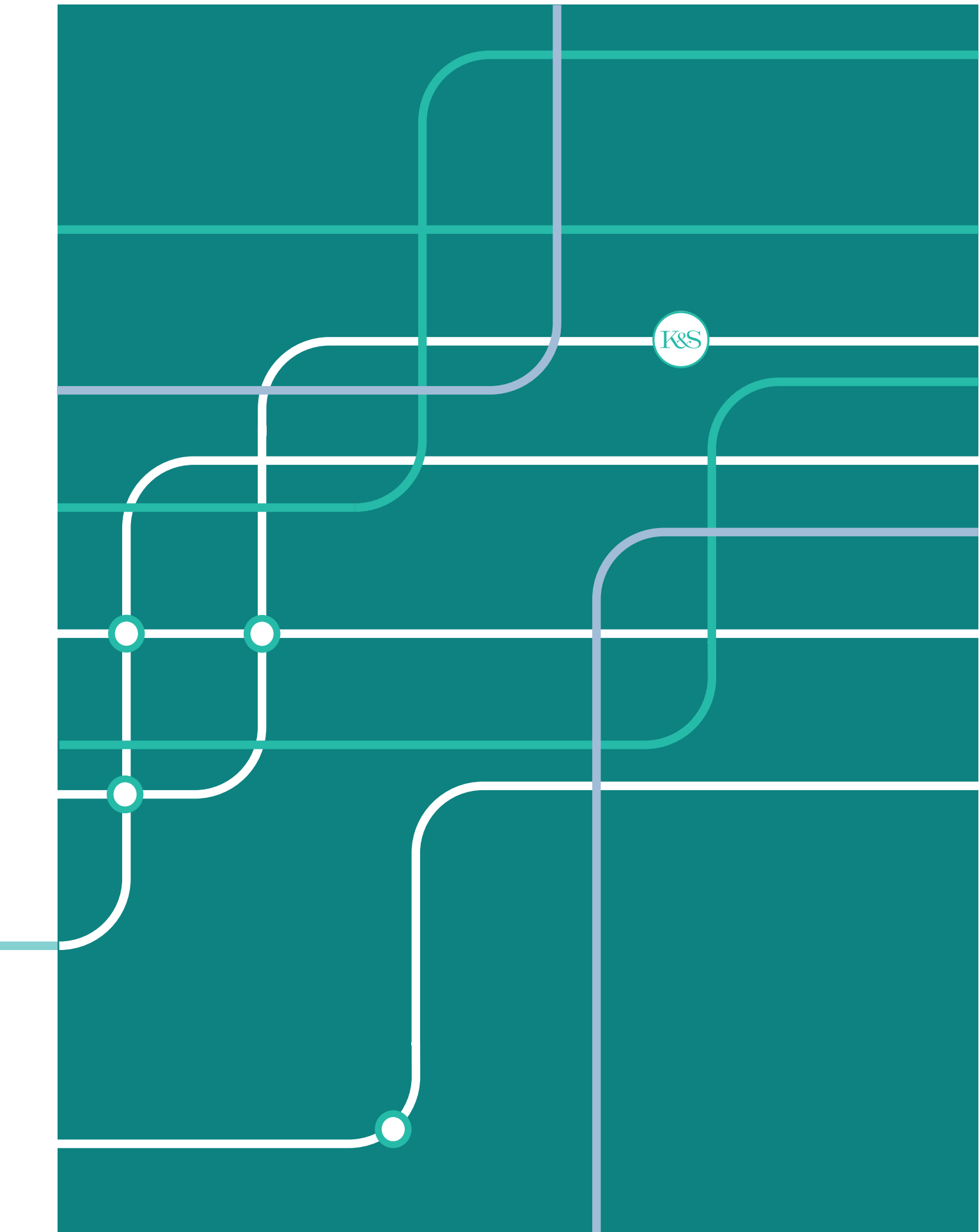
² See Securities Exchange Act of 1934 Release No. 44969 (October 23, 2001).

³ *U.S. v. Connolly, et al.*, 16-CR-370-CM (S.D.N.Y. 2019).



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