Chapter 1: Compliance is complicated

What’s not working?
Ethical misconduct seems more rampant than ever. Even heavily regulated companies with extensive compliance programmes are not immune. The level of trust within American business seems lower than ever.

Ethics scandals persist despite extensive regulatory structures and emphasis on compliance. Are we doomed to a permanent level of misconduct as a price of global corporate activity? Is cheating so deeply rooted as a character trait that we must accept it as a cost of doing business?

Or, have we been ineffective in addressing ethics and misconduct in organisations because we are focusing our efforts in the wrong places?

Business leaders are beginning to understand that achieving compliant behaviour is not just a function of good financial controls and employee awareness of code standards. The ability of individual employees to act ‘ethically’ is as much a function of their environment as it is a function of their awareness of the rules. For nearly a century social psychologists have understood that behaviour is a function of the person and their environment. However, these insights are just now being adopted by organisations to guide their ethics and compliance programmes.

The bottom line is that a company cannot achieve compliance without first addressing the behavioural issues in its culture that impact the ability and the desire, to be compliant. Companies are only now coming to understand that what causes seemingly good and honest employees to engage in unethical behaviour is neither lack of moral education nor a lack of awareness of the rules to follow. Culture matters.

Corporate culture has traditionally been seen as too amorphous to systematically evaluate with regard to ethical behaviour. The analytical approaches typically adopted by an organisation’s auditors and legal counsel have traditionally shied away from looking at the organisation’s culture. In interviews with legal counsel however, one of the major reasons why culture is not seen as strategic is due to a lack of awareness that culture can be effectively addressed.

Culture can be both measured and managed; and elements of the culture that influence behaviour can be quantitatively assessed and managed. The key is to break down culture into measurable core elements.

In Chapter 8, we will introduce the ethical culture framework as a model to effectively measure and manage the elements that influence the levels of integrity within an organisation’s culture. Based on 15 years’ experience in the ethics and compliance field, we have identified three core elements that determine the extent to which the organisation is sustaining or deterring an ethical culture. For an organisation to have an effective ethical culture, an organisation’s values, goals and standards of its employees must each be fully developed in their own right and must be in alignment, meaning that each element must complement and support
the others. If not, there are likely to be sources of frustration and pressure that can lead to unethical behaviour.

This report looks at how to determine the root causes of ethical behaviour. For compliance and risk managers that typically focus on people-based risks and what standard of behaviour is needed to mitigate that risk, this report will look at these typical policies and procedures in terms of the types of pressures and fears that generate the greatest risk for that type of standard.

This report explores the factors in the culture of an organisation that are encouraging or detracting from an ethical culture that supports compliance; and illustrates what a company can do to assess and then influence those factors.

Compliance is more complicated than ever
In the years since passage of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley) in the US, enacted as a result of the ethics scandals of 2001 and 2002, organisations’ approach to governance, risk management and compliance (referred to as GRC) has broadened considerably. Nearly US$30bn was spent in 20101 in an ever expanding field that defies easy definition.

There are multiple sets of standards that define and frame compliance efforts. Each company has its own approach. Some focus compliance efforts through the audit function. Others have their industry-specific compliance teams lead the efforts. In others still, compliance is linked more closely to values and people-based behaviour issues.

Typical compliance subject areas2 include quality management, environmental Health and Safety and industry specific requirements in:

- Chemical;
- Banking;
- Automotive;
- Pharmaceutical;
- Energy;
- Manufacturing;
- Defence contracting;
- Employment opportunity;
- Privacy;
- Security;
- Risk management; and
- Financial processing and reporting.

How have companies been managing their compliance efforts?
Leaders certainly do not want to be caught unprepared when it comes to anticipating and responding to the multiple types of risks that their organisation can face. Consequently, a significant percentage of the US$30bn spent on compliance goes towards developing better and more efficient systems and processes to monitor and prevent non-compliance in order to reduce the organisation’s risk profile. However, these efforts are still quite labour-intensive.

According to AMR Research,3 nearly US$20bn of the US$30bn spent on compliance efforts is spent on external services that encompass consulting, implementation and outsourced processes conducted onshore and/or offshore. As well as the corresponding internal efforts needed to make compliance management a reality within companies including day-to-day management and execution tasks across lines of business, IT, legal and audit roles.4

Managing all of those people resources can be challenging, if not an impossible task for compliance managers in mid to large size organisations. There are too many people, with too many interconnected issues to effectively manage them from a central compliance organisation.

While the press often focuses on the headline grabbing scandals, compliance
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management is a complex responsibility requiring measurement and reporting against a dynamic and seemingly endless array of rules, agreements, standards, regulations and legislation. Each area of compliance comes with its own requirements and in many cases requires extensive knowledge of esoteric technical subject matter; and a detailed database for the elements of compliance requirements, measurement and reporting. In many organisations, compliance management has developed and remained as a series of silos, each meeting its own needs but not coordinated across organisational levels. This tendency to ‘silo’ often results in duplication of planning effort, redundant reporting systems, misplaced priorities and can waste the scarcest resource in business: management attention.

The silo approach to compliance has often developed in organisations because of the lack of a central coordinated effort to integrate all of the compliance functions. With their limited time and budgets, most compliance managers are barely able to implement the minimum requirements of each compliance regimen. There is little time for focusing on a strategic approach. Besides, centralising compliance is not necessarily the answer. As will be discussed below, central control can often generate perceptions of lack of accountability and responsibility in the field, leading to a very reactive approach to compliance. Unwittingly, a robust centralised compliance function can dampen the willingness of managers in the field to take personal responsibility for their actions and for the compliance of employees they supervise.

So leaders are left with a decentralised compliance effort, with each functional area managing its specific compliance requirements. This can create a significant gap in the perception of the programme between the compliance leadership and the employees and managers in the field.

For the compliance leadership, their focus is being sure that employees are aware of the organisation’s responsibilities to comply with appropriate regulations. That is why many compliance training programmes often begin with background on the origins of the compliance laws or standards in question.

But that is not what is on the mind of the manager or employee. For them, compliance is knowing what specific actions or steps can or cannot be taken. They need to know how to navigate gray areas and stay compliant, while meeting aggressive business goals that require taking some risks. To an auditor a manager may be violating several provisions of Sarbanes-Oxley inspired regulations as well as the Foreign Corrupt Practices Act. For the manager, he is simply hiding a payment he made in order to get his job done.

Command and control only go so far

One of the difficult challenges compliance leadership must face is knowing when a compliance programme can be deemed fully implemented and effective. It would be nice to think that once senior management and the Board has signed off on the programme and the code of conduct, compliance rules and expectations have been communicated down to the field and an audit and enforcement infrastructure is working; that the job is done. Unfortunately deployment is when the job really begins.

Next time you are driving over the speed limit on the highway, ask yourself: ‘What would it take to get even an honest person like me to obey the law?’ You know what the rules are. There has been extensive effort put in place for awareness and
training, as well as enforcement. And yet you still speed: why?

You know the rules. And yet, even honest compliance managers engage in a sophisticated set of rationalisations as to why driving over the speed limit i.e. breaking the law, is acceptable.

‘Everyone else is speeding. I’m only travelling with the flow of traffic.’

‘I’m really in a hurry.’

‘I’m a very safe driver.’

And yet, in spite of all the sophisticated rationalisation you do, when you see a police officer you slow down. What happened to that sophistication now?

So is it only the fear of being caught that slows you down? None of us would want to have a police officer at every mile marker, even if the government could afford it. So how do we get citizens to willingly observe and obey the law? The situation inside companies is similar. It is one thing to set standards; it is another to get people to follow them. Many compliance officers oversee a multitude of policies and regulations that employees in various positions are expected to follow. Besides, leadership probably communicates the importance of following the standards. And yet in many companies, misconduct still occurs at an unacceptably high rate.

The simple fact of the matter is that mere awareness of a standard is not enough to compel compliant behaviour. In many instances, compliance professionals do not take human factors into enough consideration when programmes are implemented and standards enacted. Just because leadership determines that a policy is in the best interest of the organisation, this does not mean that adherence to that policy is followed, if even understood in the outer reaches of the organisation. And yet, little time is allocated to understanding why.

Compliance leadership does not look deeply enough into what drives individual behaviour. Usually individuals do not engage in unethical behaviour inside organisations for personal gain akin to fraud. People make decisions based on the impact of the intended action on themselves and the people around them that have the most influence. If the organisation, or senior leadership, has not succeeded in creating a personal connection with an individual employee, then that person will be influenced by the immediate circle around them – for better or for worse.

Most actions that violate company standards occur because employees feel that this behaviour is expected of them. Or, employees have rationalised that this activity is the only way to get their job done and meet the expectations of their managers. It is not that employees are dishonest. The vast majority of employees are not only honest, they want to work in a company that values trust and integrity.

The challenge faced by most compliance managers is that there is a strong bias towards solving problems with processes and systems; and not by looking at the people issues that generate the problem. Western managers are comfortable with processes and less comfortable with personal confrontation. The following story illustrates this point.

There is an organisation with a comprehensive no-smoking policy that prohibits smoking anywhere on company property, inside or out. A small group of employees gather outside the front door of the building and smoke during an afternoon break. A senior manager sees this group meeting day and after day. However, instead of going outside and reminding the employees of the policy and asking them to stop, she sends out a general e-mail to the
workforce reminding them of the no-smoking policy. While the manager could ‘cc’ her boss in on her e-mail to show that she took action, nothing else was accomplished. In fact, the manager’s actions made the situation worse. The smokers laughed at the e-mail and mocked the timidity of the manager. Now if she wants to enforce the rule, she will have to raise the issue to a more tense level of confrontation.

Having rules in place is one thing. Knowing how to enforce them is quite another.

Surveys have confirmed that compliance controls do not appear to meaningfully influence the frequency of observed misconduct. Research by the Compliance and Ethics Leadership Council of the Corporate Executive Board shows that compliance controls is an area of significant investment for many companies but appears to have limited influence on observed misconduct levels.5

Why does Pfizer keep getting into trouble?

In September 2009 American pharmaceutical giant Pfizer Inc. agreed to pay US$2.3bn, the largest health care fraud settlement in the history of the US Department of Justice (DOJ), to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products.6

While Pfizer’s subsidiary, Pharmacia & Upjohn Company Inc. pled guilty to off-label marketing charges, Pfizer’s civil settlement covered allegations of false claims and anti-kickback violations. Their new corporate integrity agreement (CIA), coming on the heels of a previous CIA in 2002, deals with a range of commercial activities: promotional material and practices, speaker programmes, consulting engagements, sponsorship of clinical research, market research, authorship of publications and other activities with compliance implications.

As noted by the Department of Justice in its press release:

“The size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer’s crimes,” said Mike Loucks, acting US Attorney for the District of Massachusetts. “Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today’s enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated.”

Pfizer is a global organisation, with over 110,000 employees and an extensive compliance infrastructure. And yet the DOJ considers Pfizer to be: “A repeating corporate cheat for illegal drug promotions that supplied doctors with free golf, massages, and resort junkets.”7

“ Authorities called Pfizer a repeat offender, noting it is the company’s fourth such settlement of government charges in the last decade. The allegations surround the marketing of 13 different drugs, including big sellers such as Viagra, Zoloft and Lipitor.

“As part of its illegal marketing, Pfizer invited doctors to consultant meetings at resort locations, paying their expenses and providing perks, prosecutors said. ‘They were entertained with golf, massages, and other activities,’ said Mike Loucks, the US attorney in Massachusetts. Loucks said that even as Pfizer was negotiating deals on past misconduct, they were continuing to violate the very same laws with other drugs.”

Pfizer’s troubles were not the result of not having a compliance programme in place. All of the major pharmaceutical companies as part of a heavily regulated industry have
extensive compliance infrastructures. There are compliance policies, procedures and personnel. And yet, violations keep happening.

The prosecutors, in reaching the 2009 settlement, saw that merely requiring an organisation to implement a compliance programme was not enough, since such a mandate did nothing to change Pfizer’s behaviour the first time Pfizer entered into a CIA in 2002. Therefore the DOJ insisted on significant new requirements for the 2009 CIA.

“The growing importance of individual accountability can be seen in the CIA’s certification requirements. Pfizer’s CIA goes farther than Cephalon’s (Sept 2008) and Eli Lilly’s (Jan 2009) CIAs by specifying the level of review: certifying individuals must examine promotional quality assessment reports, reports on speaker programmes, advisory boards, consultant payments, travel and entertainment expenses, sales compensation exclusion criteria, and corporate compliance group statistics. Also, each individual must state that they understand the certifications will be relied upon by the United States making the possibility of individual liability explicit. These requirements for certification illustrate the level of involvement (and accountability) the government expects from managers in order to ensure compliance.

“Sales and marketing must recognize that enforcement activity is becoming more personal and role-specific, moving beyond just the organisation to individual managers who must be accountable. For example, rewarding sales accomplishments which may be based, even in part, on off-label promotion creates risks for the company and everyone associated with the activity – including sales reps, management involved in leading sales and marketing efforts, and compliance officers who audit and monitor. The company’s compliance message must match its business practices – the risk from violations is increasing and could impose a huge toll on companies and individuals.”

However, even the newest regimes may not be going far enough. Recent CIAs, such as those entered into by Pfizer and by Bayer, have new government requirements whereby companies must show the ‘programme effectiveness’ of their remedial actions. This includes onerous monitoring requirements and sophisticated databases in which the government can track activity.

It is clear that the regulators have had enough. Recent statements from US regulators indicate that the next target will be the executives themselves. Food and Drug Administration (FDA) deputy chief for litigation Eric Blumberg recently said; “It’s clear we’re not getting the job done with large, monetary settlements. Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress in deterring off-label promotion.”

So the question remains, what is being done to change behaviour? In responding to the tough talk from FDA prosecutor Blumberg, a Pfizer spokesman said: “Over the past several years, we have invested substantial resources in order to create a compliance program that consists of mandatory training for every one of our employees, proactive monitoring and surveillance, and strict enforcement of all federal and state health-care laws.”

Is that going to be enough? What steps is the organisation taking to ensure that the offending personnel do not face the same situation again?

Gauging success of the compliance programme

Given the complexity of the compliance, how should an organisation define success for its ethics and compliance programme?
Success, of course, for any compliance programme would be indicated by fewer fines or reported incidents. But that goal will remain elusive if the organisation does not have a realistic plan to achieve these goals and has established success milestones along the way. Critical success factors in a compliance programme must include the intermediate causal steps that will lead to the ultimate goal of reduced incidents of misconduct. Otherwise, compliance leadership will not be able to determine the most effective course of action to prevent misconduct.

This is where many compliance programmes differ. What should be the proper success milestones along the way that indicate that the programme is moving towards its ultimate goal of fewer incidents? For example, should success be measured by the extent the organisation has complied with all of the regulatory requirements imposed on it? It would be a relief for compliance leadership to have this as the success criteria. The compliance organisation has a better chance at reaching success if its criteria are within its control, such as whether the provisions have been complied with. Yet isn’t the real success factor whether or not the members of the organisation no longer engage in misconduct? By analogy, if the goal is to reduce speeding on the highway, merely posting more speed limit signs or increasing police patrols may or may not be intermediate success factors. The only way to know, is to determine what compliance measures actually influence behaviours.

What are the behaviour and performance factors the organisation deems necessary in order to determine whether the programme is working? Leading organisations have identified the specific outcomes that demonstrate success in their programme, for example:

- Reduced misconduct observed by employees;
- Reduction of specific compliance violations;
- Increased reporting of misconduct;
- Greater satisfaction with organisational response to reports of misconduct; and
- Improved overall satisfaction.

How can an organisation achieve these success goals? Certainly a combination of training, communication and enacting effective controls will show positive results. But these steps are one-way, meaning that they can be enacted without receiving input from employees and managers as to how well they are accepted. As will be seen in the following chapters, the most effective tools are the ones that impact the organisation’s culture.

References
3. Hagerty & Kraus, ibid.
4. Ibid.