

Expert Analysis

The Path To A Stable Reporting Culture For Life Sciences Cos.

By Gary Giampetruzzi, Thomas Hauser and Jenny Pu January 2, 2020

As the people on the frontlines of medical research, sales promotions, human resources and everything in between, employees of life sciences companies are privy to critical insights that go far beyond a company's intellectual property. Employees often observe firsthand or hear about potential misconduct and legal violations the C-suite simply cannot see or access.

If employees do not share this information, companies of any size can land in jeopardy, facing the costs of reputational damage, stunted business growth and even legal action. Indeed, in April 2019, the [U.S. Department of Justice](#), widely regarded as the leading enforcement authority in the international compliance space, issued its second version of compliance guidance for life sciences and other companies, which focused on corporate reporting systems and the conduct of internal investigations.

In that document, the DOJ advised:

Another hallmark of a well-designed compliance program is the existence of an efficient and trusted mechanism by which employees can anonymously or confidentially report allegations of a breach of the company's code of conduct, company policies, or suspected or actual misconduct. Prosecutors should assess whether the company's complaint-handling process includes pro-active measures to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers. Prosecutors should also assess the company's processes for handling investigations of such complaints, including the routing of complaints to proper personnel, timely completion of thorough investigations, and appropriate follow-up and discipline.

In this leading guidance, whose approaches other prosecuting authorities worldwide could be expected to be considered informative, the DOJ focused on the effectiveness of the corporate reporting mechanisms. Compliance and legal professionals within organizations should ask how the company collected, analyzed and used information from its reporting mechanisms? How has the company assessed the seriousness of the allegations it received? Has the compliance function had full access to reporting and investigative information?

The DOJ also focused on companies ensuring that investigations are properly scoped and conducted by qualified personnel, though not defining what would constitute such qualified personnel. And how has the company ensured that the investigations were independent, objective, appropriately conducted, and properly documented?

On the back end, the DOJ advised that the investigation should be used to identify root causes, system vulnerabilities and accountability lapses, including among supervisory manager and senior executives. In other words, what has been the process for responding to investigative findings?

What should companies do in light of this kind of guidance? A company's best defense is a hearty offense in which employees feel encouraged and willing to come forward to report any such issues. But in the real world, are companies successfully prioritizing creating a healthy reporting culture? As part of an internal investigations forum, leaders from medical technology and pharmaceutical companies participated in an annual benchmark survey to understand reporting and whistleblower investigation trends among peers, and to catalyze best practices.

The forum is hosted biannually by different life sciences companies, jointly facilitated by [Navigant Consulting](#), and the legal firm [Paul Hastings](#). The survey included a select group of participants from leading medical technology manufacturing and pharmaceutical companies, ranging in size from 5,000 to over 250,000 employees worldwide, with headquarters in Europe, Japan or North America.

Survey results highlighted vast regional differences in the quantity and quality of complaint reports and showed that companies generally need to nurture trust and improve internal relations. While no one-size-fits-all approach exists for compliance, internal investigations or employee relations, analysis of the survey results and follow-up discussions with



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participants revealed several areas of opportunity. These included a general need for companies to bridge the gap between filed complaints and unreported incidents, and to strengthen their internal investigations processes and policies.

Survey Analysis: Areas of Opportunity

To get a sense of the processes that most companies used to receive, validate, assess and resolve reports, [click here](#), and to understand the volume of the reports, [click here](#).

Based on the survey results, participants take misconduct and compliance seriously. Respondents indicated most misconduct reports relate to fraud, interactions with healthcare providers, employee relation issues or scientific misconduct, all of which are under intense regulatory scrutiny, especially in coveted global markets, and can quickly be escalated to external authorities.

All of the companies represented in the survey have a standard operating procedure in place covering what issues must be reported, and 90% have an SOP in place for how to handle investigations. The majority of the participating companies have predetermined rules and criteria for screening reports. However, some rely on the reviewer to judge reports filed and determine which ones warrant investigation.

The former approach helps mitigate the inherent bias of human judgment but may also risks eliminating good leads. The latter risks human influence in the selection process and can undermine the integrity of the reporting protocols and put the company at serious legal risk. For these reasons, companies need to find the balance between standardized rules and screening procedures as well as ethical consistency.

To understand the percentage of complaints from various regions of the world and the level of substantiated cases, click [here](#).

According to the survey results, an average of 69% of reports filed move into investigation. Of those, 46% on average are substantiated. That figure leaves a gap between violations reported (a known number,) and the potential of violations seen that were not reported (an unknown number). This does not necessarily mean those cases deemed unsubstantiated were not worth pursuing — it only means there was not enough evidence to warrant pursuit. This raises several important questions, including:

- Could companies do more or improve the investigation process?
- Are companies tackling the right problems?
- Are critical underlying issues being covered up or not reported due to fear of reprisals?

Respondents indicated investigations are paid for by central funds (45% of companies,) charged back to the business (27%), or a hybrid model of both approaches. Allocating appropriate resources for compliance efforts and support — such as through dedicated human resources, employee relations and employee assistance programs — is essential.

These resources should also include tailored training for employees on what should be reported and why, how to make a complaint, what to expect once a report is made, and how business functions should handle and react to complaints, including the limits of confidentiality.

Proactive Collaboration and Understanding

In most companies, the legal or ethics/compliance department handles misconduct and whistleblower complaints. These functions generally are responsible for receiving and screening complaints, conducting investigations, as well as analytics, trends and management reporting, and recordkeeping. While legal and compliance lead these inquiries, they typically require assistance from other support functions, as well as any business areas to which a case relates.

So, depending on the subject and reach of a confirmed incident, resolution could involve multiple departments, individual business units, regional and local management, human resources and others. On average, resolution ranges between 30-180 days, depending on the incident, according to the survey results.

Of respondents, 90% provide training for investigators, including sessions covering corporate laws, finance and internal audits, employment law, compliance, as well job training, interviewing and case management. But none provide tailored training to help cross-functional leads understand the processes and procedures, nor on how to provide appropriate support to an investigation.

As a result, a lack of consistency and role-modeling remains across business functions. In real terms, this can lead to ignorance, misinformation, policy breaches and the perpetuation of the perception that legal and compliance are the to-be-avoided internal police.

To break down these barriers, training should be provided to help executives and managers across the enterprise understand how investigations work and why, their role in supporting them, and steps they can take as supervisors to create open dialogue, promote compliance, and support and protect whistleblowers.

These trainings should in particular provide understanding and methods to handle the complex behavioral factors that determine whether employees report violations or not. For example:

- Does management actively seek out discomforting facts?
- Do the company's leaders withhold or dilute findings on systemic problems?
- Are employees trained on how to conduct emotionally uncomfortable conversations?

A professional and educated approach to this area can greatly increase behavioral ethics and create a speak-up culture to help the company navigate global complexities.

Tone from the Top

In addition, anyone at the managerial level should be expected to lead by example, and to be held accountable for doing so. Their direct and indirect reports should be made to feel comfortable in asking questions and raising concerns. It also means keeping employee confidences appropriately, cooperating with misconduct investigations, and helping create long-term solutions by weighing in on how the incident happened and what can be done to prevent another one from occurring.

Keep in mind, a healthy speak-up culture, backed by a supporting “tone from the top down” and “tone from the middle,” supports business growth — and does not create limitations. This has proven true for several multinational and global companies found in breach by regulatory authorities and forced to shift course.

Bridge Cultural Barriers

To see the breakdown for the regional source of complaints, [click here](#).

Of course, to cultivate a healthy speak-up culture — or, culture of healthy disagreement, as some might call it — is easy to say and far more complicated to do, especially across global regions. This involves understanding differences in cultures and business functions regionally and providing ways to create bridges through appropriate training and coaching. Respondents surveyed noted vast regional differences in what gets reported, by whom, how often and how much of those reported are substantiated.

For example, employees in North America are far more likely to report incidents than those in Russia or the Middle East, whereas China and other Asia regions have a lower volume of reported incidents, compared to North America, but a higher substantiation rate.

These results suggest two influences that attributed to the difference in reporting and substantiation rates across regions. The first is the variance in the level of legal protection on whistleblowers. How safe employees feel filling a complaint verses potential retaliation they may face post reporting. For reference, the United States and Canada have strong legal protections for whistleblowers, and the [European Union](#) has recently proposed such a directive, but most countries in the world do not have built-in protections. The second critical factor is the variations in norms as far as cultural propensity toward outspoken vs. reticent behavior and actions.

Speak-Up Culture Leads to High Performance

Forum participants agreed the level of speak-up culture naturally varies from region to region but needs to be improved by organizations around the world. As the global head of internal investigations of a large pharmaceutical company noted: “Retaliation in the workplace continues to be an issue embedded into the fabric of our workplace cultures and a primary reason employee do not report known or suspected wrongdoing.”

Individuals that are part of a culture of retaliation consequently tend to be reluctant to report another party's misconduct, opting instead to “mind my own business.” They fear retaliation — and often rightly so. Retaliation can come in many forms, ranging from threats and public shaming to reputational damage, demotion, job loss and more. Retaliation incidents do not only demoralize individuals in the workplace but can also damage the business to its core.

Take for example, the widely publicized case of [Theranos Inc.](#), the blood-testing startup once valued at \$9 billion. It illustrates a classic case where a culture of secrecy dominated the company and employees who dared to disagree were marginalized, forced out of their jobs, or threatened with litigation, according to an interview with whistleblower Tyler Shultz, a former Theranos employee, as reported by Fraud Magazine.

“You have to have a culture where people are allowed to disagree, and are encouraged to disagree, and then encouraged to actually get to the bottom of the disagreements and design experiments to figure out where the disagreement is coming from,”[1] Shuktz told the magazine.

A healthy speak-up culture can ease the fear of retaliation in the workplace, and stimulate innovation and growth in the business, because it mitigates the costs and liabilities of bad behaviors.

Best practices for employers to create such a healthy speak-up culture include:

- “Listen up” before expecting people to “speak up”;
- Take all reports of retaliation seriously;
- Include specific examples of retaliation in the anti-retaliation policy that managers and supervisors may not have otherwise realized were legally actionable;
- Provide regular training to management of all levels and senior leadership;
- Create a mechanism through which employees can report concerns and instances of retaliation;
- Make it clear that retaliation will be subject to discipline, up to and including termination;
- Campaign success stories; and
- Promote civility, which can help reduce incidents of retaliatory behavior.

To see the breakdown of complaints filed by anonymous and identified persons, [click here](#).

Furthermore, to help tackle retaliation in the workplace, companies have created channels for employees to file reports anonymously. Survey results indicated more than half of the complaints were reported anonymously. Participants in the survey also expressed support for implementing strict anti-retaliation policies and procedures to protect complaint reporters — no matter where they reside, and whether a person’s identity becomes known.

As a global head of investigations for a global pharmaceutical company explained, when an employee files a misconduct complaint, the job of that employee is protected for six months following resolution of the complaint. (To prevent employees from taking advantage of that policy by providing a false claim as a means to, for example, protect their own position, any anti-retaliation policies should also clearly articulate repercussions for knowingly making a false claim.)

In addition, companies should prioritize leadership skills that foster behavioral integrity. As a first step, leaders should be well versed in the various psychological factors contributing to their own and their employees lapses in decision making. Secondly, leaders should be trained on the appropriate methods to mitigate these behavioral risks. For example, in the area of promoting a speak-up culture, managers should be able to quickly discern cases of group think before they evolve into harmful “esprit de corps,” and be trained on methods to counteract this.

Committing to Compliance

No one can change a corporate culture overnight. But companies can commit to compliance as part of the mission. Leaders and employees across functional areas and regions need to be educated to understand the consequences for them individually and the company as a whole if a breach occurs. They need to understand the process, purpose and investigational boundaries in order to create a forthcoming and accountable culture.

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