Feature Article

A Compliance New Year's Resolution – Assess the Company's Culture

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ABSTRACT: The topic of 'company culture' is certainly not new, but it continually emerges as a hot topic within regulatory circles. An organization's culture is recognized to exert a powerful influence on how a company and its people conduct business. Although there is an inherent understanding that by continually enhancing company culture, ethical aspects of the organization will follow suit, why isn't culture reviewed with the same rigor and principles that are required for compliance programs? This article will discuss the importance to evaluate an organization's culture of compliance, and will introduce some considerations on how this can be done.

At the start of every New Year, we hear people discussing, exchanging, making and breaking New Year's resolutions. Why should the company compliance program be any different? Frankly, we do not think it should. Therefore, for 2017, we propose that assessing the company's culture top the compliance New Year's resolution list.

Here are a couple of reasons why culture assessment should top the list. Back in May 2016, the Update published an article detailing the cultural deficiencies that plagued Olympus Corporation for 10 years, the article presented a clear case where compliance failures flowed from the erosion of ethical behavior and corporate governance, thus resulting in settlements by the organization and its subsidiaries.[2] That article emphasized the 'importance of corporate culture's impact on successful (or unsuccessful) compliance'.[3]

A similar cultural breakdown could happen to any company regardless of industry. However, considering that the Department of Justice ("DOJ") will increase enforcement efforts of healthcare related companies, the life sciences industry is under the DOJ's microscope now more than ever.[4] In fact, when looking at Foreign Corrupt Practices Act (FCPA) matters alone, in the last five years, 25 life science companies were involved in FCPA matters, 13 of which were just in the last two years.[5] Additionally, the new FCPA Corporate Enforcement Policy announced on November 29, offers guidance on what an effective compliance program would look like,

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1 *FRA provides multi-jurisdictional expertise in financial and electronic forensics to help companies manage risks in an increasingly regulated business climate. www.forensicrisk.com*

2 *See Kathleen Drennan, Peeling Back the Olympus Onion - The Importance of Culture, 2.5 LIFE SCIENCE COMPLIANCE UPDATE (2016). Available at: https://www.lifescicompliance.com.*

3 *Id.*

4 *See Mark Scallon, Jenny McVey & Jimmy Ko, To Disclose or Not to Disclose... That is the Question: he DOJ's FCPA Pilot Program – Insights from Year One and Beyond, 3.9 LIFE SCIENCE COMPLIANCE UPDATE 13–18 (2017),*
available at: https://www.lifescicompliance.com.

5 *TRACE International, Inc. https://www.traceinternational.org/compendium*

which includes "the company's culture of compliance, including awareness among employees that any criminal conduct."[6]

This begs the question – how can compliance professionals focus on corporate culture with the same rigor as standard business activities and transactions? This concern has been echoed before, and continues to resurface at regular intervals.[7]

Can culture be evaluated like other elements of compliance programs?

For all its implied significance, as culture is often considered a 'soft issue', companies struggle to measure its effectiveness. Typically, organizations execute employee surveys to get a pulse on cultural perceptions, while alternatively, when evaluating compliance programs the organization requires a comprehensive approach consisting of:

- monitoring and auditing plans,

- risk assessment procedures, interviews with key personnel,

- governance documentation review, and

- a stringent record of assessment activities performed.

Similar to assessing the effectiveness of a compliance program, why shouldn't assessing culture also use a methodology consisting of several mechanisms that gathers a parameter of data points, over various points in time? The framework of traditional monitoring plans includes selecting a business activity to review against compliance requirements, documenting employee procedures, determining corrective actions, if needed, and repeating over time to determine if the risk is remediated. A similar framework for measuring culture should be applied such that a cultural attribute (e.g., tone at the top) can be identified, reviewed, and re-evaluated over time to recognize changes or shifts within the organization.

So, how exactly can companies measure culture?

Some of the tools that can be used to measure culture are familiar. However, like any approach, it is critical to understand how to effectively apply these tools. Effective application of these tools will allow the user to gather the most relevant data. The matrix on page 3 outlines examples of tools that if used collectively can bring the company's culture into sharp focus.

Making culture a science tied to risk management

Employing multiple and effective approaches over periods of time can help companies better measure how employees are conducting ethical business. Similar to compliance program risk assessments, the data gathered from a combination of the tools mentioned above can be scored, ranked, and therefore inform a company where behavioral risks may occur.

Coupled with metrics traditionally gathered from compliance program assessments, this information could provide a more holistic view of an organizations' risk profile. For example, when analyzing monitoring reports, a company may find incidents of off-label promotion are high during field visits, while reports of such incidents are low. Training records may show that all field-sales have recently taken and passed an off-label training module, and company policies clearly outline prohibition of this behavior. Based on this information alone, many assumptions of why the training is not working can be made.

One possibility is that field-sales may be incentivized to promote products 'at all costs'. However, when

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6 *United Stated Department of Justice: Office of the United States Attorneys – 9-47.000 – Foreign Corrupt Practices Act of 1977, 9-47.120 – FCPA Corporate Enforcement Policy; see also Sally Foroughi & Kaitlin Fallon Wildoner, Effectiveness, The Holy Grail of Compliance - Both the DOJ & OIG Weigh In, 3.7 LIFE SCIENCE COMPLIANCE UPDATE 7–15 (2017).*

7 *See Tracey Keele, A Prescription for Life Science's Regulatory Woes, 2.3 LIFE SCIENCE COMPLIANCE UPDATE6–10 (2016), available at:* https://www.lifescicompliance.com.

Employee Survey:

Employee surveys that allow anonymity are an effective and efficient way to measure company culture. Surveys allow companies to establish a "baseline" and measure progress (or the lack thereof) over time. These types of surveys also allow companies to gain employee perspective, beliefs, and even practices when it comes to ethical behaviors driven by culture.

However, companies often do not phrase questions to receive the most accurate responses. A common mistake is posing leading questions, which tend to influence the reader to choose the 'right' answer, rather than an honest answer, therefore creating bias.[8] Additionally, employee surveys are typically executed once. Although the results may inform the organization where they need to improve, implementing a one-time survey does not allow the company to track if remediation efforts are impactful over time.

Assessing Your Leaders:

Because 'tone from the top' sets the foundation upon which an ethical culture is built, replacing leaders within a company that has, for example, undergone FCPA enforcement action, is often seen as "table stakes" in any remediation effort. Typically, new leaders are current company employees or come with known associations to the company. While this this makes sense from a continuity and human resources perspective (the organization has working knowledge of this individual, can quickly put them in place, and frankly, these individuals may have been up for a leadership position in the short term anyway) it is not without risks. Those risks are what assurances are there that new leaders will convey the right messaging and change the compliance culture?

Prior working knowledge, 'good interviews', or other subjective measures may not simply be enough to effectively evaluate if new leadership has the skills to fulfill ethical objectives. A series of leadership evaluations to better understand if they can establish a culture of ethics that is consistent and long-lasting should be considered.

Companies seeking to remediate compliance issues should develop an assessment tool, with the help of experienced human resources experts, to better understand leadership's values with respect to compliance and ethics. In addition, the assessment tool should weigh the desired values and styles and compare and measure them versus commercial interests, including profitability, time and resource constraints and business development. Finally, because of the specialized nature and sensitivity of this assessment, it should be outsourced to an independent expert who specializes in behavior and leadership values analysis.

In-Person Feedback:

Employee focus groups can add a valuable data point of culture measurement. Well-run focus groups allow employees to vocally provide their perspective, beliefs, and concerns around ethical behavior. Employees not only bring concerns, but they often provide solutions that are valuable for the company to consider.

In this setting, anonymity is unavailable, therefore consider holding groups consisting of peers, where they feel comfortable to provide honest answers. Additionally, groups that consist of different role levels (e.g., staff, managers, directors, etc.) may provide a broader view on beliefs and perceptions. However, care must be taken to ensure that the voices of the lower role levels are not drowned out by those in higher roles.

Focus groups should be facilitated in a way which allows participants to feel comfortable, and that their voices will be heard. Developing topics for discussion that elicit these types of assurances is crucial to receive the most honest responses. Coupled with the results gathered from employee surveys, this can allow companies to evaluate where further efforts need to be taken.

Find out what others think of you.

The employee 360° has long been part of programs identifying key leadership talent within organizations. The same should apply to clients and key business partners. Clients and key business partners avoid association with companies that are known for unethical behavior. It's important to gauge public perception - is your ethical culture reflected in how you work with clients? Some other effective ways to measure this is by simple media searches, client surveys, and even focus groups, similar to the principles of transaction testing.

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8 See Survey Money "5 Common Survey Questions Mistakes That'll Ruin Your Data" available at http://www.surveymonkey.com

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examining the results of a culture assessment, the organization may reveal a culture of lack of confidentiality and a fear of retaliation. Therefore, field-sales may feel confident they will not be reported and are willing to take higher risks. This example is limited and oversimplified, however, evaluating culture alongside aspects of compliance provides a comprehensive perspective of how business is conducted. Additionally, if employed correctly, evaluating ethical culture can potentially provide some predictive measure on how the outcomes of a compliance assessment may be.

Conclusion

Compliance professionals recognize the need to deeply embed compliance within a company - corporate compliance programs are continually evaluated and large amounts of resource are spent towards efforts to mitigate risk. Compliance should not just be a set of company rules and standards that are regurgitated for the sake of audits or inspections. Compliance should instead be part of an employee's everyday decision making. Culture and compliance are linked. As the DOJ views the healthcare industry as one that "faces serious compliance and corruption challenges not only in high risk markets oversees but right here at home as well," compliance professionals need to focus on a company's culture with the same stringency or 'science' as assessing compliance programs.[9] Therefore, we think assessing a company's compliance and ethical culture is a worthy New Year's Resolution.

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9   See, JAMPOL AND AIBEL: DOJ TARGETS HEALTHCARE WITH FCPA ENFORCEMENT, THE FCPA BLOG (2017), *http://www.fcpablog.com/blog/2017/8/10/jampol-and-aibel-doj-targets-healthcare-with-fcpa-enforcemen.html).*

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