



For more information,
contact:

Dixie L. Johnson
+1 202 626 8984
djohnson@kslaw.com

Aaron Lipson
+1 404 572 2447
alipson@kslaw.com

Seth H. Lundy
+1 202 626 2924
slundy@kslaw.com

Gina Cavalier
+1 213 443 4393
gcavalier@kslaw.com

Peter Leininger
+1 202 626 5586
pleininger@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue,
NW
Washington, D.C. 20006-
4707
Tel: +1 202 737 0500

Atlanta
1180 Peachtree Street, NE
Atlanta, Georgia 30309-3521
Tel: +1 404 572 4600

General Counsels Decision Tree for Investigations of Life Sciences Companies

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. 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, False Claims Act matters, HIPAA protections, supply chain compliance, or more general corporate concerns equally applicable to the entire life sciences industry, such as import/export controls, Foreign Corrupt Practices Act compliance, product liability issues, data breaches, environmental catastrophes, or human resource issues, there are more than enough landmines in today's legal and regulatory environment to keep any general counsel up at night. While not all issues may be avoided, having a playbook in place for conducting an internal investigation that facilitates the identification and remediation of issues is an important step in feeling prepared for whatever may come. Further, following that playbook helps a company to meet the expectations of enforcement authorities, such as the Department of Justice and Department of Health and Human Services Office of Inspector General, which can materially mitigate potential enforcement efforts and penalties.

When a developing situation requires an internal investigation, a general counsel faces 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:



- local, state, and federal governmental authorities (including diverse government contractors)
- the board of directors
- board committees
- board committee chairs
- senior officers
- employees
- internal auditors
- independent auditors
- shareholders or debtholders
- distributors and suppliers
- Insurers and health plans
- customers and patients

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

This work flow document is designed to help navigate through the myriad decisions, twists and turns of an internal investigation while maintaining focus on the various constituents and how best to emerge on the other side of the situation. This document should be used in conjunction with communications with counsel and existing company policies – it is not a complete legal or strategic analysis on any topic. Even so, and although no one document can anticipate everything, this document is intended to provide an efficient, easy reference for what can be a difficult process.

Policy. Does the company have policies, procedures, guidelines or other governing documents that govern how an internal investigation should be conducted? If so, to the extent governing documents differ from these suggestions, 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.

Scope. Internal investigations may be required due to questions or information arising from internal sources (e.g. hotlines) or external sources (e.g. government agencies). Once the initial information is received and an internal investigation is deemed necessary, consider the following:

- **Determine Initial Scope.** Identify the relevant time period, potential witnesses, and subject matters quickly.
- **Expect Changes.** Recognize each could change as investigators (internal or external) learn more during the process.
- **Expand if Needed.** It is important for internal investigators to be able to confirm that no one hindered them from expanding 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 an investigation believed they (or someone else) adequately followed up on what they learned during the investigation.

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

- **Stop destruction.** Involve an Information Technology resource, within the company if possible, who can stop any ongoing, routine document and data destruction or recycling.
- **Secure essential documents and data quickly.** Electronic documents that are centrally monitored are the easiest to secure — these can include email and instant message systems, shared servers, and archived



sources. Investigators should work with internal stakeholders at the company to identify and preserve the most relevant essential data.

- **Devices.**
 - Consider imaging laptops and individually-controlled storage devices like USB thumb drives
 - Consider mobile devices – do the relevant witnesses communicate using means that are not centrally stored by the company (e.g., SMS, iMessage, or mobile apps like Slack or WhatsApp)? Are employees' mobile devices property of the company? Are their contents company property? Will relevant personnel give permission for imaging their phones if permission is not already granted by company policy?
- **Data Retention Memo.** Consider sending a data retention memorandum to selected employees, and potentially directors
- **Keep Records.** Be ready to describe the retention activity and to evaluate whether to expand it as you learn more

VOCABULARY FOR 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, someone in internal audit or compliance, but someone 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
- **Conduct** – typically outside counsel, inside counsel, or inside employees such as internal audit or compliance personnel, conduct the investigation, in coordination with whoever is serving as Lead
- **Support** – often one or more vendors are used, typically engaged by outside counsel if maintaining the attorney-client privilege is desired – these may include:
 - Document vendors for gathering, processing, hosting, and reviewing documents
 - Subject matter experts such as forensic accountants, information technology experts, or others
 - Clinicians, researchers, or engineers needed to analyze product functions, patient related care and clinical interactions
 - Consultants with the ability to perform data and benchmarking analyses
 - Company employees 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 should be considered carefully at the outset. Companies often have procedures that provide a guide in answering this question. Check there first. Critically, once decided, make sure stakeholders have a good understanding of the reporting structure. This will help clarify expectations about communication channels and improve the likelihood of maintaining available privileges and protections.



- **When is independence required?** An independent investigation is likely required if the allegations potentially include senior management or widespread or systemic concerns. Independence may also be useful to increase confidence in the findings (especially where findings may need to be shared with enforcement authorities or disclosed to shareholders). 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 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 noneconomic factors, all designed to ensure impartiality and objectivity when making decisions for 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.
- **Who oversees and who leads?**
 - Consider having a board committee or specially created committee oversee or lead the investigation if it involves entity-wide issues including:
 - Systemic compliance issues, such as payments to health care professionals or off-label marketing, that may involve conduct by senior management
 - Material quality or safety issues involving noncompliance with regulatory standards
 - Any matters that could have criminal implications
 - Integrity, “Me Too” or other conduct issues involving conduct by senior management
 - Allegations that, if true, could significantly harm the public, the entity, and/or its constituents
 - A derivative lawsuit
 - 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, a board committee or other appropriate management or compliance designee should lead the investigation and independent outside counsel should conduct it
 - 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 them from being fired if bad facts regarding senior management are discovered)
 - If internal audit or compliance leads the investigation, consider whether an attorney-client privilege is desirable, and if so, whether the legal department and/or outside counsel also needs to be involved in order to maintain the privilege
 - Be prepared to adjust leadership of an investigation if it is initially overseen by internal audit or compliance outside of the protections of the attorney-client privilege and facts or issues are 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 to establish and preserve an attorney-client privilege and attorney work product

- **Who conducts?** If legal advice is needed regarding the investigation or its findings, lawyers need to be involved and steps need to be taken to 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.
 - 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 inside or outside counsel, a decision driven by:
 - Whether the greater resources available to outside counsel are needed to handle the investigation quickly and efficiently
 - Whether the expertise of outside counsel is needed to provide attorneys familiar with 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 for complex judgment calls
 - Whether establishment and preservation of the attorney-client privilege and attorney work product document could be better achieved by using outside counsel
- **Who Supports?**
 - Those who are conducting the investigation typically would engage necessary consultants. If outside counsel is conducting the investigation and forensic accountants are necessary, for example, the outside counsel typically would hire the accounting firm using a special engagement letter describing how attorney-client privilege will be handled.
 - 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.

WITNESS INTERVIEWS.

- **When?** Different investigations require different strategies. In some investigations, it is important to talk with witnesses quickly, even before any documents have been reviewed, and then perhaps interview them again with a document set once those conducting the investigation know more. In other situations, reviewing the documents before interviewing witnesses is essential to an orderly and efficient process.
- **Where?** Usually 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 are able to gather the most information and best impressions when conducting interviews in person. Thus, 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.
- Those conducting the investigation typically would lead the interviews.
- When board members are overseeing or leading the investigation, various board members might want to attend the witness interviews and perhaps even ask questions of the witnesses. This certainly is not required, as board members are entitled to rely on the experts they hire to conduct the investigation and their presence during interviews could create complications.
- In-house counsel or compliance personnel sometimes attend witness interviews that are being conducted by outside counsel. Depending on the circumstances, the presence of in-house counsel or compliance personnel could 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 is advisable to have at least two participants from the investigation team to later corroborate statements should there be a disagreement with the interviewee.

- **Counsel for the Witnesses?**

- 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, or legal department). It also is often the case when outside counsel is asking the questions.
- 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.
- 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 would be responsible to ensure that they could 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 not include the company, subject to specific common interest understandings.
- Senior officers may want 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 expertise and can work collaboratively with the company’s own counsel.
- Officers and employees may 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 By-laws, and relevant provisions of the state corporate code.

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., acted in good faith), and also “advance” indemnification payments along the way so the officer does not bear legal fees out of pocket. Companies typically require officers to sign an “undertaking” 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 if no litigation has been filed, coverage is less likely. Coverage will be governed by the policy and negotiations with the 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 coverage.
- Sometimes, witnesses want to bring their own individual counsel to the internal investigation interview. Companies typically evaluate whether to proceed with interviews with counsel based on the relevant circumstances at the time.
- **“Upjohn Warnings.”** At the outset of interviews of company employees conducted by counsel for the company, it is important that the witness understand as much about the context as the investigators can share without impacting the integrity of the investigation. Witnesses should be informed of how the attorney-client privilege applies to the interview and of their obligation to maintain the confidentiality of the interview. It also is essential that the witness understands that the investigators represent only the company (or the board committee) and do not represent the witnesses 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.
 - The warning typically clarifies that:
 - the lawyers represent the company (or the board committee) and not the employee;
 - communication occurring during the interview is protected by the company’s attorney-client privilege; and
 - only the company will control whether to provide information learned through the interview to anyone outside of the company, including a government agency.
- **Documentation of the Witness Interviews.**
 - Attorneys often take notes during the interviews, and practices differ as to whether the notes are in the form of a transcript (Q, A) or include the attorney’s inferences, shorthand, and mental impressions. The latter, however, are more easily protected from discovery as attorney work product.
 - Interview memoranda are more formal records of the communication during the interview.
 - These often are created by one of the lawyers who attended the interview, and then may be edited by other lawyers on the investigation team.



- 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.
- At a minimum, 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.

INVESTIGATION REPORT.

- **Investigation findings may include 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)
 - Whether the company and/or individuals violated company policy or procedure
 - Whether there was a root cause of any determined non-compliance
 - Whether any potential non-compliance could have been prevented
 - Whether any potential non-compliance has been remediated and/or whether corrective measures have been put in place to prevent similar future non-compliance
 - Whether any affirmative defenses might be applicable
 - Whether, given their conduct as determined by the investigation, company officers and employees can be relied upon by the various outside third parties, such as governmental authorities or, as applicable, the company's independent auditors
 - Were senior management's representations accurate?
 - Were their certifications accurate?
 - Was the tone they set at the company supportive of ethical conduct by employees (a good "tone at the top")?
 - And for publicly held companies:
 - Whether the company's public filings remain reliable in light of the information learned, and if not, whether restatement is required (using, among other things, a SAB 99 materiality analysis)
 - Whether the investigation revealed material weaknesses or significant deficiencies in the company's internal controls
- 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 that may ultimately be made public. Others may prefer only oral reports and no public disclosure at all. Whether the ultimate report remains privileged or not depends on the facts and circumstances of the specific investigation, the



company's obligations to its board or shareholders, whether or not there is an active government or third party investigation, and will require detailed analysis and thoughtful legal advice.

SPECIAL OBLIGATIONS OF INDEPENDENT AUDITORS FOR PUBLICLY HELD COMPANIES.

- Securities Exchange Act of 1934 Section 10A (15 U.S.C. Section 78j-1) requires a 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."
- 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
 - determining whether senior management (or the board) has taken timely and appropriate remedial actions
- 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 1 business day and provide a copy of this notice to the auditor
 - if the auditor does not receive a copy within 1 business day, the auditor must resign or furnish a copy of its own report to the SEC within 1 business day
 - if the auditor resigns under this provision, it must furnish a copy of its own report to the SEC within 1 business day after resigning.
- 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.



- 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.

Government Investigations. Whether because of the government's own information sources or as a result of the company's "self-report" to the government, the government may conduct an investigation at the same time as the company's own internal investigation.

- The government could include civil or criminal authorities, at federal, state, local or international levels. More than one government inquiry could occur simultaneously.
- 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.
- The extent to which government investigators offer "cooperation credit" to a company for promptly sharing with the government information gathered during the internal investigation differs between government agencies and organizations, and sometimes even between teams within the same agency.
 - For example, the Department of Justice issued guidance to its False Claims Act litigators on May 7, 2019 regarding the incentives the Department offers to companies that provide "voluntary disclosure," "cooperate" with the Department's investigation, "shar[e] information gleaned from an internal investigation and tak[e] remedial steps through new or improved compliance programs." Similarly, the Office of Inspector General will consider disclosure context and remediation efforts in decision-making about its exercise of its enforcement authorities, including whether to impose a Corporate Integrity Agreement or to seek civil monetary penalties and/or exclusion.
 - The SEC's cooperation program is rooted in a Report of Investigation from October 2001 that is commonly known as the "Seaboard Report." See Securities Exchange Act of 1934 Release No. 44969 (October 23, 2001). The SEC has provided updated guidance on cooperation through the years, including a formal cooperation program launched in January 2010 and multiple statements in speeches and enforcement settlements.
 - 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.
- In attempting to cooperate with a government investigation, a company and its counsel can become so intertwined with the government that an 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 either provide statements to counsel conducting an investigation or face potential termination – can potentially be violated.
 - Recently, 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. *U.S. v. Connolly, et al.*, 16-CR-370-CM (S.D.N.Y. 2019). 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 may complicate both the internal investigation and government investigations, often without the company having any knowledge that a whistleblower has contacted the government.
 - Both *qui tam* relators and SEC whistleblowers are entitled to certain confidentiality and non-retaliation protections and have clear monetary incentives for bringing matters to the attention of the government.
 - Companies are prohibited from “retaliating” against a *qui tam* relator or SEC whistleblower, with retaliation potentially including discharging, demoting, suspending, threatening, harassing, or discriminating (directly or indirectly) against the relator or whistleblower.
 - In the SEC whistleblower context, there are additional prohibitions 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.
 - There is a well-established legal industry that focuses on cultivating and promoting *qui tam* and SEC 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. Here again, experienced counsel can be very helpful.

Interests of Various Constituents. First and foremost, the company and those conducting an internal investigation must always be cognizant of whether the conduct and/or individuals subject to investigation present any risk of harm or even reduced quality of care to current or prospective patients, or the more broadly



considered public-at-large. During the course of an internal investigation, it may also be helpful to pause and consider whether the interests of the various other constituents are being addressed. While it may not be possible to address all of these interests, and while the list below is not exhaustive, keeping these various interests top of mind will help those leading an investigation serve their companies more effectively during the pendency of the investigation.

Constituent	Interests in the Internal Investigation Include:
Patients and the public	<ul style="list-style-type: none"> • 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
The board of directors	<ul style="list-style-type: none"> • 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	(In addition to interests as board members) <ul style="list-style-type: none"> • 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	(in addition to interests as board and committee members) <ul style="list-style-type: none"> • Audit or Oversight Committee chair needs to understand information being provided to independent auditors • Audit or Oversight Committee chair needs to understand if 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	<ul style="list-style-type: none"> • Doing their jobs, and leading the workforce to continue doing their jobs, despite the distraction of the investigation • Potential personal liability
Government entities	<ul style="list-style-type: none"> • 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, making witnesses available to meet with the government • Disclosure-related compliance related to potential municipal finance obligations
Employees	<ul style="list-style-type: none"> • Information flow • Confidence in fairness of process and integrity of management • Job security
Independent auditors	<ul style="list-style-type: none"> • Early alerts of potential illegal acts that may trigger special procedures by the auditors • Confidence in those overseeing, leading, conducting, and supporting the investigation



Constituent	Interests in the Internal Investigation Include:
	<ul style="list-style-type: none"> • Timely and accurate updates regarding investigation process, information learned during investigation, findings, remedial measures • Thoroughness of investigation • Confirmation of reliability of senior officers and management • 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
Lenders and debtholders	<ul style="list-style-type: none"> • Timely disclosures of any provisions required by agreements, including covenant breaches • Timely filings if at all possible
Suppliers, vendors and customers	<ul style="list-style-type: none"> • Timely and reliable payments • Integrity of ultimate products containing suppliers’ parts/ingredients/contents
Listing exchange (for publicly held companies)	<ul style="list-style-type: none"> • Timely disclosures • Compliance with listing standards
Shareholders (for publicly held companies)	<ul style="list-style-type: none"> • Clear and accurate financial statements and disclosures • Timely filings if at all possible

Internal investigations can be extremely complex, but being prepared with a plan that evaluates the scope and considers carefully the roles of the all stakeholders involved goes a long way in ensuring that an investigation will start on the right foot.

ABOUT KING & SPALDING

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