

Preparing for a Government Investigation/Inquiry

An evolving regulatory environment and increased scrutiny in the life sciences industry has opened the door for government investigations and/or inquiries. When such circumstances arise, companies who are not prepared may find themselves at great risk for penalties and consequences that can sink their business. Here's what you need to know to ensure your company is prepared:

Do you have a "government knock" policy?

All employees should be well-versed and trained in the company's policy regarding interaction (including raids) with government enforcement agencies. Employees should understand their rights, duties and obligations when such circumstances arise, and the policy (and training) should be continually updated as the company evolves.

Related, companies should also implement and enforce a formal corporate compliance program that can identify potential risks and issues before they result in government action. The program should be continually updated and include internal investigation policies and processes.

Do you know who to contact?

Companies should maintain a detailed record of all internal and external legal counsel who currently serve, or have served, the company. The record should include relevant areas of expertise, dates of services, and information on specific projects and duties during their service to the company.

Similarly, companies should also have ready-made list of legal counsel, public relations firms, and crisis management firms, in the event immediate assistance is needed. These firms should ideally be focused in the life sciences industry, and should be prepared to act quickly when called upon.

Who To Contact



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How is your data stored and maintained?

Life science companies traditionally manage voluminous amounts of data. It is imperative that companies have comprehensive policies surrounding the intake, storage, use, maintenance and destruction of this data – each of which could be critical throughout the course of a government investigation or inquiry.

Companies should also maintain a repository of all active and retired systems, vendors, dates of operation and purpose, as well as detailed records surrounding the company's IT infrastructure, including hardware, software and cloud systems.

It is also critical to have a formal disaster recovery and business continuity policy related to company data. All employees should be well-versed, and trained as needed, on data and records management policies.

Responding to a Government Investigation/Inquiry

Government investigations and inquiries can severely impact a company's operations, as well as stressing employees and resources. Understanding that investigations and inquiries can be deliberate and methodical, it's important that companies have a comprehensive plan to comply with the government while still maintaining business operations. Below are some key considerations if your company is facing a government investigation or inquiry:

How was the company notified of the investigation or inquiry?

Did the company receive a subpoena duces tecum or civil investigative demand? Was it issued under civil, criminal, and/or administrative authority? What is the nature of the matter(s) referenced, and/or what statutes are cited? Assessing the full scope of the investigation or inquiry is the first step in preparing a response and ensuring compliance.

What steps do I need to take?

Determine what resources, including staff and/or personnel, will be needed. Beyond internal resources, will the company need to engage outside counsel? Will subject experts be required? Are there securities implications that need to be addressed? Will the company need litigation support to assist with document production? Determining if the company intends to challenge the matter in court, and establishing the amount of information the company is willing to disclose, will also help in shaping the strategy and determining what resources may be needed.

Next, determine if targeted education is needed for the Board of Education or other company officials regarding the scope of the investigation or inquiry. Similarly, which employees, vendors, and/or agents need to receive the document hold notice, and what messaging needs to be conveyed to them?

What type of investigation or inquiry am I facing?

Government investigations and inquiries can take many shapes. Beyond determining whether your company is a target, subject or witness in the matter, it is also important to identify whether the matter is civil or criminal in nature. Which government agencies are involved? Does the matter involve a qui tam relator? The company's response should flow from these determinations.

What will the company need to provide?

The company will likely be asked to fulfill a variety of document requests, as well as disclose information about products and services. It is important to determine what document populations need to be prioritized, whether the government will allow rolling productions, and other steps that the company needs to take to meet the requests.

In the same vein, the company must determine where the responsive electronically-stored information (ESI) is housed, how it can be collected and managed, and which e-discovery tools may be necessary to comply with the government's request. This includes identifying which employees and departments are responsible for the responsive documents, as well as determining any challenges that may exist in obtaining said documents.

How do I determine which documents will be needed?

To preserve efficiency, it is critical to establish parameters on document review strategies, including addressing searching, reviewing, duplication, and privilege. With many documents containing confidential and sensitive information, including personal patient data, it is important to understand how documents will be reviewed at the outset of the investigation and inquiry. It is also vital to determine who should have access to the documents, including not only government officials, but also outside counsel, third-party vendors, and/or company officials.

Should I conduct an internal investigation?

Depending on the nature of the government investigation/inquiry, it may be appropriate to conduct an internal investigation. If this occurs, it is vital to establish who will conduct the investigation, whether the internal investigation will be conducted under applicable legal privilege, and what conflicts of interest might exist.

Who is being targeted in the government investigation/inquiry?

If employees are being targeted, the company must first determine whether the employee is being requested for informal discussions with the government, or if the employee is being requested to formally testify in a deposition or before a grand jury. The company must also determine if counsel will be provided to the employee, if the employee needs to also obtain their own counsel, and/or whether a joint defense agreement is appropriate.

What needs to occur to resolve a government investigation/inquiry?

Under a global resolution, it is important to whether all matters under investigation are being resolved, including existing civil and criminal matters, as well as any qui tam cases filed under the False Claims Act (FCA). It is also important to identify what the government is seeking (e.g. debarment or exclusion), and whether all investigating agencies are involved in the settlement. Finally, the global resolution will impact all aspects of a company's business. The company must identify and prepare for any collateral consequences that may arise from the resolution.

The company should also be prepared to sign a corporate integrity agreement (CIA) or other post-settlement compliance form. Any CIA or post-settlement form should be thoroughly reviewed, with potential issues that may impact the company or its operations identified and addressed, prior to signing.

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