

DON'T WORRY. WE'RE FROM THE GOVERNMENT.
AND WE'RE HERE TO HELP.

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Introduction

Among the myriad legal issues and potential liabilities that businesses need to be aware of, regulatory investigations can present some of the most significant and hazardous risks. Investigations by regulatory agencies, and accompanying potential enforcement actions, present unique financial and reputational exposure risks for businesses of all sizes. Managing these risks effectively is essential to minimize business disruption, collateral consequences and parallel proceedings, runaway costs, and other potential penalties. Agencies such as the Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and Equal Employment Opportunity Commission (EEOC), all pursue their varying statutory and regulatory goals in different ways, with the common thread being that businesses subject to these various regulations need to not only monitor continued compliance, but also prepare for them, as well as have strategies in place for response to investigations as they arise.

Investigations by regulatory agencies can arise in a variety of contexts, from a reported violation to a routine check. In response to reported violations, many regulatory agencies will initiate an investigation to determine the efficacy and substantiation of the reported violation. While investigations of this type often begin in a focused scope surrounding the specific allegation or violation, as documents are reviewed and witnesses interviewed, there is always the potential for a wider investigation to arise.

In addition to investigation stemming reports of specific violations, regulatory agencies enact their enforcement strategies by conducting routine inspections or investigations of businesses in a variety of contexts as well. Even without a specific complaint, these routine inspections can potentially be even more disruptive, given their wider scope. As will be discussed below, understanding the enforcement strategies to which a business must report can be of great assistance in anticipating and preparing for these sorts of investigations. It is similarly important to continue to monitor agencies' changing enforcement strategies as they evolve over time.

Finally, investigations can stem from reports of whistle blowers within the organization. A recently announced Department of Justice initiative to provide for whistleblower rewards, while still in its infancy, presents the risk of significantly increasing whistle blower complaints and resulting regulatory investigations stemming therefrom.

In the remainder of this paper, we will discuss the particular outreach efforts seen in investigations from various regulatory bodies as examples of the concerns businesses need to be aware of.

Common Forms of Outreach

Common forms of outreach from a regulatory body can include informal emails or phone calls to the Company's public facing emails or phone calls. It is recommended that an organization have in place procedures for first ensuring that these email boxes/message lines are monitored. Next, do you have a policy in place informing employees how to respond, do they know to whom to escalate? What are the internal timelines you have for responding? Do the employees have the authority to answer questions, if they do choose to answer questions have they been trained and do they know how to evaluate risk and the scope of questioning?

Informal outreach often next escalates to a request for meeting or documents. It is important to understand the scope of the request and the nature of the agency. A number of regulatory bodies were noted above (including FDA, OSHA, DOL, EEOC) those regulatory bodies will have their own personalities and processes for outreach. There is a whole host of considerations where the agency seeking outreach has close ties with Federal (Criminal) enforcement possibilities. This could include, the Federal Trade Commission (FTC), the U.S. Securities and Exchange Commission (SEC), the Environmental Protection Agency (EPA) and Office of Inspector General (OIG). We would be remiss to ignore the state agencies and investigatory powers of State Attorney's Generals and for instance their consumer protection departments and other civil and criminal investigative arms.

In short, the most benign of outreach outside of "community outreach programs" which do exist, will lead to additional questions. It is imperative that you assess which agency has contacted you, (and within the agency the role of the individual contacting you), and the deadlines for responding.

Handling Friendly Calls

Handling a call for information is different than the receipt of a subpoena or civil investigative demand. In the latter, there is something that is clearly requested, a response date and some issuing authority you can review. With informal calls you will have to ensure that someone with knowledge of the company and knowledge of the agency is fielding questions and assessing as the conversation unfolds what the interest may be and what the potential exposure or risk may be.

Internal Investigations

May result from the outreach, the outreach may have highlighted certain issues that require memorialization and assessment of litigation risk. One of the first decisions the legal team needs to make includes whether you use internal resources (HR, legal team), or external counsel. Again you have to balance whether privilege exists and the topic at hand. Should they be conducted by counsel, there should be consideration of the *Upjohn* (and their progeny) cases. Employees need to understand that they are not represented by counsel, but that counsel for the Company is conducting an investigation and be given an opportunity to consult with counsel if desired.

Voluntary Disclosures

Various state agencies and certain federal agencies have established informal or formal voluntary disclosure processes. The agency wants to encourage early reporting and remediation against not learning about a potential misstep at the outset. The agency promises expedited resolutions and potential reductions in civil fines. The corporation however has to balance whether a voluntary disclosure makes sense in light of not having all the facts and understanding best how to remediate. You also lose privilege by sharing findings with the Government. Voluntary disclosures where there is potential for criminal consequences is further complicated by the evolution of the program and the type of “fulsome” disclosure required by the Government from executives.

Crisis Coordination

For certain situations, it is advisable that legal work closely with the communications team to ensure that internal messaging and external messaging is consistent. It is recommended that an organization have in place a crisis communication plan and escalation process to ensure that what is being reported publicly aligns with a larger strategy, and is truthful and appropriate to the type of investigation.

For instance, the public comment on an incident relating to an environmental issue may be very different from the public comment to allegations of misconduct levied against a senior executive. There is no privilege in these statements and care must be taken to ensure that in the processing of working with messaging, documents are not created that would misinform or mislead an investigator.

Examples of Agency Investigations:

EEOC Investigations

The U.S. Equal Employment Commission (EEOC) is charged with enforcing Federal Laws against discrimination in job applications or employment relationships based on race, color, religion, sex (including pregnancy and related conditions), gender identity, and sexual orientation, national origin, age (40 or older), disability or genetic information. Generally,

Federal employment litigation requires as a procedural prerequisite that a claim be pursued through the EEOC, and EEOC investigations are typically initiated by a claim of discrimination in hiring, firing, promotion, harassment, training, other employment opportunity, or compensation. Once a claim is filed, the employer has an opportunity to provide a position statement setting forth its response to the claim. The EEOC typically offers the opportunity for some conciliation and/or mediation or beyond, and then begins its investigation.

EEOC investigations generally begin with a request for information in which the EEOC seeks documentation (to the extent it was not provided with the position statement) from the employer, often seeking demographic information and information regarding similarly situated employees. An EEOC investigator will then determine whether employee interviews are necessary, at which point the investigator will identify the individuals employed within the organization who will be interviewed. In recent years, these interviews are increasingly done in a remote environment, generally by telephone. Following the completion of its investigation, the EEOC can either pursue an enforcement action on its own (all of this is relatively rare), or issue to the complainant a right to sue letter, which will allow the Plaintiff to go forward with private action. This right to sue letter can, but does not always set forth the EEOC's impressions or finding of the case; alternatively, the EEOC may indicate that it has made no finding in the case and issues a right to sue in that event.

OSHA Investigations

The Occupational Safety and Health Administration (OSHA) is responsible for ensuring safe and healthy working conditions for employees by setting and enforcing standards and providing training, outreach, education, and assistance. When a workplace incident occurs or a complaint is filed, OSHA may conduct an investigation. Below are the typical steps involved in an OSHA investigation.

An OSHA investigation can be initiated in several ways, e.g., employee complaints, referrals from other government agencies or organizations, following a severe injury or fatality, programmed or follow-up inspections. Once an OSHA investigator arrives on-site, they will conduct an opening conference with the employer to explain the reason for the visit, the scope of the inspection, and the procedures that will be followed.

After the opening conference, the investigator will likely perform an inspection of the area of the incident (at the very least, but they may also expand the inspection to other areas). During the inspection, the investigator will inspect the workplace for hazards, review safety and health programs, and observe work practices. They will also likely have questions related to the area(s) being inspected. For this reason, and others, it is best to escort the investigator to the area(s) being inspected.

Often times during and following the inspection of the site, the investigator will have "action items" they desire to complete. Action items typically include taking photos or video, interviewing employees, reviewing records related to the activity/process in question, reviewing records related to general safety matters, etc. Notably, it isn't uncommon for additional/subsequent inspections to take place following the initial inspection.

Once the investigation is complete a closing conference will take place to review the agency's findings. At that time, any apparent violations will be discussed along with any corrective actions required (and the timeframe for the identified corrective actions).

If violations are found, OSHA will issue a citation and propose penalties. Violations can vary in terms of severity. Irrespective of the severity of the citation, however, the employer can either accept the violation(s) and agree to correct the issue by a certain date or the employer can contest the citation(s) and/or penalty by filing a notice with the OSHA Area Director within a specified time.

Ultimately, it's important to appreciate the significance of an OSHA investigation. A misstep at the beginning, during, or at the end of one can be detrimental for a myriad of reasons.

FDA Investigations

The Food and Drug Administration (FDA) is the federal agency charged with protecting the public health by ensuring the safety and efficacy of products it regulates, including human and veterinary drugs, biological products, medical devices, food, tobacco, cosmetics, and radiation emitting products. This amounts to a trillion dollars worth of consumer products regulated by FDA each year. FDA is responsible for advancing the public health by evaluating innovations that make regulated products safer and more effective, and by providing accurate, science-based information about the products it regulates.

FDA has broad enforcement authority, consistent with the public welfare purpose of its primary authorizing statute, the Federal Food Drug & Cosmetic Act (FDCA). In addition to providing FDA with sweeping authority to inspect establishments worldwide that produce FDA regulated products, the FDCA provides FDA with broad administrative and judicial tools to enforce the FDCA. This authority includes situations when FDA obtains information that an FDA-regulated product poses a risk to the public health. In these instances, FDA typically works with the company to ensure public notification about the product's risks and to remove it from the market.

If FDA decides to take action for suspected violations of the FDCA, FDA can utilize advisory actions, administrative actions and enforcement actions (civil or criminal), all of which are authorized by the FDCA.

Conclusion:

As we can see, an organization's preparation for responding to regulatory investigations is critical. Most businesses are subject to the oversight of more generally focused bodies like OSHA and EEOC, and particular industries will also be under the guidance of more narrowly targeted regulation, some more rigorous than others. Open and appropriate communication with the regulatory bodies conducting these investigations must meet needs of the regulatory intent, serving the public protection the agency is tasked with. But this should be balanced with care and the knowledge that investigations may lead to negative consequences if violations are found. In addition, and particularly in cases in which an investigation is spurred by a particular claim or incident, concerns of potential liability to other parties down the line need to be considered.

Ultimately, the responsibility of complying with these regulations, and demonstrating compliance through the investigative process, must be balanced with knowing and protecting the organization's rights.