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The Role and Place of Compliance
Within Life Sciences:
The Imperative of Chief Ethics and
Compliance Officer Independence

Kathleen M. Boozung*

Timothy P. Glynn**

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The Role and Place of Compliance Within Life Sciences: The Imperative of Chief Ethics and Compliance Officer Independence

Part I: Introduction

The recognition of “compliance” as a distinct function within an organization is a relatively new phenomenon. Tracing back to the United States Sentencing Commission’s promulgation of the Organizational Sentencing Guidelines (“Sentencing Guidelines” or “OSG”) in 1991,¹ a spectrum of enforcement agencies have issued guidance offering powerful incentives for corporations to maintain compliance infrastructure to prevent, detect, report, and remedy legal violations.²

A second generation of compliance guidance has focused on proactive detection of compliance issues, particularly in the Medicare context, with attendant self-reporting to enforcement officials. Some observe, not necessarily approvingly, that the government has “out-sourced” its discovery and investigative functions to industry.³ Moreover, U.S. prosecution of foreign companies, as well as internationally collaborative prosecutions, have transformed compliance into an international phenomenon, giving rise to a burgeoning global compliance profession. The Appendix to this White Paper traces the extensive history of the various laws that urged the development of compliance in the U.S. and abroad.

Yet, for a host of reasons, uncertainty exists about the scope of the compliance function, best practices for ensuring effective compliance, and the risks attendant to deviations from regulator preferences regarding compliance.⁴ This White Paper addresses one aspect of this uncertainty: whether and how the position of compliance and the Chief Ethics and Compliance Officer (CECO) within the organizational structure affects actual compliance effectiveness as well as government perceptions of effectiveness.

An analysis of this question necessarily begins with an exploration of the respective duties of General Counsel (GC) and the CECO. This White Paper suggests that these duties are increasingly diverging, as the GC retains the primary responsibility to advocate for and defend the corporate client, while compliance increasingly bears responsibility to execute what traditionally has been perceived as enforcement agencies’ responsibilities—to detect and respond to legal wrongdoing. Today’s CECO’s primary duties of prevention, detection, and remediation are

expanding to include affirmative discovery of illegal behavior and, in some instances, at least in the United States, an expectation of self-reporting to an enforcement agency.

We begin by acknowledging that it may be easier to measure satisfaction of government expectations of how compliance should be structured and organized than actual compliance program effectiveness, but keeping enforcement agencies happy has its benefits. While guidance from enforcement agencies states that compliance should be configured in a way that best suits the particular firm, the same guidance often demands much—including compliance program and officer autonomy, access to high-ranking decision makers, and resources—that strongly suggests a very prominent place for CECOs in the organization.⁵

Nonetheless, two views of the relationship between legal and compliance currently compete. One, exemplified by the preference the Office of Inspector General for the United States Department of Health and Human Services (“HHS OIG” or “OIG”) advances in both its guidance⁶ and settlements with companies,⁷ seeks separation of the two functions. This perspective imagines a healthy tension between counsel and compliance—an opportunity for a different perspective by an autonomous, highly-respected senior executive who acts with the insulated independence to “push back” when appropriate.⁸ In fact, many would advocate that no resolution to a compliance matter should be adopted without the CECO’s sign off. The competing perspective, often offered by legal scholars and practitioners, usually acknowledges the need for CECO independence but does not compel separation of compliance from legal or that the CECO report directly to the CEO or board. This view emphasizes collaboration between compliance and legal in pursuit of the interests of the organization,⁹ in part to ensure that they speak with a single voice to the CEO and board.¹⁰ Notably, surveys reveal that most industry sectors are mixed in their approach to these issues, with both deep divisions on the appointment of a stand-alone CECO¹¹ and to whom the CECO reports—the CEO, GC, board, or others.¹²

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These structural issues are complicated by the myriad factors that legitimately inform how companies determine what works best for them. Indeed, a single view of how compliance should be structured remains elusive in part because it depends on the regulatory environment of the particular industry, company size and resources, the skill set of the person designated as CECO at any point in time, and the unique history of compliance in a particular company.

This White Paper focuses on the life sciences industry,¹³ but recognizes the breadth of what the term “life sciences” potentially encompasses—that is, that there are differences among pharmaceutical, medical device, and biotech companies, as well as between start-ups and publicly-traded entities, between global and domestic firms, and between companies that have operated under Corporate Integrity Agreements (CIAs) and those that have not. There also are distinctions between health care compliance and other compliance obligations, such as financial, human resources, and privacy law compliance. Thus, while this White Paper is principally focused on the health care compliance function in life sciences companies, we envision significant opportunity for growth in the CECO’s portfolio, which may expand beyond the traditional health care compliance role.

Ultimately, this White Paper concludes that, absent a government settlement to the contrary, the key to ensuring the effectiveness of compliance is not structure but the *independence* of the CECO. The requirement of separation demanded in settlements occurs when the behavior that provoked enforcement intervention evidenced the absence of independence, thereby requiring a structural recalibration. While separation of compliance from legal or finance, or formal

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placement of the CECO in a specific location in the corporate hierarchy, is neither necessary nor sufficient to achieve compliance independence, it does increase the probability of independence. Nevertheless, the most important factor in achieving a pervasive ethical business culture is a board and CEO who value an independent CECO possessing real and perceived *autonomy* and *authority* to identify and meet ethical and compliance objectives.

In light of this, the **Ten Basic Ingredients of Compliance Independence** in any life sciences company include the following:

- 1) high visibility within the organization;
- 2) access to all information necessary to identify compliance risks and fulfill compliance responsibilities, in both real time and post hoc;
- 3) direct access to decision makers on matters affecting both institutional integrity and compliance;

- 4) the ability to partner with the board and senior management to effectuate necessary organizational change to ensure ethical behavior and prevent, detect, and remedy wrongdoing;
- 5) the authority to approve proposed resolution of compliance matters;
- 6) adequate resources in light of the company's compliance risk profile to maintain autonomy;
- 7) competence;
- 8) access to *independent* legal counsel when necessary;
- 9) an approach to CECO compensation that does not impede independence; and
- 10) resources and empowerment to anticipate and proactively address future ethical challenges.

These ten ingredients may not exist even if the CECO and the ethics and compliance department sit high in the organizational chart, but the absence of at least some factors is more likely if the CECO resides lower in the hierarchy or his or her path to top decision makers is obscure.

The remainder of this White Paper is organized as follows: Part II describes the maturation of the compliance profession with increasingly specialized skills as well as the recognition that compliance is inextricably entangled with both ethics and organizational culture.

Part III discusses the placement of compliance within the organizational structure, the status of the CECO within senior management, and the reporting lines of the CECO within the organization. What emerges, again, are competing visions of the respective roles of compliance and legal, as well as differences in terms of reporting structure and the placement of compliance.

Part IV defines what has emerged as the essence of the compliance function. It concludes that the core of the compliance function, at least in the life sciences context, is (1) assisting the CEO and board in stewarding an ethical business culture; (2) participating in strategic conversations and vetting new ventures to ensure their pursuit adheres to the company's values and the law; (3) developing (and improving) structures, policies, and procedures that deter, detect, and remedy violations of ethical, legal, and policy standards; and (4) aiding the company in avoiding behaviors that have the potential to impact negatively the company's reputation. It then distinguishes compliance and the CECO from the GC function which, like compliance, has been

evolving and expanding. This Part further concludes that empowering the CECO to engage in independent, ethical stewardship of the organization is the best way to facilitate a flexible and productive partnership among the CEO, GC, and CECO.

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Part V elaborates on the Ten Basic Ingredients of Compliance Independence. It also suggests concerns about ensuring a pipeline of talent for the compliance

profession and the need for educational opportunities for those who aspire to executive-level responsibility in compliance. It calls upon the industry to reward compliance professionals through advancement opportunities and compensation in a manner that both preserves independence and retains talent.

Finally, Part VI observes three phenomena that are further transforming compliance: maturation to an organization-wide values-based ethos, embedding of increasing swaths of compliance responsibilities into business practices at the operational level, and leveraging of data analytics and artificial intelligence (AI) to assist in monitoring and predicting potential new risks. This evolution may result in increased divergence of the skill sets and activities of compliance and legal professionals and new opportunities for CECOs to expand their focus beyond compliance narrowly defined to both persistent and emerging ethical issues that confront life sciences companies.

Part II: Maturation of the Compliance Function

The “compliance professional” or “ethics and compliance professional” barely existed a quarter century ago. The last decade has seen a maturation of compliance programs as well as growth in sophistication and stature of the compliance profession.¹⁴ Today, despite the fact that there is no single educational or licensure route to compliance—unlike, for example, law, medicine, or accounting—a set of professionals with a discrete set of skills, responsibilities, best practices, and norms has emerged.

The profession that is emerging, while populated by many with legal training, is increasingly distinct from the legal profession. Although there is overlap between compliance and other functions within an organization, and compliance responsibilities are increasingly embedded

in the business units, there is now widespread recognition that the role and duties of compliance officers are distinguishable from those of other professionals.¹⁵ In other words, both the menu of duties and responsibilities within the purview of compliance¹⁶ and the hard and soft skills to be effective are unique. Already, the compliance professional's leveraging of data analytics and deployment of AI, as well as the use of metrics and measurements to determine compliance effectiveness, distinguish the basic compliance skill from traditional legal skills.

Compliance plays a significant role in preserving an entity's *reputation* for integrity. The law inevitably lags behind business practices, and industry frequently complains about the lack of warning by enforcement agencies of their intent to prosecute new business behaviors. Compliance programs grounded in legal and *ethical* principles can prevent their organizations from becoming ensnared by new legal prohibitions reactive to industry practices reflecting ethical deficiencies that lead ultimately to regulation. In addition, law and ethics never completely align, thereby making it imperative that the compliance portfolio broadly include both disciplines. Thus, we observe the increasing use of "ethics" in the titles of compliance officers, which prompted the use of CECO in this White Paper.¹⁷

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Ultimately, then, success of the compliance enterprise depends on nurturing a business culture that centers on and conforms to a set of values, ethical principles, or norms. This recognition explains the shift of the maturing compliance program from a rules-oriented approach—in company codes of conduct and elsewhere—to one that is values or principles oriented (backed by appropriate rules). Such a values-based approach has consistently been shown to be positively associated with employee awareness of ethical implications of their decisions, a willingness to seek ethical advice and report misconduct, and lower levels of observed misconduct.¹⁸ Another key component is assuring that the tone at the top reflects these values. To be genuinely effective, leaders must not only act and communicate consistently with norms, but they must also ensure that middle-level management does as well, since rank-and-file employees view leadership tone through the lens of those who directly supervise them. Moreover, managing culture requires integration into operations: the key principles or norms should factor into planning

and decision-making at all stages and be embedded in all practices, woven into all training, reflected in performance evaluations, and championed by leaders outside of compliance.¹⁹

Part III: The Placement of Compliance and the CECO in a Life Sciences Company:

The State of the Debate

Corporate America remains deeply split on where compliance belongs within the corporate structure. Across industries, the number of companies with stand-alone CECOs and compliance departments appears to be growing, but still does not constitute a majority.²⁰ And there is no prevailing approach with regard to whom the CECO reports. Recent survey results are mixed, but several indicate that, while reporting to the GC may be the plurality approach, many CECOs also report to the CEO, the board, and, to a lesser extent, others.²¹

Approaches to structure in life sciences companies are also divided. In a 2014 survey, 62% of pharmaceutical industry respondents reported having a stand-alone Chief Compliance Officer (CCO) or CECO, and just over half indicated that compliance reports directly to the CEO.²²

Turning to enforcement agency guidance, the OIG has articulated its expectation in the health care provider context that a “[health care] organization’s Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner.”²³ In contrast, with regard to life sciences companies, neither the OIG nor other federal enforcement agencies have taken the position in their *ex ante* guidance that compliance always must be separate from legal. For example, in its 2003 guidance, the OIG indicated that, while every pharmaceutical manufacturer should designate a compliance officer, that responsibility may be the individual’s sole duty or added other to responsibilities, depending on the size and resources of the company. Similarly, the OIG has not mandated any CECO reporting structure.²⁴

However, in its guidance and even more so in its enforcement actions in the life sciences context, the OIG has pressed in directions that strongly indicate a preference for separation of compliance from legal, as well as direct reporting lines to the CEO and board. In the 2003 guidance, after stating that optimal placement of the compliance officer will vary according to the particular situation of the manufacturer, the agency states in a footnote:

The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer’s general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure

independent and objective legal reviews and financial analysis of the company's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.²⁵

The OIG emphasizes that the compliance officer have appropriate authority and high-level status with direct access to the company's president, CEO, board of directors, and all other senior managers.²⁶ The 2017 Resource Guide from the Health Care Compliance Association (HCCA) and OIG on measuring compliance effectiveness pushes in this direction by asking whether the CECO reports directly to the CEO or the board, and not the CFO or legal.²⁷ And, notably, the CIAs that the OIG has entered into with life sciences companies consistently both provide for separation of legal and compliance, and direct that compliance report to the CEO and board.²⁸ This perspective imagines a dynamic of healthy tension between counsel and compliance—an opportunity for a different perspective by an autonomous, high-ranking firm actor who has sufficient autonomy and authority to “push back” when appropriate.

The Department of Justice (DOJ) also focuses on whether an entity's compliance program is effective and has emphasized the need for compliance to have stature within the company and access to high-ranking decision makers.²⁹ However, the DOJ has not included compliance placement and reporting requirements in recent Deferred Prosecution Agreements (DPAs) and Non-Prosecution Agreements (NPAs) with life sciences companies.³⁰ In other words, unlike the OIG, the DOJ has not offered a specific vision of the organizational chart.³¹

For reasons similar to those articulated by enforcement authorities—e.g., authority, autonomy, access, stature, an independent check on management—compliance professionals have advocated for a direct reporting line from the CECO to the CEO or the board. They also contend that compliance should be separate from legal, given the perceived tendency of GCs to focus narrowly on legal aspects, while compliance's self-perception is that it serves as the “moral conscience” of the organization and promotes broader ethical norms.³² Moreover, experienced compliance professionals frequently state that separation of compliance and legal is necessary because the two functions require very different skill sets—compliance officers need to be experts in processes development and fact gathering, while those in the legal department are focused more on counseling and advocacy.

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Some argue for separating the functions of legal and compliance not only because their duties are different, but also because they can sometimes be in tension. This tension arises from the fact that legal's central obligation is advocating for and defending the company, while compliance is expected to prevent, root out, and mitigate situations where behavior deviates from the law.³³ For this reason, legal may be more inclined to interpret the law to the benefit of its client, while compliance is more likely to adopt what it believes will be the perspective of enforcement agencies.³⁴

Indeed, the law is increasingly placing affirmative compliance obligations on companies that may seem to conflict with the historic “defend and advocate” perspective of counsel. For example, the combination of so-called “reverse False Claims” and the 60-Day Rule³⁵ impose affirmative obligations on companies to identify and report to the government potential overpayments. These laws essentially “out-source” to companies the discovery and investigatory functions normally undertaken by enforcement agencies. Compliance may be better suited to carry out these responsibilities, given that the legal department is primarily concerned with defending the entity's behavior and avoiding liability.

This growing distinction between the nature of responsibilities of the GC and the CECO can make it difficult for both functions to be reporting to the same person. While it may be easier for a board to receive a unified message from legal and compliance, the board may be best served by understanding the duties of remediation and/or self-reporting of uncovered wrongdoing from compliance, and then working with legal to frame the company's defense.

The obvious response to this perspective is that it applies only in the hopefully rare instances of serious wrongdoing that must be reported to the government. However, the government approaches the compliance function as viewing corporate behavior from an enforcement perspective, which necessarily requires the CECO to view the world through a different lens than the GC, whose duty it is to advise and defend. It is precisely this tension of perspectives—a system of checks and balances—which the OIG has encouraged since its first compliance guidances.

It must be acknowledged that the government's views have not evolved from its "conversations" with industry, and there has been little litigation of its positions since few companies risk the consequences of unsuccessfully trying, for example, a False Claims Act or Anti-Kickback case. As a result, some dissent from the government's concept of the role of compliance, as well as its expectations that compliance create cases for government enforcement by discovering, investigating, and reporting illegal activity.³⁶

Some legal scholars and practitioners further push back against the notion that compliance should be treated as inherently distinct from legal.³⁷ This view emphasizes collaboration between compliance and legal in pursuit of the interests of the organization,³⁸ and seeks to ensure that legal and compliance speak with a single voice to the CEO and board.³⁹ Some also contend that departmentalization of compliance and legal can lead to working in silos, which puts at risk the collaboration needed to access and address ethical and legal compliance risks.⁴⁰ Similarly, some raise concerns that separating the compliance function might lead CECOs (or others) to make legal determinations or to assess legal risks without input and oversight by the GC.⁴¹ Still others worry that lawyers working as compliance officers not accountable to corporate counsel might fall short in various respects or confuse their roles.⁴² Further, many lawyers who object to the separation of legal and compliance believe that enforcement agencies prefer this separation as a means to undermine the attorney-client privilege and work product doctrine.⁴³

Finally, some scholars resist the notion that the CECO, as opposed to the GC, should be primarily responsible for the company's ethical tone. They hew to the view that, given their historical role, status within the company, and unique skill set, GCs ultimately ensure the organization acts with integrity.⁴⁴ Those taking this view reject the notion that there is any inherent conflict between counsel's duty to the corporation and providing ethical leadership.⁴⁵

Thus, both opinions and company practices remain deeply divided on the placement of compliance and the CECO in the organization, in both life sciences and elsewhere. This persistence is due not only to differing views on these questions and great variation in companies and circumstances, but also to the lack of a definitive empirical resolution, despite the fact that our understanding of how to make compliance effective has advanced significantly over the last quarter century. We now turn to addressing these matters in light of the information currently available.

Part IV: The Essence of the Compliance Function Today: Ethical Stewardship and Effective Compliance Infrastructure

To confront the issues of structure this White Paper addresses, it is necessary to distill the essence of the compliance function, and then describe the overlap with and distinctions between compliance and other functions, most importantly legal. The core of the compliance function, at least in the life sciences context, is (1) assisting the CEO and board in stewarding an ethical business culture;⁴⁶ (2) participating in strategic conversations and vetting new ventures to ensure they adhere to the company's values and the law; (3) developing (and improving) structures, policies, and procedures that deter, detect, and remedy violations of ethical, legal, and policy standards; and (4) aiding the company in avoiding behavior with the potential to impact negatively the company's reputation. The CECO—whether stand alone or in a combined role—is the officer directly responsible for overseeing how compliance is achieved, and what should happen in events of failure.⁴⁷

The OIG offers a similar definition:

The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards. This responsibility includes the obligation to develop policies and procedures that provide employees guidance, the creation of incentives to promote employee compliance, the development of plans to improve or sustain compliance, the development of metrics to measure execution (particularly by management) of the program and implementation of corrective actions, and the development of reports and dashboards that help management and the Board evaluate the effectiveness of the program.⁴⁸

Elevation of ethical stewardship to the most important aspect of the compliance function should no longer be controversial, given the consensus discussed in the prior section that fostering an ethical business culture is indispensable in ensuring effective compliance over time. The fact that some companies separate “ethics” and “compliance,” and some scholars argue that other actors—most notably GCs—ought to possess the chief ethics designation, does not alter this conclusion. Irrespective of structure and reporting issues, cultivating ethics or values remains central to the compliance function.

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Of course, achieving compliance is not exclusive territory for one officer or office. The greatest overlap is with legal. To illustrate, consider the common tasks performed by compliance and overseen by the CECO: conducting compliance risk assessments, drafting policies and procedures, monitoring, auditing, training, maintaining internal reporting mechanisms, conducting investigations, engaging in data collection and analysis, developing of metrics, performing third-party and acquisition due diligence, remediating following misconduct, and reporting to the CEO and board. Legal would be—indeed, should be—involved in some way in many aspects of these activities, including, most obviously, working collaboratively on risk assessment, reviewing and even drafting policies, and offering legal advice on training, due diligence, and remediation. In addition, under certain circumstances, legal would oversee directly some of these matters, including substantial internal investigations.

Other functions, including finance, internal audit, human resources, and quality control naturally would perform parallel or overlapping “compliance” and “compliance-like” tasks.⁴⁹ Indeed, such tasks are so dispersed among functional areas that it is worth clarifying again that, while we use the term “compliance,” our principal focus is core health care compliance in life sciences companies, rather than the entire sweep of activities that might have a compliance component.

Furthermore, someone formally identified as being in the compliance department need not perform all aspects of compliance. On the contrary, there is widespread agreement that compliance is most effective if core aspects—e.g., training, championing, messaging, enforcing, and rewarding—are embedded or integrated in the business.⁵⁰ The role of compliance is to oversee, assist, monitor, and otherwise manage these efforts, but who actually performs various tasks will depend on circumstance and effectiveness.

Nevertheless, the compliance function, as defined here and elsewhere, is distinguishable at its core from these other functions. Again, the OIG Guidance for Healthcare Governing Boards seeks to define, at least as an illustrative matter, the functional boundaries between compliance, legal, internal audit, human resources, and quality improvement.⁵¹

This guidance offers a useful starting point for distinguishing compliance from legal:

The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the Board about relevant laws and regulations that govern, relate to, or impact the

organization. The function also defends the organization in legal proceedings and initiates legal proceedings against other parties if such action is warranted.⁵²

This description, when compared to the one for compliance, draws out the basic differences

The legal function provides legal advice and, when necessary, defends the company, while compliance is concerned with developing and improving the infrastructure needed to prevent, detect, correct, and remediate behaviors that violate company and legal norms.

discussed previously: the legal function provides legal advice and, when necessary, defends the company, while compliance is concerned with developing and improving the infrastructure needed to prevent, detect, correct, and remediate behaviors that violate company and legal norms. The latter may be largely divorced from the legal function.

However, this description reflects the bare bones of what often comprises the GC's portfolio in today's corporate setting. The role of the GC has both expanded and been transformed in the last quarter century—a metamorphosis not captured by the limited focus on legal advice and advocacy. Part of this is attributable to the Sarbanes-Oxley Act (SOX) and its progeny, which emphasize counsel's gatekeeping role in the securities context through up-the-ladder reporting and other obligations.⁵³ Yet, even more dramatically, today's GC is one of the key business leaders in the company, working in partnership with the entity's highest-ranking executives and directors to achieve the corporate strategic vision.⁵⁴

The multiplicity of roles filled by today's GC includes, first and most obviously, serving as counsel to the corporation, and advising the board of directors, CEO, and other senior executives on legal matters. This means the GC serves as the entity's chief deal maker, represents the entity before the judiciary and regulators, and oversees internal or external lawyers managing antitrust, tax, litigation, contracts, mergers and acquisitions,⁵⁵ human resources, regulatory affairs, government affairs, and intellectual property matters. Post-SOX, the GC in a publicly-traded company is generally perceived as the individual responsible for ensuring compliance with securities and financial regulation.

Yet, according to a recent study, GCs are among the most highly-compensated executives in over 40% of publicly-traded corporations, they now frequently rank among the handful of top officers in the corporate structure, and they commonly serve as corporate secretary (thereby

making them both officers and inside directors). This expansive role takes the senior in-house lawyer beyond that of legal advisor with certain compliance responsibilities to the level of partner in business development and risk management.⁵⁶ In some industries—health care and life sciences as prime examples—the lawyers are significant advisers to the CEO on the legal and public policy changes informing business strategy.⁵⁷

This all leads back to the CECO's function and the relationship to the GC. Consistent with what many commentators and regulators have argued, independence is the touchstone to serving as the lead internal ethics and compliance monitor for any corporate entity. The heightened and multifaceted role of the modern GC—as business advisor to the CEO, as one socialized to be a key player in the C-suite, and as key contributor to new strategic policies and initiatives—raises concerns about the GC's ability to achieve the degree of independence sought by enforcement agencies and the public to fulfill the compliance function.⁵⁸

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The question inevitably arises whether expansion of the GC role to that of business partner undermines the lawyer's role as ethical and compliance gatekeeper. The limited empirical findings on this issue are mixed. On the one hand, situating the GC position in an executive capacity contributes significantly to financial compliance, as measured by a reduction in insider trading, securities fraud, and general breaches.⁵⁹ On the other hand, lawyers can be diverted from their monitoring activities by time spent on business development.⁶⁰ In addition, one study found that in-house lawyers' impact on reducing corporate fraud is reduced by about 25% when the lawyer has high equity incentives.⁶¹

This conversation undoubtedly would benefit from additional empirical research. Nevertheless, at minimum, it raises questions about the ability of a GC to be both a key business partner and the principal guardian of integrity in the organization. That is, it calls into question whether the GC is always able to provide a truly independent ethical check in C-Suite and board strategic decision-making—something a truly independent CECO could provide. It also implicates directly the structural issues addressed in this White Paper in that the GC's status and centrality to

charting the entity's business strategy raise questions about the ability of a CECO who reports to the GC to disagree with or critique strategic directions, business plans, or policies that are wholly or partially developed by the GC.

These concerns are in addition to others that might at least create tensions between the legal and independent ethical gatekeeper roles. One such tension arises if the CECO believes that an enforcement agency might challenge a strategy or venture of which the GC was an architect. Another emerges when the GC may, for defense purposes, take positions that are inconsistent with corporate values or ethical norms. As previously mentioned, these points of conflict may be sharpened when decisions regarding self-reporting have to be made. To be clear, we are not contending that there is an inherent conflict between zealous advocacy and ethical leadership, nor do we share the perception of some compliance officers that in-house counsel is rarely interested in thinking beyond what is legal. We do see, however, the challenges GCs may face in overcoming some of these tensions in practice, as well as prioritizing broader values or ethical concerns when faced with pressing legal and business risks. This too augurs towards a separation of roles.

Yet, as foreshadowed in Part III, there is another perspective. Legal scholars and practitioners contend that the GC maintains superior stature and visibility in the company, and that because the GC is always a lawyer and the CECO is only sometimes a lawyer, GCs are better equipped and positioned to ensure the company is governed by both the right ethical tone and legal expertise.⁶²

As a descriptive matter, this disparity between the stature of GCs and CECOs is evolving. GCs often still have more clout, depending upon the company and context, and CECOs, while corporate officers, rarely have ascended (in fact or perception) to a level equivalent to GCs. Yet circumstances on the ground are rapidly and necessarily changing. The CECO position has only existed in many companies for one or two decades. Despite the relative newness of the position, it is increasingly the case that the CECO has greater internal visibility because the CECO who is performing her job consistent with best practices is ubiquitous—known to every internal constituency and likely more familiar to more employees than the GC. In addition, the CECO may not yet, but ultimately must have the stature and authority for direct access to the board, or at the very least the board's compliance committee, as well as the power to pursue any matter she deems a potential compliance issue and to assent or reject the resolution of a compliance matter. If compliance lacks the political sway, access, and authority necessary to press C-Suite and board

decision makers to ensure organizational integrity in any particular instance, regulators may conclude that the corporate structure is inherently flawed.

In conclusion, the essence of the compliance and CECO function is a combination of ethical stewardship, business acumen, and the ability to deploy policies and procedures to deter, detect, and remedy violations. This function necessarily overlaps with the functions of others within the enterprise, most notably legal, but in both its mission and sweep, compliance's role and posture are unique. With adequate independence and stature, CECOs can bring a perspective on ethics and compliance that other key business leaders may not possess.

Part V: The Ten Basic Ingredients of Compliance Independence

The role, status, and place of compliance and the CECO in the corporate structure have evolved significantly over the last fifteen years. Still, this role varies today depending upon industry sector, size of company,⁶³ product line, reimbursement mix, business model, degree of regulation to which the industry is subject, whether the company is global and/or domestic, and enforcement history/obligations.⁶⁴

Irrespective of the many differences among companies' approaches to accomplishing an ethical and compliant business model, the goal of all compliance initiatives should be both that they are effective and that enforcement agencies believe they are structured to fulfill their mission. Most essential to achieving these goals is independence, which is assured by practices and structures that provide the CECO with true autonomy and authority.⁶⁵ Independence does not mean isolation; on the contrary, to be effective, CECOs must engage constantly and successfully with senior business leaders.

The following discussion explains what we view as the **Ten Basic Ingredients of Compliance Independence**:

1) High visibility within the organization

CECO independence requires visibility. Success in the compliance role requires the leader to be known and visible throughout the organization, as well as to be approachable. The effective CECO must be ubiquitous.

Moreover, setting the tone from the top demands an organizational prominence for the ethics and compliance function that conveys to all the importance of doing business with integrity.

The CECO therefore should be seen as a senior leader whose role and relationship with the senior management team and board signals both her autonomy and stature.

We acknowledge that there is a tension here, requiring a somewhat delicate balance. An institutional commitment to integrity is conveyed by treating the CECO as a key colleague to the senior management team while, at the same time, the CECO—as distinct from other high-ranking officers (including the GC, as described above)—must retain the distance and perspective not to become normed to the point of losing her objectivity.⁶⁶

As discussed in Part IV, this challenge reflects continuing discomfort with and uncertainty about the CECO's role. Because it has no direct precedent, compliance as now understood constitutes a disruptive innovation to both governance and management. No analog or label has yet fully captured the essence of the truly independent CECO: trusted advisor, objective insider, corporate conscience, and steward of integrity all convey overlapping yet distinct conceptualizations, and commentators and compliance professionals will prefer one analogy over another to convey the CECO's role. Nevertheless, as a core manifestation of the company's commitment to the value of doing business with integrity, the CECO must possess—and be *perceived* as possessing—a combination of responsibilities and skills common to senior leadership positions, but be different enough in orientation to be viewed as a genuinely objective check on culture and behavior.

Compliance as now understood constitutes a disruptive innovation to both governance and management.

2) Access to all information necessary to identify compliance challenges and fulfill compliance responsibilities, in real time and post hoc

The CECO must have sufficient knowledge of corporate operations and the strategic vision to help chart ethical pathways, perform risk assessment that enables the most strategic and effective investment of compliance resources, spot compliance issues in a broad spectrum of contexts (even if not able personally to resolve every issue that arises), and make pragmatic recommendations for compliance and business solutions. The CECO cannot affect the direction of business aspects of which she is unaware.

Thus, the CECO and compliance generally need access to all information—in real time and post hoc—necessary to fulfill these functions. Such access has both vertical and horizontal dimensions. The CECO must have access to the information high-ranking managers possess and utilize in making strategic decisions that have ethical and compliance dimensions; otherwise, the direct access to decision makers discussed below will be far less meaningful. To perform their monitoring, auditing, and stewardship functions, the CECO and others in compliance also must have access to information from all parts of the business operations. This access must be genuine and direct. It cannot be impeded, for example, by the need for compliance to get permission from other senior managers to perform compliance functions or by compliance’s limited access to certain data systems, practices, or personnel.

For CECOs in companies with mature compliance programs, the challenge often is not that of accessing needed data, but rather of managing the massive amount of information to which they have access.

For some CECOs, such access to information presents no challenge. Rather, for CECOs in companies with mature compliance programs, the challenge often is not that of accessing needed data, but rather of managing the massive amount of information to which they have access. Indeed, the amount of data—both internally and publicly accessible—potentially available to inform and improve strategic decision making and compliance monitoring continues to grow, often exceeding the capacity of compliance and other departments. CECOs therefore not only need access but also, as discussed further below, the resources to aid them in setting priorities for data analysis. These include compliance professionals with the experience to know the right questions to ask, as well as data analytics experts embedded in the compliance function with sufficient training to understand the relevance of the data, and software that enables them to conduct effective and appropriate analyses.

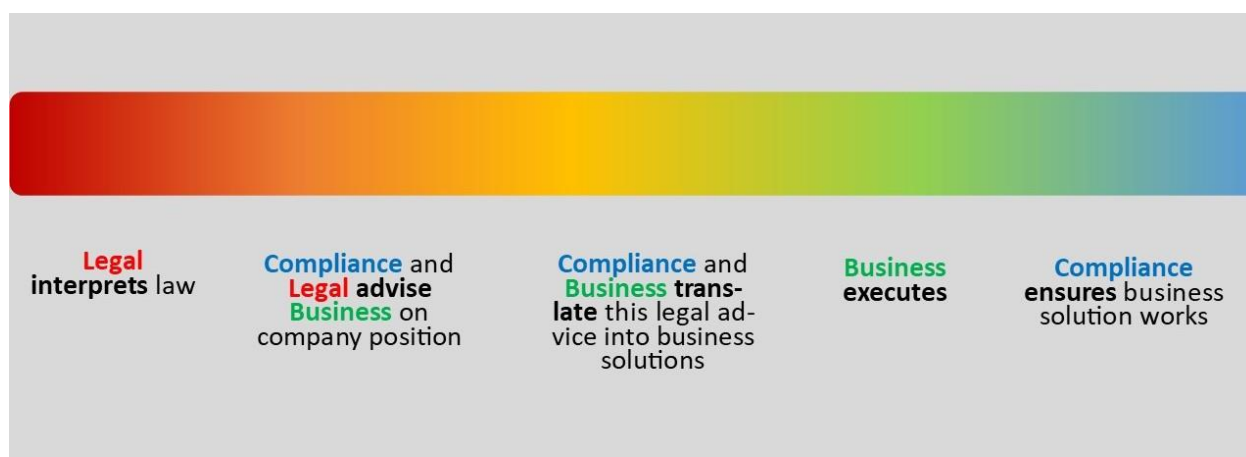
Going forward, marshaling such information presents dramatic opportunities to prevent rather than respond to unethical behavior, thereby increasing business accountability in real time. To achieve this, compliance requires both continued and unimpeded access to information and the on-going infusion of resources to analyze and operationalize the conclusions that emerge from this data analysis and resultant strategic insights.

3) *Direct access to decision makers on matters affecting both institutional integrity and compliance*

To build and maintain corporate integrity and protect the entity's public image, leaders in every aspect of the organization need to embrace their responsibility to be engaged with the CECO. The CECO needs direct access to decision makers on all matters that potentially affect corporate integrity, compliance, and reputation. The CECO cannot serve the business as an issue spotter, an influencer, or a persuader without this unimpeded ability to interact directly with key decision makers.

Business leaders, as opposed to the CECO, are the decision makers about how the business goes forward, and must be held accountable internally for the choices they make—whether they are ethical, adhere to the company's values, and are legally compliant. However, if significant legal, ethical, or reputational issues arise, enforcement agencies, shareholders, and the public likely will be asking the following: Where was the CECO? How did this happen in a company with a compliance program? As such, the CECO needs access to these decision makers to facilitate the identification of the greatest risks to the business and collaborate strategically with them to build solutions to avoid or mitigate these risks.

The following graphic offers an overview of the dynamic among legal, compliance, and business decision makers:



Naturally, the entity's lawyers interpret the law, and, to the extent uncertainty exists, work with others, including the CECO, to determine the entity's risk tolerance. Compliance and legal collaboratively advise the business leaders on the company's legal position, and on the legal parameters within which the business must operate. Compliance partners strategically with business leaders to develop the policies that ensure legal compliance, as well as business solutions that will ensure ethical marketplace behavior. Ultimately, however, it is the business leaders who, from the available options, elect the path down which the entity will proceed, and who work with compliance (sometimes with the sign off from legal as well) to devise approaches that avoid or mitigate potential risks. Necessarily, the handoff from compliance to business is not complete until it is determined that the business approach taken is practicable on the ground.

4) The ability to partner with the board and senior management to effectuate necessary organizational change to ensure ethical behavior and prevent, detect, and remedy wrongdoing

Building on the prior discussion, the CECO must have the ability to partner with the board and senior management to effectuate the organizational change necessary to ensure integrity and prevent and correct wrongdoing. The ubiquitous and autonomous CECO should be of sufficient stature, skill, and experience to engage the senior management team and board; know the business sufficiently well to partner with business units in achieving their goals in an ethical and compliant manner; be a trusted confidante of and advisor to those who raise ethical or compliance concerns; and instill confidence in enforcement agencies that she is sufficiently empowered to steward an ethical business culture and oversee an effective compliance program.

Put another way, a truly independent CECO is an "empowered" compliance leader who is a respected strategic partner in maintaining or achieving an ethical business environment. The CECO therefore must possess the charisma and leadership qualities to encourage change where necessary, and to escalate information and concerns about potential or discovered unethical or illegal behavior to the CEO, GC, and board. In interactions with an enforcement agency, the CECO's stature and competence should inspire confidence in the company's commitment to an ethical culture and an effective compliance program.

The CECO's portfolio must be broad enough so that she can spot risk in any aspect of the company's operations. Whether the issues relate to privacy, quality, financial integrity, vendor

risks, clinical trials, or cybersecurity, the CECO must possess the authority to spotlight the risks and ensure that the appropriate business leaders, or those best able to affect a resolution, assume responsibility for those risks. If the business unit does not embrace its responsibility, or fashions responses inconsistent with the law or the company's values or ethical norms, the CECO must possess the autonomy and authority to negotiate an appropriate resolution or escalate the matter to senior management or the board. If the problem requires the creation of better processes, retraining, or improved structures, compliance should be positioned to devise a solution for execution by the appropriate unit.

Establishing systems to comply with new transparency regulations for life sciences companies is an obvious example of a situation where compliance might itself set up, or contract with a vendor to establish, the policies and processes to accomplish data collection and reporting, which tasks are then assigned to the appropriate business unit for long-term execution. Privacy might represent a similar example. In other instances, such as quality or financial integrity, the

The key point is that the CECO must be empowered to raise integrity issues about any aspect of the business, even if devising the solution is beyond the compliance function's in-house expertise.

expertise required to analyze the risks or potential instances of non-compliance may fall beyond the expertise of the CECO. In those cases, the CECO's responsibility is to ensure that the matter is addressed and appropriately resolved by experts. The key point is that the CECO must be empowered to raise integrity issues about any aspect of the business, even if devising the solution is beyond the compliance function's in-

house expertise. Depending upon the situation, compliance may remain involved to assent to any final resolution.

5) *The authority to approve proposed resolution of compliance matters*

Companies' resolution of the most serious compliance matters they uncover, and whether they report them to an enforcement agency, will involve at the very least outside counsel as well as the CEO, GC, and board, unless, of course, one or more of these actors is implicated in the underlying legal matter. The CECO should be an active participant in addressing such matters from discovery through resolution, and should have the authority to object to any courses of action under consideration. The first reason for this scope of power is pragmatic—any enforcement agency that discovers or receives a report of a legal violation will ask whether compliance caught the problem,

The CECO's authority must be commensurate with the CECO's duties.

and how compliance handled it. A compliance officer or program that had no inkling of a problem, failed to implement sufficient preventive measures, lacked the power to address the problem as it deemed appropriate

(including hiring counsel), or whose resolution was overruled, will likely be deemed ineffective. In short, the CECO's authority must be commensurate with the CECO's duties, including making sure systems are in place to deter, detect, and remedy legal and ethical violations.

6) Adequate resources in light of the company's compliance risk profile to maintain autonomy

As suggested in the discussion of the other ingredients, genuine independence requires adequate resources. What constitutes "adequate" will vary by company and depends on factors such as size and risk profile. Although few CECOs would say that they have all of the resources they need, company investments in compliance have grown in recent years, since compliance risks have gained prominence as the understanding of the compliance function has matured. Still, there is little doubt that many compliance departments are underfunded. This is a serious concern, since inadequate resources will undercut CECO authority and effectiveness even if other ingredients—such as visibility, access, and competence—are nominally present. For this reason, it is unsurprising that resources are a focus of enforcement agencies, in their guidance, their assessments of whether and how to sanction companies that failed to prevent wrongdoing, and in their settlements with these companies (i.e., CIAs, NPAs, and DPAs).

At the aspirational level, the resources of compliance in medium-to-large companies should be invested in achieving a culture of integrity throughout the entity. If successful, such an investment "calibrates the firm's risk appetite with its institutional capacity, not only motivates individual employees to act ethically, but just as importantly, equips them with the analytical tools and mindset to identify breaches of compliance."⁶⁷

In addition to adequacy, independence also requires autonomy over resource allocation. CECOs should control their budgets⁶⁸ so that they can decide how to best invest their resources, to structure their

CECOs should control their budgets so that they can decide how to best invest their resources, to structure their departments, and to decide what kind of personnel they require to fulfill the compliance mission.

departments, and to decide what kind of personnel they require to fulfill the compliance mission. This is particularly important at a time when emerging technology and the opportunity to employ AI will likely expand the scope of skills that compliance seeks in its new hires. Managing the risk of cybersecurity and privacy breaches similarly requires a skill set that differs from that traditionally sought in compliance professionals. As such, even if the CECO reports to the GC, the CECO should have the ability to manage assets—that is, budget and people—to achieve the evolving ends of the compliance portfolio.

CECOs must be financial stewards, investing resources to achieve an ethical culture, responding to the expectations of enforcement authorities, and addressing the most serious risks facing the entity, while also being sensitive to the entity's overall financial health and capacity. Resources must support the core functions of compliance: creating structure, processes, and policies; providing education to multiple generations of employees whose learning styles may differ dramatically; and conducting monitoring and audits.

7) *Competence*

While it might be obvious, a CECO cannot be a truly independent leader in the organization without having the skill set to interact with other leaders effectively, assess and navigate compliance-related risks, influence decision making at all levels, and develop systems for preventing and remedying wrongdoing. Thus, ensuring CECO competence is critical. What this requires, more precisely, will vary by organization and over time.

The profile of the CECO evolves during the life of the company, as the compliance function matures, enforcement priorities change, the industry and economy shift, and the profession itself matures, and more senior compliance professionals become available. The pipeline for entry-level compliance professionals will expand as universities continue to add compliance to the curriculum and create compliance programs, majors, and advanced degrees. While business school curricula have long addressed ethics, only recently have textbooks begun to emerge on the specific subject of compliance. Further, the last ten to fifteen years have witnessed the emergence of professional societies, training programs, ethical codes, and other accouterments of a recognized profession.

While substantive knowledge is imperative to compliance success, the personal characteristics of compliance professionals are equally important. These include high integrity, good judgment, assertiveness, approachable demeanor, and an ability to elicit respect and trust.⁶⁹ Compliance has advanced sufficiently as a profession that today, CEOs should recognize,

appreciate, and seek out compliance officers who possess the specific skill set that ensures an effective compliance program. Further, the structure of the compliance function, to whom the CECO reports, the independence of compliance, and the career track of compliance professionals within the organization all may affect the quality of the hire that a CEO can accomplish in senior compliance officer searches.

8) *Access to independent legal counsel when necessary*

No matter the corporate structure, a good working relationship between compliance and corporate counsel is essential, even when the two disagree. The entity's lawyers—in-house as well as outside firms—serve as the primary legal counsel to compliance. Legal counsel is responsible for interpreting the law, and determining whether the company has potentially violated it. The company's lawyers may delegate to compliance an internal investigation, or information gathering related to a potential regulatory or enforcement matter, aspects of which activity, if properly conducted, will be protected by attorney-client privilege or comprise attorney work product.

But, as explored in Parts III and IV, compliance and legal sometimes play different roles of necessity. There are instances in which legal serves an advocacy role on behalf of the company, even while compliance simultaneously would take the company in a more conservative direction. Alternatively, compliance might recommend changes in anticipation of an enforcement agency's view prevailing over the company's position. In light of these differences, while attention must always be paid to maintaining attorney-client privilege, the CECO requires the authority and autonomy to retain independent counsel when the circumstances require it.

The most common situation in which compliance may need to retain independent legal counsel is when an enforcement agency appears to be investigating a practice or transaction structured by in-house counsel. There also may be instances in which legal has worked with an outside law firm to structure a transaction or develop a policy that compliance concludes is problematic. In some such cases, it may be appropriate and useful for the CECO to seek an independent law firm to render another opinion before the matter proceeds to the ultimate decision maker. Conflict resolution between legal and compliance can be particularly difficult for an outside law firm regularly retained by the legal department, in which case a neutral third party may be especially helpful. While having multiple conflicting legal opinions is not always ideal from a defense perspective, we believe the need for independent legal advice will outweigh this risk in some circumstances.

In sum, while the preference is not to have compliance retain its own counsel, the CECO should have the authority to do so for the infrequent circumstances where additional counsel becomes a necessity.

9) An approach to CECO compensation that does not impede independence

While enforcement agencies have referred to CECO compensation, the topic has received inadequate attention in relation to the question of creating an effective compliance program. We do not argue that any particular approach to compensation is necessary for CECO independence. We do believe, however, that both the nature of CECO compensation and how it is determined can *impede* independence; that is, any approach to compensation should not undercut the CECO's genuine independence to steward the company towards ethical business practices. Thus, the following broad parameters should inform policies regarding CECO compensation.

First, the size of the CECO's compensation package should be sufficient to attract and retain the level of experience and breadth of skills in compliance appropriate to a senior leadership position (as discussed above). CECO compensation that is incommensurate with that of other senior leaders in the business often would fail to serve these ends and might send the wrong message regarding the primacy of ethics and compliance within the organization.

In addition, the CECO should be compensated for assuming a risk-based portfolio of responsibilities. The CECO's position might be analogized to the corporate executives who are negotiating their company's acquisition. They face an obvious conflict of interest that is frequently mitigated with special compensation arrangements during these periods to ensure that they act in the company's best interest rather than out of concern that they are negotiating themselves into unemployment.

At the same time, the performance-based components of the CECO's compensation should be structured to mitigate other CECO conflicts of interest. CECO opposition to any particular business strategy should not be deterred by potential adverse impacts on her compensation. Similarly, a best practice would be to avoid closely tying the CECO's annual bonus to the sales performance of a particular product or service. In addition, the CECO's compensation should be insulated from the effects of compliance issues that emerge in a newly-acquired company or that otherwise occurred before the CECO was in a position to affect change. It also is preferable to tie the equity portion of CECO compensation to the long rather than short-term health of the enterprise, although we do not offer a specific prescription on the makeup of equity components,

since we recognize that appropriateness considerations are complicated and can vary by circumstances.

Finally, CECO compensation ideally would be set by the board or board compensation committee, so that the CECO does not worry in any particular instance as to whether holding a view divergent from the CEO, the GC, or other officers will adversely affect her pay. We recognize that, in practice, many CECOs currently do not work closely enough with the board on an ongoing basis for the board to set their compensation. If this is the case, then the highest ranking officer (usually the CEO) should make this determination. However, our vision of the CECO position is that eventually, the board should have sufficient familiarity with the CECO to make this decision. If the board or compensation committee is setting CECO compensation, there should be CEO input, since the CEO will have daily contact with the CECO.

Again, there may be a variety of appropriate approaches to CECO compensation. Because CECOs might face a conflict of interest that undermines independence if they fear pursuing their

Because CECOs might face a conflict of interest that undermines independence if they fear pursuing their concerns about ethics or legality will adversely affect their compensation, any compensation structure should seek to mitigate this conflict to the extent possible.

concerns about ethics or legality will adversely affect their compensation, any compensation structure should seek to mitigate this conflict to the extent possible.

10) Resources and empowerment to anticipate and proactively address future ethical challenges

The focus of compliance must simultaneously be retrospective, real time, and forward thinking. A CECO with limited vision, little opportunity to think about the future, or minimal resources will, by necessity, be limited to reacting to current and emerging crises. The best CECOs always have one eye on the horizon—the risks of a new product line, of a changing reimbursement system, of expansion to emerging economies, of continuing to do business in a country with a corruption-plagued government. The CECO must predict the ethical or legal implications of novel products early in the development pipeline. The CECO will be thinking about the ethical challenges arising from new market practices about which enforcement agencies do not yet know, or wonder, for example, whether the EU's focus on sustainability might also benefit how the company operates in the U.S., Latin America, or China.

We envision a mature ethics and compliance enterprise, at least in large global operations,

The company's values should inspire out-of-the-box consideration of issues beyond the portfolio of the compliance professional who first inaugurated the position ten or twenty years ago.

that has the stature and influence to raise topics that are core human rights issues. The aspirational CECO should begin conversations about child labor, third-party vendors that pay below-sustenance wages, and supervisors who engage in sexual harassment because they work in countries where it is not illegal, or the law is not enforced. CECOs may

also raise questions about whether clinical trials should be conducted in places where the community will never be able to afford or have need for the product being tested. With the CEO, a CECO should ask whether the company should hold itself to higher standards when it manufacture goods in countries with sub-standard or non-existent environmental or worker safety regulations. In sum, the CECO, together with the company's board and leadership team, should have a vision of what it means to conduct business in an ethical manner. The company's values should inspire out-of-the-box consideration of issues beyond the portfolio of the compliance professional who first inaugurated the position ten or twenty years ago.

Recent OIG guidance in the health care space imagines a high-level independent CECO whose portfolio is enterprise wide and includes input on such things as quality of care⁷⁰ and new strategic initiatives.⁷¹ We believe that the ingredients of independence we propose capture the OIG's expectations, but with the greater flexibility in execution that is required by the diversity among the companies that comprise the life sciences industry. Indeed, the OIG's perspective seeks a compliance "function [that] has uninhibited access to the relevant board committees, is free from organizational bias through an appropriate administrative reporting relationship, and receives fair compensation adjustments based on input from any relevant board committee."⁷²

Part VI: Some Predictions about the Role of Compliance in the Future

Compliance is likely to obtain greater organizational autonomy simply by virtue of its increasingly distinct set of tools and skills.

We predict that the skill sets and roles of compliance and legal professionals will continue to evolve, such that the natural outcome likely will be a complementary partnership of their roles and functions. Indeed, compliance is likely to obtain greater organizational autonomy simply by virtue of its increasingly distinct set of tools and skills.

CECOs overseeing mature compliance programs, at least in medium-to-large companies, are likely to retain executive functions: stewarding the company's ethos, policies, and programs; performing risk assessment; creating the structural components of compliance; increasing attention on monitoring effectiveness; and predicting emerging and future risks. The act of making business decisions that are ethical, reflect the company's principles, and are legally compliant will have to occur at the business level, as a function integrated into business operations.⁷³ Such a structure reflects the vision articulated by the DOJ that "business and operational managers, Finance, Procurement, Legal and HR" all demonstrate a shared commitment to compliance.⁷⁴

But we also foresee that CECOs in life sciences companies soon will be confronting a new generation of ethical and compliance challenges. For one thing, the continuing impact of emerging technology and the use of analytics and AI in health care should cause compliance professionals to increase significantly their ethical analysis of the issues that arise from these new opportunities. Privacy concerns are obvious and pervasive, and legislation will necessarily evolve in this space as society struggles to balance the interests of privacy, transparency, efficiency, and medical advancement. The use of AI to screen prospective employees and analyze patient data is already raising questions about whether AI is a new instrument of discrimination.⁷⁵ AI also raises clinical ethical questions, which will again raise the issue of whether and how compliance should engage with issues in clinical care.

Issues related to product pricing and access to life-saving products are emerging in every health care system, regardless of where the system exists on the free market or government-financed spectrum. These questions are inextricably linked with patent issues, patient assistance

programs, and companies' charitable endeavors. The legal and ethical analyses to resolve these quandaries in turn depend upon whether the market at issue is emerging or developed.⁷⁶ A conversation about these issues led by the CECO would enable broad consideration of all of the legal and ethical issues implicated by what are ultimately access concerns, which are core to many companies' values.

European Union Directive 2014/95/EU, which seeks transparency of non-financial issues to spotlight companies' actualization of corporate social responsibility (CSR), social justice, and environmental issues, may also fall within the purview of compliance. The language of the Directive itself suggests a relationship between CSR and issues traditionally within the scope of compliance: "environmental matters, social and employee-related matters, respect for human rights, anti-corruption and bribery matters." The enterprise of identifying issues encompassed by the Directive, engaging in risk assessment, and developing policies to prevent and mitigate such risks is one that is familiar to compliance and in which compliance should at least be involved.

Finally, CECOs might also take up issues related to employees' working conditions, whether they are paid a living wage, and the gap in pay between the highest and lowest wage workers, particularly those employed by companies working in emerging economies. Companies doing business in many countries must also worry about child and trafficked labor.

CECOs are naturally inclined to invest their scarce resources to prevent and mitigate the most pressing and greatest risks their companies face. The ideal for ethics and compliance programs is for CECOs to be focused ultimately on the big picture question—are we conducting business in an ethical manner—which necessarily requires consideration of some of these large and difficult-to-overcome ethical questions. The best ethics and compliance programs should be leaders in raising the hard questions, and, if not primarily responsible for issues of CSR, compliance should at least be a strong partner in identifying issues and implementing solutions.

In addition to the myriad substantive issues that one can imagine adding to the ethics and compliance portfolio, the tools available to perform some of the tasks of compliance are expanding, and will bring their own benefits and risks. Data analytics and AI are beginning to transform not only monitoring, but also risk identification and avoidance. The potential enterprise-wide utility of such skills is already manifest. It is unquestionably the case that enforcement agencies are using data analytics, and expect industry compliance operations to be doing the same, at the very least with publicly-available data, such as the Open Payments government disclosure

program.⁷⁷ Unsurprisingly, the health care sector appears to be ahead of others in its effective use of big data for risk management and compliance. Seventy-five percent of pharmaceutical companies report using data analytics for governance, risk management, and compliance, but many continue to observe that technology does not yet meet their needs or is not being effectively leveraged.⁷⁸ More generally, surveys suggest that companies are awash in risk identification data collected by human resources, hotline and website reports, conflict of interest statements, enterprise risk management, audit, finance, and legal, with insufficient integration of platforms or the resources to synthesize and analyze what exists.⁷⁹

As CECOs begin to manage the promise of data analysis and AI effectively, this should enhance greatly their capabilities, especially with respect to risk avoidance. Facility with these tools will also

As CECOs begin to manage the promise of data analysis and AI effectively, this should enhance greatly their capabilities, especially with respect to risk avoidance. Facility with these tools will also further distinguish the compliance role from that of the GC.

further distinguish the compliance role from that of the GC. Within the constraints of privacy and other laws, the compliance function of the future will be connected to business units in real time, engaging predictive analytics to identify risk proactively—spotting trends and hotspots—in addition to the current employment of descriptive analytics, which is retrospective.⁸⁰ While lawyers will certainly be swept up by the opportunities offered by data analytics, it is more likely that CECOs will be primarily responsible for collecting and analyzing the data that will enable risk identification and avoidance. As such, the adoption of AI and data analytics as essential compliance tools will serve as an additional factor that naturally distinguishes the roles of compliance and legal.

While adoption of AI and attendant analysis will become firm wide for a variety of purposes, it will become a core expertise of compliance, thereby enabling compliance to assume greater company-wide responsibility for risk. The audit and monitoring functions that determine employee adherence to corporate social media policies may end up resembling those employed to detect the fraud and corruption that increasingly occurs digitally. These functions and the responses thereto may resemble those that detect data and privacy breaches. Technology may enable real-time compliance monitoring of ethical sourcing and third-party vendors, which may

shift responsibility for this oversight to a central source. That central source may be compliance, or a subsidiary unit that works in tandem with compliance.

Even while new technology offers CECOs the opportunity to have better command of entity risk, it will become even more essential that CECOs do not lose sight of their core mission, which is an *ethical* business culture. The Guidance for Pharmaceutical Manufacturers embodies this notion by its call for a code of conduct that summarizes “the broad ethical and legal principles under which the company must operate.”⁸¹ Ethics

and compliance are not redundant; myriad behaviors that are legal may nonetheless be unethical. For many entities, this aspect of the CECO’s mission remains amorphous. Even enforcement agencies that invoke the importance

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of organizational ethics, such as the United States Sentencing Commission, describe corporate compliance and ethics programs as ones “designed to prevent and detect criminal conduct.”⁸² Enforcement agencies have not yet articulated a strong vision of the ethical business culture.

The fact that a company has created effective systems to achieve legal compliance does not necessarily mean that it has created an ethical culture, which is something different. What is needed is a clear embrace by CECOs of the ethics part of their portfolio, in part because they will have to confront existing and emergent ethical issues that may remain extra-legal but may create great potential risk for reputational damage.⁸³ Compliance programs’ current focus on a value-based culture should naturally embrace a greater responsibility for institutional ethics, social responsibility, and sustainability, especially in unregulated areas.

The ethical issues potentially beyond legal regulation life sciences companies will have to confront abound, including tax avoidance, product pricing, and a host of labor and environmental issues, just to name a few. Issues adequately regulated in some countries may present tremendous ethical challenges in others, particularly in emerging economies where regulations may be limited or under enforced. Even the question of whether a company should enter into a particular market can be fraught with ethical questions.⁸⁴ The point is that, going forward, CECOs will have to anticipate such issues and be prepared to play a central role in ensuring their companies take a genuinely values-based approach to confronting these issues.

CONCLUSION

Essential to inspiring prosecutors' confidence in, and actually achieving the goals of, a company's compliance program is a structure that ensures CECO independence, which requires both autonomy and authority. A variety of factors affect whether housing compliance separate from legal is necessary to achieve independence, including company size and product lines; whether it is publicly traded or a startup, global, or domestic; and whether it is operating under a CIA.

One might safely hypothesize that, during the nascent stages, when a compliance program disproportionately focuses on the law and rule adherence, a strong rationale exists for the chief legal and compliance responsibilities to reside in one position. In particular, the limited resources of startups and small companies generally necessitate that the same person serve in the capacity of both GC and CECO. As the responsibilities grow, it is not uncommon for the compliance function to report to the chief legal officer, who likely has the clout and resources necessary to ensure the status of and investment in compliance as it takes root.⁸⁵ As the business matures, however, so too should compliance—from a rule based, siloed “policing” function to a more ethos-focused appreciation of ethics and corporate values. In time, the executive role of the CECO should become more strategic and enterprise wide as compliance functions become embedded in the business operations of the organization.⁸⁶

As this transformation occurs, we urge the appointment or advancement of a CECO who is not also the GC, and who has the compliance experience to be a strong voice in setting the tone of the corporate ethos, a partner in the corporate-wide inculcation of the entity's values, and a respected contributor to strategic conversations. The CECO should possess the executive functions and expertise required to create or oversee the structure, systems, policies, and procedures necessary to train, prevent, monitor, audit, and resolve ethics and compliance challenges.

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Third-party vendors are essential to the nascent business enterprise in accomplishing many of the tasks of building out a compliance program. They can be efficient and cost-effective choices in numerous other instances of policy and program development for large compliance operations as well. But compliance as a whole cannot be outsourced. The creation of an ethical culture and long-term stewardship of an ethics and compliance program requires the internal presence, leadership, and oversight of one whose profession is compliance. While many individuals who began their careers practicing law fill these roles quite successfully, the portfolio of skills required for compliance is not taught in most law schools, and so far, must be acquired through experience (and, as many know, not every lawyer is well suited for many aspects of the compliance role).

The ability to attract and retain talent to the compliance profession requires the promise of a fulfilling career trajectory. The profession is too young to evidence a pathway from compliance to a CEO or COO position, for example. Uncertain in many contexts is the long-term career impact on a lawyer, who aspires to a chief legal officer or chief compliance role, of spending time in a compliance position. In some settings, compliance professionals, even if they are trained as lawyers, experience the sting of “second class citizenship.” In the end, such a structure will not attract the best and brightest to compliance.

Companies should devise strategies for attracting and growing talent for compliance roles, ensuring career advancement, and according senior compliance professionals the status that will achieve the goals set out in this White Paper. In this context, it might be that one potential downside to compliance reporting to legal is that compliance professionals will not see opportunities for career advancement. Further, it might be difficult for lawyers supervising compliance professionals to treat these compliance colleagues as peers, to nurture the skill set unique to the compliance profession, or to appreciate and reward these unique talents in performance evaluations.

Companies should be aware of and mitigate these status issues and develop clear performance and succession planning processes that promise advancement and rewards to talented

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professionals who choose the compliance pathway. The CECO role should not be used as a compensation prize for the disappointed aspirations of someone passed over for the GC position, or a holding pattern for future GCs whose turn has yet to come, unless a turn in compliance is

deemed essential to the preparation of a future GC. The CECO is a unique position to which qualified individuals whose career path is compliance should be appointed. Companies that experience “brain drain” from compliance to other departments should discover and remediate the source of discontent. They also should work to develop compliance professionals who are talented, helping them to obtain the experience, wisdom, and stature to be successful and respected senior leaders with the experience and maturity to be the independent actors this White Paper imagines.

This White Paper identifies ten basic ingredients to compliance independence that are key to effective compliance. The CECO should be a ubiquitous figure with the authority to fulfill her duties, and the autonomy to obtain access to information and decision makers, as well as independent legal counsel. Compliance professionals should be recognized as possessing responsibilities and skills increasingly distinct from those of corporate counsel and, ideally, they should be supervised by a high-level executive who appreciates that compliance has evolved into a mature profession. The compensation structure for the CECO should seek to minimize conflicts of interest and insulate the CECO from threats to independence.

APPENDIX

The Development of Compliance: A Historical Overview

Traditionally, compliance was thought to be a basic component of corporate governance by the board,⁸⁷ whose monitoring responsibilities are embodied in the fiduciary duties of care and loyalty.⁸⁸ So viewed, “enforcement” existed, if at all, in suits against boards for their alleged failures. More recently, however, enforcement and regulatory agencies have enhanced their scrutiny of corporate compliance mechanisms. This is in part a result of courts’ weak demands on corporate boards, exemplified by the business judgment rule, which gives deference to most board decisions and makes it difficult for shareholders to enforce the board’s duty to engage in meaningful oversight.⁸⁹ It is also because of the relatively recent recognition of the potential efficiency and efficacy of incentivizing enterprise self-regulation through various legal sticks and carrots.

A. The Regulatory Origins of Modern-Day Compliance Programs

The rise of modern-day compliance can be traced to the U.S. Sentencing Commission’s adoption of the Organizational Sentencing Guidelines (OSG) in 1991.⁹⁰ The OSG sought to press organizations to self-regulate by offering lesser (mitigated) sanctions for criminal wrongdoing within the enterprise if an effective compliance program was present. This incentive ameliorated enhanced penalties for organizational wrongdoing. Thus, the OSG offered a powerful carrot and stick combination for corporations to take legal compliance seriously.⁹¹

The OSG then went further, setting forth the initial guidance on the components of an effective compliance program. The initial draft included four such components: policies and procedures, communication, monitoring, and enforcement.⁹² Ultimately, the OSG enumerated seven factors:

1. The organization must establish standards and procedures designed to reduce the risk of criminal conduct.
2. High-level personnel must oversee the compliance program.
3. The organization should avoid granting substantial discretionary authority to any individual who has a propensity to engage in criminal conduct.
4. The organization’s standards and procedures must be communicated to all employees.

5. The organization must enforce its program, ensure compliance with its standards and procedures through monitoring and auditing systems, and provide means for employees to report wrongdoing without risk of retribution.
6. The organization must consistently enforce its standards.
7. Any violation of the program should be followed with appropriate disciplinary action and updating of the program as necessary.⁹³

Three other characteristics of the OSG are worth mentioning. First, as suggested above, it does not operate as “law” or a “legal mandate,” but, rather sets baseline requirements for organizations seeking to point to compliance efforts to mitigate sanctions for wrongdoing within the enterprise. Second, the OSG is somewhat generalized, and the components themselves leave significant space for variation within individual companies. Indeed, the supporting commentary makes clear that the forgoing components are basic minimums, but what is required of each organization will depend on factors including industry practices and size.⁹⁴ And, of course, a prosecutor can decide that a company’s compliance program is actually a “paper program” that does not justify a reduction in sanctions. Third, as discussed below, the OSG evolved over time, with later versions increasingly emphasizing the role of organizational culture and ethics.

The impact of the OSG was dramatic, even though cases in which corporations are convicted and sentenced are rare.⁹⁵ Compliance programs became a staple in large corporations, especially in heavily-regulated industries like life sciences. In effect, the OSG offered a basic template that set the stage for scrutiny of compliance programs by enforcement agencies.

Of particular import for life sciences companies, the Office of Inspector General for the U.S. Department of Health and Human Services (HHS OIG or OIG) published its Compliance Guidance for Pharmaceutical Manufacturers in 2003, building on guidance it had directed at other segments of the health care industry.⁹⁶ The OIG guidance set forth the now well-known “seven elements” of an effective compliance program: (1) implementing written policies and procedures, (2) designating a compliance officer and compliance committee, (3) conducting effective training and education, (4) developing effective lines of communication, (5) conducting internal monitoring and auditing, (6) enforcing standards through well-publicized disciplinary guidelines, and (7) responding promptly to detecting problems and undertaking corrective action.⁹⁷

Akin to the commentary underlying the OSG, the OIG’s guidance explicitly recognized that there is no single best pharmaceutical manufacturer compliance program and that differences among companies—including size and types of compliance risk—would affect how compliance programs are implemented. Thus, it recommended that each manufacturer develop a compliance program appropriate to its own particular circumstances.⁹⁸

Somewhat contemporaneously, the Department of Justice (DOJ) began to standardize its focus on compliance programs in its charging decisions for organizations. In 1999, the DOJ set forth a set of principles for federal prosecutions in the so-called “Holder Memorandum” (named

for then-Deputy Attorney General Eric Holder). Among the considerations was the existence and adequacy of the entity's compliance program. This was later incorporated in the U.S. Attorneys' Manual.⁹⁹ Like the OSG and OIG guidance, the comments to the relevant Manual section make clear that there are no set formulaic requirements for all compliance programs. Unlike the other guidance, the Manual does not set forth the components of an effective compliance program. Instead, the comments simply offer an overview of how prosecutors should analyze programs:

The fundamental questions any prosecutor should ask are: Is the corporation's compliance program well designed? Is the program being applied earnestly and in good faith? Does the corporation's compliance program work? In answering these questions, the prosecutor should consider the comprehensiveness of the compliance program; the extent and pervasiveness of the criminal misconduct; the number and level of the corporate employees involved; the seriousness, duration, and frequency of the misconduct; and any remedial actions taken by the corporation, including, for example, disciplinary action against past violators uncovered by the prior compliance program, and revisions to corporate compliance programs in light of lessons learned.¹⁰⁰

Other agency guidance affecting compliance choices in life sciences companies also has emerged. One notable example is the Resource Guide to the Foreign Corrupt Practices Act, authored jointly by the DOJ and Securities Exchange Commission (SEC), which contains its own discussion of the elements of an effective compliance program.¹⁰¹ Like the other sources, the Resource Guide eschews a one-size-fits-all approach. International bodies that seek to set standards for corporate conduct, including the Organization of Economic Cooperation and Development (OECD), have also offered similar guidance.¹⁰²

Given the somewhat vague—or at least generalized—prescriptions offered by these and other enforcement authorities, actual enforcement efforts emerged as a central indicator of regulator expectations. Settlements between individual organizations and the OIG, embodied in Corporate Integrity Agreements (CIAs), and resolutions of criminal actions between the DOJ and companies, set forth in Deferred Prosecution Agreements (DPAs) and Non-Prosecution Agreements (NPAs), became a key source of compliance guidance. Although the subject of ongoing controversy, there is little doubt that, over time, these various settlements have provided significant compliance guidance to companies, sometimes offering details absent from agency articulations. Through this iterative process, enforcement agencies have pressed companies to enhance their internal governance and oversight structures, as well as implement particular compliance reforms. Examples include adoption of a compliance code, specific training requirements, hiring additional compliance personnel, altering reporting structures, and changing compensation structures.¹⁰³

In light of this history, it is not surprising that expectations regarding the “what” and “how” of compliance have rarely made their way into case law, formal agency rule making, or the

legislative process. Rather, they continue to be articulated through agency guidance, settlement agreements, and prosecutors' speeches. As a result, corporate decision makers still have a paucity of binding law guiding the execution of their compliance responsibilities.

Yet, as time has gone on, in addition to the accumulated knowledge to be gleaned from CIAs, DPAs, and NPAs, guidance from enforcement authorities has become more particularized, and, arguably, more helpful in terms of clarifying expectations. For instance, the 2010 amendments to the OSG added an expectation that compliance personnel should have direct access to the board of directors.¹⁰⁴ Also, the OIG has provided additional guidance for other types of health care organizations that may inform compliance programs in life sciences companies.¹⁰⁵ Finally, consistent with its growing focus on organizations' obligation to engage in self-assessment, the OIG hosted a roundtable on compliance metrics and measurement in 2017, and then produced a resource guide detailing ideas for how to measure the effectiveness of a company's implementation of each of the seven elements.¹⁰⁶ Of greatest importance to this White Paper is the Guide's clear vision that the compliance officer be a key stakeholder with pervasive responsibility throughout the organization and direct reporting to the CEO and board.¹⁰⁷

The DOJ, too, has now offered greater insights into what aspects of compliance programs it will analyze in its charging determinations. In a 2014 speech, then-Assistant Attorney General for the Criminal Division Leslie Caldwell set forth ten "hallmarks" of a good compliance program, many of which are included in DPAs.¹⁰⁸ Although much of what she discussed reflects prior guidance, she identified some components, including periodic risk-based assessments that might be added to the list. She also emphasized and clarified other aspects, such as that "high-level commitment" to compliance requires strong, explicit, and visible commitment by directors and senior managers.

Another source is the guidance the DOJ issued in 2017, in which it sets forth in detail the questions prosecutors are likely to ask when analyzing the effectiveness of a compliance program as part of an assessment of whether to investigate a company for wrongdoing.¹⁰⁹ Of particular relevance is the DOJ's focus on Chief Ethics and Compliance Officer (CECO) stature, as reflected by "compensation levels, rank/title, reporting line, resources, and access to key decision-makers." Specifically, the guidance asks: "What role has compliance played in the company's strategic and operational decisions?"¹¹⁰ Questions about autonomy focus on the CECO's access to the board, as well as field compliance officers' access to corporate headquarters. The DOJ aspires to a compliance function that is empowered and has the ability to raise concerns about potential transactions or deals, even to the point of having those transactions "stopped, modified, or more closely examined as a result of compliance concerns."¹¹¹

Finally, other legal developments have pressed organizations to bolster their compliance infrastructure or consider alternative ways to address wrongdoing within the organization. In the life sciences space in particular, recent regulatory demands and growing legal risks have pressed companies to develop new and more sophisticated monitoring, data collection, and internal reporting practices. Among others, these include the rise of robust transparency requirements by federal, state, and foreign authorities; the ratcheting up of anti-corruption enforcement in other

regions of the world; and new protections and incentives for whistleblowers. Moreover, the DOJ's recent emphasis on individual accountability and the corresponding role identifying individual wrongdoers plays in charging decisions and cooperation, as exemplified in the "Yates Memorandum,"¹¹² has heightened the stakes and altered practices at the remediation stage.

B. Maturation in Compliance Guidance, Practice, and Understanding

Over the course of the foregoing history, compliance in the life sciences space has matured considerably in both practice and understanding. For example, as discussed in the main body of this White Paper, this transformation includes the emergence of a skilled compliance profession. Yet this maturation also includes clearer and more exacting guidance from enforcement officials, which has led to more robust and sophisticated compliance programs, as well as the recognition by both regulatory authorities and compliance practitioners that compliance is inextricably linked with ethics and organizational culture.

As discussed in the prior section, over time and through various means—OSG amendments, new agency guidance, speeches by enforcement officials, a growing body of settlements, and industry-agency interaction—regulatory authorities have set forth more exacting and arguably more helpful guidance on the key components of a compliance program. Although the "no one-size-fits-all" approach remains,¹¹³ and each company's circumstances will be at least somewhat unique, the cumulative effect of this guidance has been a clearer picture of these authorities' expectations. Thus, at least in larger enterprises with compliance departments focused on this guidance, there are fewer gaps in understanding of such expectations.

Intertwined with this growing clarity of expectations has been the emergence and spread of mature compliance programs, particularly in larger life sciences companies. These programs are now, on average, more resourced and far more sophisticated than they were two decades ago.¹¹⁴ These advances are reflected in both the survey literature and commentary.¹¹⁵ And, while there remain important differences among companies, there has been standardization as well around the key components regulatory authorities have articulated, bolstered by industry codes and shared best practices.¹¹⁶

This does not mean that compliance programs are always effective, or that every company invests sufficient resources or otherwise takes compliance seriously enough. Smaller and newer companies in particular often fall short—indeed, the gap between large and small companies in terms of program maturity is a frequently-articulated concern. Global companies continue to face significant challenges in standardizing compliance norms and practices across regions and countries. Moreover, there remain high profile compliance failures even among larger life sciences companies, reflected in recent CIAs and other settlements,¹¹⁷ which sometimes shed light on surprising shortfalls. Changes in the regulatory landscape (e.g., enhanced transparency requirements and changing pricing and reimbursement standards), technology (such as technologies that facilitate ongoing interactions between manufacturers and patients), and the market for life sciences products (including shifts in the criteria for purchasing decisions and

formulary inclusion), continually create new compliance challenges that undoubtedly will lead to oversight gaps and other compliance failures. Yet, overall, there is general agreement among those in the life sciences industry and close industry observers that compliance programs have grown and matured considerably in the last two decades, with positive effects.¹¹⁸

In addition, over the last two decades, the conceptualization of compliance has expanded beyond law-focused responsibilities to include ethics. Although the journey from viewing compliance as legal standard centered to one embodying ethics was partially driven by theoretical conceptions (about the ends organizations and organizational leaders ought to serve), the emphasis on ethics and ethical leadership is more the product of collective experience than theory. Indeed, there is now a *striking* consensus among enforcement officials, industry professionals and professional organizations, scholars, and enlightened business leaders on the need to cultivate an ethical business culture to maintain legal compliance over time. Again, this accounts for the increasing use of “ethics” in the titles of compliance officers, and the use of CECO in this White Paper, although not all companies place responsibility for ethics in the compliance officer, and some commentators argue it should be elsewhere.¹¹⁹

The OSG and other early forays into incentivizing self-regulation focused principally on enhancing internal policies and procedures. But the colossal failures of Enron and others at the beginning of this century, despite the presence of codes of conduct and the other trappings of compliance, convinced legislators and regulators that the presence of compliance policies and procedures alone is insufficient. Commentators likewise warned that the compliance programs and other self-regulatory practices (such as sexual harassment policies) might be mere “window-dressing” to gain the benefits of mitigation and other legal carrots.¹²⁰ Thus, the Sarbanes-Oxley Act (SOX), as well as other regulation and guidance, have increased the focus on fostering ethics within the organization.¹²¹ The 2004 OSG amendments are one example, defining an effective compliance program as one that “encourages ethical conduct and a commitment to follow the law.”¹²² Ethics is mentioned in OIG guidance as well,¹²³ including, most recently, in the 2017 Resource Guide, which emphasizes the integration of values and ethical principles in codes of conduct.¹²⁴ Moreover, enforcement officials frequently state that, when wrongdoing is discovered in an organization, they will look beyond the formal compliance program to organizational culture to determine if they are genuinely aligned. For instance, in 2015, then-SEC chair Mary Jo White emphasized that senior management and boards of directors are expected to “imbue the organization from top to bottom with corporate culture demanding compliance with the law and the highest ethical standards. We are not talking here about a check-the-box compliance program or nice sounding code of conduct. The goal is much deeper.”¹²⁵

Correspondingly, the behavioral and other scholarship that has emerged points to fostering an ethical business culture—sometimes referred to as a “culture of integrity”¹²⁶—as essential to ensuring compliance.¹²⁷ Indeed, the most recent, most sophisticated survey-based studies of effective compliance programs confirm that values-based approaches that focus on organizational culture are far more effective than those that do not.¹²⁸

Such findings are unsurprising, since—well beyond discussions of compliance—business leaders and management scholars emphasize that behavior within an organization is driven by the organization’s culture.¹²⁹ And culture has been quickly and aptly identified as a central culprit when companies experience ethical or legal lapses.¹³⁰

Thus, a key component of maturation of compliance regulation and practice has been the recognition that a robust compliance infrastructure is not enough; ultimately, success depends on nurturing a business culture that centers on and conforms to a set of values, ethical principles, or norms. Still, achieving and maintaining such a culture is neither easy nor one dimensional. While recognition of the need for such cultural management and transformation is widespread, life sciences companies vary in approach and success. As discussed in the White Paper, most appear to be shifting to a values-based code of conduct, containing a set of principles commonly emphasizing patient welfare and access, honesty or integrity, ethical research practices, nondiscrimination, fair treatment of workers and other stakeholders, and sustainability. In fact, greater understanding of effective techniques for developing culture within an organization has emerged.¹³¹ Nevertheless, many compliance professionals acknowledge that consistency in tone through all levels of management and success in integration remains a work in progress in both large and small companies, and such issues remain acute for global companies operating in disparate regions.

*Dean and Professor of Law, Seton Hall Law School.

**Senior Associate Dean and Andrea J. Catania Professor of Law, Seton Hall Law School.

¹ See U.S. SENTENCING GUIDELINES MANUAL ch. 8, introductory cmt. (U.S. SENTENCING COMM’N 2016). Congress’s enactment of the Foreign Corrupt Practices Act in 1977 required the implementation of certain internal controls to eliminate foreign bribery. See generally, Robert Bird & Stephen Kim Park, *The Domains of Corporate Counsel in an Era of Compliance*, 53 AM. BUS. L. J. 203, 211 (2016); Michele DeStefano, *Creating a Culture of Compliance: Why Departmentalization May Not Be the Answer*, 10 HASTINGS BUS. L.J. 71, 88 (2014).

² See, e.g., Leonard Orland, *The Transformation of Corporate Criminal Law*, 1 BROOK. J. CORP. FIN. & COM. L. 45, 48 (2006); Lori Richards, Dir., Office of Compliance Inspections & Examinations, U.S. Sec. & Exch. Comm’n, Speech by SEC Staff: Remarks Before the Investment Adviser Compliance Best Practices Summit: Compliance Programs: Our Shared Mission (Feb. 28, 2005), <https://www.sec.gov/news/speech/spch022805lar.htm>.

³ Government has “essentially privatized corporate law enforcement,” outsourcing discovery and reporting to companies themselves who conduct investigations to appear cooperative. Jesse Eisinger, *Why Manafort and Cohen Thought They’d Get Away with It*, N.Y. TIMES, Aug. 26, 2018, at SR1. While this privatization of government functions can be implemented for efficiency, “[a]ccountability is a countervailing principle of democracy,” and when efficiency clashes with accountability it “undermines democratic values.” PAUL R. VERKUIL, *OUTSOURCING SOVEREIGNTY: WHY PRIVATIZATION OF GOVERNMENT FUNCTIONS THREATENS DEMOCRACY AND WHAT WE CAN DO ABOUT IT* 4 (2007).

⁴ For example, this uncertainty is partially due to the slow (but accelerating) emergence of empirical literature or other evidence-based assessments guiding corporations and government on all of the factors that contribute to an “effective compliance program.” See, e.g., Sean J. Griffith, *Corporate Governance in an Era of Compliance*, 57 WM. & MARY L. REV. 2075, 2105-06 (2016).

⁵ See, e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23732 (May 5, 2003) (recommending each manufacturer should adopt the guidance objectives and principles based on its own circumstances); OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4859 (Jan. 31, 2005), (“[T]he OIG recommends that each hospital adapt the objectives and principles underlying this guidance to its own particular circumstances.”).

⁶ HHS OIG has stated repeatedly its expectation that a “[health care] organization’s Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any

manner.” OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS. ET AL., PRACTICAL GUIDANCE FOR HEALTH CARE GOVERNING BOARDS ON COMPLIANCE OVERSIGHT 7 (2015), <https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf> [hereinafter PRACTICAL GUIDANCE]. And, in 2003, the guidance for pharmaceutical manufacturers also suggests in a footnote that these roles be separated, if feasible. *See* 68 Fed. Reg. at 23743 n.13 (“By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.”). The 2017 Resource Guide from HCCA and OIG asks: “Does [the CECO] report directly to CEO, board (not CFO/Legal)?” HCCA-OIG COMPLIANCE EFFECTIVENESS ROUNDTABLE, MEASURING COMPLIANCE PROGRAM EFFECTIVENESS: A RESOURCE GUIDE 11 (2017), <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf> [hereinafter HCCA-OIG RESOURCE GUIDE].

⁷ Settlement agreements between companies and the OIG almost always require compliance to be independent of General Counsel (GC) or Chief Financial Officer (CFO), with direct reporting lines to the governing board and CEO. *See supra* note 6 and accompanying text. *See also* DeStefano, *supra* note 1, at 103-04; Press Release, U.S. Dep’t of Justice, Hospital Chain Will Pay over \$513 Million for Defrauding the United States and Making Illegal Payments in Exchange for Patient Referrals; Two Subsidiaries Agree to Plead Guilty (Oct. 3, 2016), <https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-513-million-defrauding-united-states-and-making-illegal-payments>.

⁸ While the Department of Justice also focuses on whether an entity’s compliance program is effective, and has recognized the importance of compliance program autonomy and stature within an organization, it has not been driven by a specific vision of the organizational chart. *See generally* U.S. DEP’T OF JUSTICE, EVALUATION OF COMPLIANCE PROGRAMS (2017) [hereinafter EVALUATION OF COMPLIANCE PROGRAMS], <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

⁹ A number of legal scholars and commentators have taken the position that there is no single reporting structure that is necessary, nor are the roles of CECO and GC or CFO so disparate or in conflict that they must be separated. *See, e.g.,* Bird & Park, *supra* note 1, at 208; DeStefano, *supra* note 1, at 85. Indeed, some suggest that merging of compliance and legal, or a reporting structure that places the CECO under the GC or the CFO, is preferable. *See, e.g.,* BEN W. HEINEMAN, JR., THE INSIDE COUNSEL REVOLUTION 168-75 (2016).

¹⁰ *See generally*, Bird & Park, *supra* note 1.

¹¹ A 2016 Deloitte survey reports “an increase in the number of designated chief compliance officers that are stand-alone positions, and an increase in those reporting directly to the chief executive officer and board.” Deloitte, *Compliance Week in Focus: 2016 Compliance Trends Survey* 6 (2017), <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/governance-risk-compliance/us-advisory-compliance-week-survey.pdf>. Whether the CECO was stand alone was, unsurprisingly, much less likely in smaller firms. *Id.* A 2017 survey by Ethisphere confirms this trend, reporting that in 2015, 16% of compliance officers reported to the CEO, compared with 30% in 2017. *See* ETHISPHERE & CONVERCENT, 2017 ETHICS AND COMPLIANCE SURVEY 3 (2017), <http://www.convercent.com/resource/2017-ethics-and-compliance-survey-ethisphere-and-convercent.pdf>.

¹² One 2016 survey of 558 respondents shows about 32% CECOs report directly to the CEO, 23% report to the General Counsel, and 14% report to the board or a board committee. Deloitte, *supra* note 11, at 6. 43% of the respondents indicated that the CECO “held a seat on the CEO’s executive management committee.” *Id.* at 7. A 2016 PwC cross-industry survey shows 36% of reporting companies’ compliance functions reporting to the chief legal counsel. *See* PwC, PwC State of Compliance Study 2016 (2016), <https://www.pwc.com/us/en/risk-assurance/state-of-compliance-study/assets/state-of-compliance-study-2016.pdf>. The survey reported in LRN’s 2015 Ethics and Compliance Effectiveness Report indicated that just over 40% of CECOs report to the GC, slightly less than 30% report to the CEO, and just under 15% report to the board. *See* LRN, THE 2015 ETHICS AND COMPLIANCE EFFECTIVENESS REPORT 7 (2015), <http://content.lrn.com/research-insights/pei-report-2015>.

¹³ By life sciences companies, we mean companies that manufacture or sell pharmaceutical, medical device, and biotech and biopharma products. We do not include physicians, group practices, hospitals, or other providers.

¹⁴ *See* Bird & Park, *supra* note 1, at 213 (“A consequence of the new compliance era is the growth of compliance as a separate and distinct professional field.”).

¹⁵ *See id.* at 214.

¹⁶ Among these are compliance risk assessment, policy creation and drafting, training, monitoring, auditing, investigations, remediation, and measurement.

¹⁷ We recognize that not all companies place responsibility for ethics in the compliance officer, and some commentators argue it should be elsewhere. *See* Bird & Park, *supra* note 1.

¹⁸ See LRN, *supra* note 12 (reporting findings from a compliance effectiveness survey showing that values-based approaches outperform rules-based approaches on almost every measure).

¹⁹ See generally Linda Klebe Trevino, *Out of Touch: The CEOs Role in Corporate Misbehavior*, 70 BROOKLYN L. REV. 1195, 1200 (2005) (discussing the behavioral literature and findings).

²⁰ See discussion, *supra*, note 11 and accompanying text.

²¹ See discussion, *supra*, note 12 and accompanying text.

²² PwC, *State of Compliance 2014: Pharmaceutical and Life Sciences Industry Brief* 7-8 (2014), <https://www.pwc.com/us/en/risk-management/state-of-compliance-survey/assets/pwc-soc-pharma-and-life-sciences.pdf>.

²³ PRACTICAL GUIDANCE, *supra* note 6.

²⁴ See 68 Fed. Reg. at 23739.

²⁵ *Id.* at 54 n.13.

²⁶ See *id.* at 39.

²⁷ HCCA-OIG Resource Guide, *supra* note 6 (“Does [the CECO] report directly to CEO, board (not CFO/Legal)?”).

²⁸ ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE § 9.05(4) n.22 (2018) (ebook). For example, a recent CIA between the OIG and Med-Fast Pharmacy, Inc., a pharmaceutical company located in Pennsylvania, requires that within ninety days after the effective date, Med-Fast appoint a CCO who would report directly to the CEO and be a part of senior management. The CIA requires that the CCO is not subordinate to general counsel or the CFO, or have any responsibilities that involve acting as legal counsel or supervising legal counsel functions. This essentially requires that the CCO be completely separate from the legal department. See, e.g., Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Med-Fast Pharmacy, Inc. (Sept. 11, 2017), https://oig.hhs.gov/fraud/cia/agreements/Med-Fast_Pharmacy_Inc_Med-Fast_Pharmacy_LP_Douglas_Kaleugher_A_Jane_K_LLC_09112017.pdf. See also Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Aegerion Pharm. (Sept. 22, 2017), https://oig.hhs.gov/fraud/cia/agreements/Aegerion_Pharmaceuticals_Inc_09222017.pdf; Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Medi-Lynx Cardiac Monitoring LLC (June 23, 2017), https://oig.hhs.gov/fraud/cia/agreements/Medi-Lynx_Cardiac_Monitoring_LLC_06232017.pdf; Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Sightpath Med., Inc. (Aug. 10, 2017), https://oig.hhs.gov/fraud/cia/agreements/Sightpath_Medical_Inc_08102017.pdf; Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Mylan Inc. (Aug. 16, 2017), https://oig.hhs.gov/fraud/cia/agreements/Mylan_Inc_and_Mylan_Specialty_LP_08162017.pdf.

²⁹ See generally, EVALUATION OF COMPLIANCE PROGRAMS, *supra* note 8.

³⁰ While some recent DPAs/NPAs have required an independent monitor, they do not require a separation of compliance and legal. See, e.g., U.S. DEP’T OF JUSTICE, Deferred-Prosecution Agreement with Olympus Corp. of the Americas (Feb. 29, 2016), <https://www.justice.gov/usao-nj/file/867021/download>; U.S. DEP’T OF JUSTICE, Non-Prosecution Agreement with BK Med. ApS (June 21, 2016), <https://www.justice.gov/opa/file/868771/download>; see also U.S. DEP’T OF JUSTICE, Non-Prosecution Agreement with Tenet HealthSystem Med., Inc. (Sept. 30, 2016) <https://www.justice.gov/opa/file/899961/download>; U.S. DEP’T OF JUSTICE, Deferred-Prosecution Agreement with Teva Pharm. Indus., Ltd. (Dec. 22, 2016), <https://www.justice.gov/opa/file/899961/download>.

³¹ See generally note 30, *supra* (listing DPAs and NPAs).

³² Bird & Park, *supra* note 1, at 205; Griffith, *supra* note 4, at 2124-25.

³³ José A. Tabuena, *The Chief Compliance Officer vs the General Counsel: Friend or Foe?*, COMPLIANCE & ETHICS, Dec. 2006, at 4-7, 10-15, https://www.corporatecompliance.org/Portals/1/PDF/Resources/past_handouts/CEI/2008/601-3.pdf.

³⁴ *Id.*

³⁵ The False Claims Act (FCA) prohibits persons from knowingly avoiding or concealing obligations to pay the government, commonly referred to as reverse false claims. This prohibition in combination with the Affordable Care Act’s 60 Day Rule inflicts a demanding timeframe on entities to report and return any overpayment of government funds. David A. Mata, *Identifying Schrödinger’s Cat: Ex Rel. Kane and the Future of the Sixty Day Report and Return Rule*, 13 IND. HEALTH L. REV. 415, 418 (2016).

³⁶ See, e.g., Griffith, *supra* note 4, at 2117-34 (offering a critical assessment of prosecutor and enforcement-agency driven compliance interventions).

³⁷ While most of these critics resist the push for formal separation of legal and compliance departments, fewer oppose the trend towards having someone besides the GC serve as the chief compliance officer (at least in larger companies). Ben Heineman, for example, believes that companies should have a separately-designated chief compliance officer

but that officer should report to the GC and CFO. Heineman, *supra* note 9, at 168-75. Most acknowledge that the CECO must have the ability to access highest-ranking officers and the board when necessary to avoid or address legal violations.

³⁸ See Heineman, *supra* note 9 and accompanying text.

³⁹ See generally Bird & Park, *supra* note 1.

⁴⁰ DeStefano, *supra* note 1, at 132.

⁴¹ See, e.g., R. William “Bill” Ide & Crystal J. Clark, *The Chief Legal Officer’s Critical Role in the Compliance Function*, BNA NEWS (July 1, 2014),

https://www.dentons.com/~media/MLA%20Import/pdf/B/BloombergBNA_Ide_Clark.pdf

⁴² See, e.g., Bird & Park, *supra* note 1, at 206.

⁴³ We do not delve deeply into the details of the privilege in this White Paper, but it is worth mentioning that we are skeptical that reporting structure and the placement of the CECO in the organization directly affects the scope of the privilege. The privilege protects communications between attorney and client for the purpose of rendering or seeking legal advice; in the corporate setting in the United States, this typically covers communications between corporate counsel and those acting within the scope of their duties for the organization for the purpose of obtaining or providing advice on behalf of the corporation. See, e.g., *Upjohn v. United States*, 449 U.S. 383 (1981). Certainly, many communications between legal counsel and those performing compliance functions—e.g., discussions about policy drafting, the content of trainings, or the legal implications of data discovered through monitoring, auditing, or an investigation—can be privileged, regardless of where the person communicating with counsel resides in the organizational chart. The opposite is also true: facts shared or communications between counsel and compliance officers (or compliance officers and others) that are not otherwise privileged are not made so because of reporting structure. Moreover, simply placing compliance within or under legal does not mean that compliance will automatically be viewed as assisting legal; there are plenty of tasks compliance performs—e.g., monitoring, training, auditing, advising on compliance matters on an ongoing basis—that cannot be characterized as simply assisting counsel in rendering or transmitting advice. Further, because the key is that the communications are with or from counsel functioning in a legal capacity, an organizational structure that obscures the role of the GC—making unclear whether the GC is serving as legal adviser, business adviser, compliance officer, or some combination of these—might actually put privilege protections at risk. See, e.g., *In re Kellogg Brown & Root, Inc.*, 756 F.3d 754, 759-60 (D.C. Cir. 2014) (upholding privilege protection in the particular context but confirming that the rendering of legal advice must be a primary purpose of the communication); *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 789, 798-99 (2007) (discussing in detail the difficulty of determining the primary purpose of in-house counsel’s communications when counsel’s role in the company extends beyond merely providing legal advice). For these reasons, we are unconvinced that privilege issues cut definitively in favor of or against compliance or the CECO being placed in or reporting to legal.

⁴⁴ See Part IV, *infra*.

⁴⁵ See, e.g., Ide & Clark, *supra* note 41.

⁴⁶ See DeStefano, *supra* note 1, at 92; see also Griffith, *supra* note 4, at 2082.

⁴⁷ This definition largely conforms to the understanding of many scholars and enforcement officials, as well as the common understanding of those engaged in compliance work. Professor Geoffrey Miller, a leading scholar in the area, states “compliance” refers to “the processes by which an organization seeks to ensure that employees and other constituents conform to applicable norms—which can include either the requirements of laws or regulations or the internal rules.” GEOFFREY P. MILLER, *THE LAW OF GOVERNANCE, RISK MANAGEMENT, AND COMPLIANCE* 3 (2014). The compliance function serves as an “internalized norm enforcement” within corporations. *Id.* at 137.

⁴⁸ See PRACTICAL GUIDANCE, *supra* note 6, at 6. Elsewhere the OIG has also stated that compliance generally consists of four elements: a well-structured compliance department, adequate information flow from the compliance department to senior management, monitoring and surveillance, and enforcement. See Griffith, *supra* note 4, at 2093-98.

⁴⁹ See generally PRACTICAL GUIDANCE, *supra* note 6. As one commenter has suggested to us, “compliance” might be too broad a title. For life sciences companies, for example, perhaps “compliance” ought to be renamed “health care compliance” to avoid confusion with other functions—e.g., human resources’ efforts to ensure compliance with employment and labor standards and quality assurance’s attempts to ensure benchmarks.

⁵⁰ See LRN, *supra* note 12. Compliance professionals often refer to this as “getting the business to own compliance.”

⁵¹ See PRACTICAL GUIDANCE, *supra* note 6.

⁵² See *id.* at 6. The OIG states that the compliance officer should be neither counsel for the provider nor subordinate in function or position to counsel or the legal department.

⁵³ See Bird & Park, *supra* note 1, at 212.

⁵⁴ For a robust discussion of the evolution of the role of inside counsel, *see, e.g.*, Heineman, *supra* note 9; Bird & Park, *supra* note 1, at 224; DeStefano, *supra* note 1, at 82.

⁵⁵ *See* Bird & Park, *supra* note 1, at 209 (explaining that compliance is likely to be involved in the due diligence aspects of a merger or acquisition).

⁵⁶ Adair Morse et al., *Executive Lawyers: Gatekeepers or Strategic Officers?*, 59 J. of L. & Econ. 847, 849 (2016).

⁵⁷ *See generally* Deborah Mott, *The Discrete Roles of General Counsel*, 74 FORDHAM L. REV. 955, 965 (2005).

⁵⁸ *Id.* at 966 et seq. Indeed, one of the great appeals to some of an in-house legal position is the opportunity to expand beyond the traditional lawyer role into the entrepreneurial role, perhaps even with the lure of a pathway to becoming CEO. And, of course, the GC role frequently carries with it the potential for much greater compensation than is likely in a law firm, especially if the GC package includes stock options. In fact, the compensation structure of most GCs suggests that they are incentivized to contribute to the value of the entity. According to one study, GC compensation is about 37% of the CEO's; they earn another \$55,000 in equity income, on average, for every 1% increase in shareholder value. Adair Morse et al., *supra* note 56, at 858.

⁵⁹ Adair Morse et al., *supra* note 56, at 863-64.

⁶⁰ *Id.* at 851. The research suggests that this diversion of time benefits the companies' investment in research and resultant patent filings. *Id.*

⁶¹ *Id.*

⁶² *See* Bird & Park, *supra* note 1, at 224 ("An influential CLO acts as a monitor of corporate transactions and ensures that interactions with the market more accurately reflect firm conditions and are more conservative in their future assessments. The CLO's stature allows it to maintain the system of internal checks and balances, ensuring that the agency costs motivated by self-serving behavior are kept at a minimum."). *See also* Heineman, *supra* note 9; DeStefano, *supra* note 1, at 82 ("A compliance officer needs a certain level of political power and influence to be able to utilize an understanding of the law, corporations, and individual motivation to play both an independent and dependent role - acting in both the interest of the public and the corporation. General counsels have that political power.").

⁶³ A 2016 survey of almost 600 respondents makes clear that while smaller companies are much less likely to have designated a stand-alone chief compliance officer, those who serve this role in smaller companies are more likely to have direct access to the board, likely due to the greater hierarchy in larger companies. Deloitte, *supra* note 11, at 6-7.

⁶⁴ *See generally* Christopher Zalesky, *Getting it Right: Practical Guidance for Health Care Compliance Professionals in the Pharmaceutical and Medical Device Industries—Principles, Choices, Questions, Tools* (forthcoming 2018).

⁶⁵ Thus, independence, rather than structure, should be the focus for achieving and assessing effectiveness. Separation of compliance from legal or finance, or formal placement of the CECO in a specific location in the corporate hierarchy, is neither always necessary nor independently sufficient. Indeed, just as compliance policies and procedures can be mere "window dressing" unless consistently backed by leadership and the right organizational culture, so too may a heightened placement of the CECO be meaningless without genuine stature and influence. To achieve and maintain a pervasive ethical business culture actualized by an adequate set of compliance policies and procedures, the CECO and the compliance function as a whole must possess genuine independence – i.e., real and perceived autonomy and authority within the organization to identify and meet ethical and compliance objectives over time, as well as the authority to remediate problems that are uncovered.

As we turn to the essential ingredients of such CECO independence, we offer several clarifications. First, given the disparate functions, expertise, and perspectives of the CECO and the GC, and the enormous responsibilities of both, we are skeptical—along with many others on all sides of the debate—that one person can adequately perform both roles in large life sciences companies. And, as discussed in the last part, we are concerned about the loss of a stand-alone CECO's autonomous voice (again, regardless of where the CECO is placed within the company structure). Practical realities may press towards a dual role in smaller companies, and we remain open to the possibility that combined roles can work in somewhat larger enterprises. Yet, we suspect that over time, the divergent skill sets and increasingly different duties of legal and compliance will make it practically impossible for a single person to perform or oversee both roles simultaneously.

Second, our emphasis on independence is not, in itself, controversial. Even some who favor having the CECO report to the GC or the CFO emphasize CECO independence. However, the ingredients of independence we propose below are demanding—as demanding as recent guidance from the HHS OIG and DOJ would suggest, although without the preference for any particular structure. These ingredients may be present or absent anywhere the CECO and the ethics and compliance department may reside in the organizational chart, but absence is *more likely* if the CECO resides lower in the hierarchy or the nature of the position makes it difficult to recruit strong talent for the position.

Finally, how companies achieve these factors will vary dramatically and will be affected by the respective skill sets of the GC and CECO. Consequently, while we anticipate that some companies can achieve independence in a structure where compliance reports to legal, we also note recent research that suggests that programs led by senior leaders who report directly to the CEO are more effective. At least for medium to large companies, we anticipate that CECOs who possess the stature, autonomy, input into strategic decision making, and resources essential to independence will evolve naturally into a sphere that is a partner to, but separate from, legal. We offer some further predictions along these lines in Part VI.

⁶⁶ See generally CASS R. SUNSTEIN & REID HASTIE, WISER (2015).

⁶⁷ Robert C. Bird & Stephen Kim Park, *Turning Corporate Compliance into Competitive Advantage*, 19 U. PENN BUS. J. 285, 334 (2017).

⁶⁸ Donna C. Boehme, *Structuring the Chief Ethics and Compliance Officer and Compliance Function for Success*, SOCIETY OF CORPORATE COMPLIANCE AND ETHICS, THE COMPLETE COMPLIANCE AND ETHICS MANUAL, 2.37-2.40 (2d ed. 2010).

⁶⁹ Zalesky, *supra* note 64.

⁷⁰ HCCA-OIG Resource Guide, *supra* note 6, at 2.

⁷¹ *Id.* at 11.

⁷² *Id.* at n.13.

⁷³ CEB Compliance & Ethics Leadership Council, *The Next General of Compliance & Ethics Program Effectiveness: From Bolt on to Built In* (2016),

<https://higherlogicdownload.s3.amazonaws.com/GOVERNANCEPROFESSIONALS/a8892c7c-6297-4149-b9fc-378577d0b150/UploadedImages/2016%20Topical%20Pages/CEB-Compliance-and-Ethics-Program-Effectiveness-From-Bolt-On-To-Built-In.pdf>. PwC's 2016 survey reports that 72% of respondents "indicated they have dedicated business unit or business area compliance officers." PwC State of Compliance Study, *supra* note 12, at 12.

⁷⁴ See generally EVALUATION OF COMPLIANCE PROGRAMS, *supra* note 8.

⁷⁵ Danton S. Char, *Implementing Machine Learning in Health Care—Addressing Ethical Challenges*, 378 NEW ENG. J. MED. 981, 981-83 (Mar. 15, 2018). A screening algorithm may, for example, eliminate from consideration employees with an excess of twelve months of unemployment that could implicate Title VII for women who had been on maternity leave and the ADA for individuals seeking treatment for substance use disorder. One can easily imagine the multiple ways that algorithms that include factors that translate into improper considerations could be used in screening patient data for eligibility for insurance, a clinical trial, a patient assistance program, an organ transplant, or even a particular drug or device.

⁷⁶ See Carl H. Coleman, *Ethical Considerations in Selling Pharmaceuticals in Emerging Markets* (June 2017), <https://issuu.com/seton-hall-law-school/docs/whitepaper-ethical-considerations-s?e=19054437/49569732>.

⁷⁷ CENTERS FOR MEDICARE & MEDICAID SERVICES OPEN PAYMENTS, <https://www.cms.gov/openpayments/> (last visited Aug. 24, 2018). Again, data can be used in problematic ways as well. One government official observed in a public address that a risk factor for over-prescribing opioids is whether a physician is an international medical graduate, suggesting that companies should take this into consideration when deciding whether to engage the physician for speakers' bureaus and other such programs—sloppy deployment of such analysis could result in violation of state or federal anti-discrimination laws.

⁷⁸ Deloitte, *supra* note 11, at 13.

⁷⁹ See generally Ethisphere and Convergent, *supra* note 11; Deloitte, *supra* note 11, at 5.

⁸⁰ See generally Malcolm Murray & Barton Edgerton, *Data Analytics Becomes Reality*, CORPORATE COMPLIANCE INSIGHTS (Jul. 18 2017), <http://www.corporatecomplianceinsights.com/data-analytics-becomes-reality/> (discussing the best uses to which descriptive analytics, diagnostic analytics, predictive analytics, and prescriptive analytics might be put for compliance purposes).

⁸¹ 68 Fed. Reg. 23731, 23733

⁸² U.S. SENTENCING GUIDELINES MANUAL, *supra* note 1, ch. 8, introductory cmt. See, e.g., Thomas C. Baxter, Keynote Address: The Changing Face of Corporate Compliance and Corporate Governance, 21 FORDHAM J. CORP & FIN L. 61, 63 (2016) (articulating aspiration for merged Ethics and Compliance departments/officers).

⁸³ A question not specifically addressed by this project, but worthy of consideration, is whether behavioral differences exist between those companies with ethics and compliance professionals versus compliance professionals, and whether the ethical norms of a company are more effectively addressed if ethics resides in a separate entity or is part of the responsibility of compliance. In a 2016 survey of compliance across industries, 9% of respondents' organizations had a Chief Ethics Officer separate from compliance, with 33% of Chief Compliance Officers also responsible for ethics. PwC State of Compliance Study, *supra* note 12, at 13-14. Fifty-six percent of respondent companies lacked a person responsible for corporate ethics. *Id.* at 14.

⁸⁴ See generally Coleman, *supra* note 76.

⁸⁵ See PwC State of Compliance Study, *supra* note 12, at 12.

⁸⁶ See PRACTICAL GUIDANCE, *supra* note 6, at 6-13.

⁸⁷ DeStefano, *supra* note 1, at 72.

⁸⁸ In what has been colloquially referred to as a *Caremark* claim, directors can be held liable for corporate losses predicated upon either (a) a failure to implement any compliance system or controls, or (b) the conscious failure to monitor or oversee such controls, “thus disabling themselves from being informed of risks or problems requiring their attention.” *Stone v. Ritter*, 911 A.2d 362, 370 (Del. 2006); *In re Caremark Int’l Inc. Deriv. Litig.*, 698 A.2d 959, 971 (Del. Ch. 1996). Either situation leads to the conclusion that the directors have failed to discharge their fiduciary obligations in good faith, thereby breaching the duty of loyalty. *Stone*, 911 A.2d at 370.

⁸⁹ When the underlying allegation is that the corporation’s employees have engaged in fraudulent or other illegal conduct, the Delaware Supreme Court has characterized director oversight liability as “possibly the most difficult theory in corporation law upon which a plaintiff may hope to win a judgment.” *Stone*, 911 A.2d at 372 (affirming dismissal of *Caremark* claim for failure to excuse demand because, despite the imposition of \$50,000,000 in fines and civil penalties for compliance program’s failure to detect employee fraud, plaintiffs’ derivative complaint failed to allege particularized facts that created reasonable doubt as to whether the directors had acted in good faith in exercising their oversight responsibilities).

⁹⁰ Bird & Park, *supra* note 1, at 211. For a brief discussion of legal incentives to develop compliance programs prior to the OSG, see David Hess, *Ethical Infrastructures and Evidence-based Corporate Compliance and Ethics Programs: Policy Implications from the Empirical Evidence*, 12 N.Y.U. J.L. & Bus. 317, 325-26 (2016).

⁹¹ Griffith, *supra* note 4, at 2084-85.

⁹² *Id.* at 2085.

⁹³ See Hess, *supra* note 90, at 328; see also SENTENCING GUIDELINES, *supra* note 1, at § 8B2.1(b).

⁹⁴ See SENTENCING GUIDELINES, *supra* note 1, at § 8B2.1(b) (commentary). Of course, in the health care industry, this is largely because settlements generally seek to avoid the entity’s exclusion from the Federal Healthcare Programs.

⁹⁵ See, e.g., Griffith, *supra* note 4, at 2086. Of course, a major reason for the rarity of conviction is the government’s acknowledgement of the tremendously adverse impact on the public of certain entities’ exclusion from the Federal Health Programs, particularly in health care.

⁹⁶ 68 Fed. Reg. 23731 (May 5, 2003).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ U.S. DEP’T OF JUSTICE, JUSTICE MANUAL § 9-28.800 (2018), <https://www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations#9-28.800>.

¹⁰⁰ *Id.*

¹⁰¹ CRIMINAL DIV. OF THE U.S. DEP’T OF JUSTICE, ENF’T DIV. OF THE U.S. SEC. AND EXCH. COMM’N, *A Resource Guide to the U.S. Foreign Corrupt Practices Act* (Nov. 2012), <https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf>.

¹⁰² See, e.g., Organization for Economic Cooperation and Development (“OECD”) Council, *Good Practice Guidance on Internal Controls, Ethics, and Compliance*, (Feb. 18, 2010); OECD, United Nations Office on Drugs and Crime & The World Bank, *Anti-Corruption Ethics and Compliance Handbook for Business* (2013) [hereinafter OECD Handbook].

¹⁰³ See 2 Health L. Prac. Guide § 36:91, *Corporate Integrity Agreements*, Westlaw (2018).

¹⁰⁴ See DeStefano, *supra* note 1, at 111 (“The revised guidelines provide leniency to companies who not only allocate appropriate authority to compliance personnel, but also give them ‘direct access’ to the board of directors.”).

¹⁰⁵ See OFFICE OF INSPECTOR GEN. U.S. DEP’T OF HEALTH & HUMAN SERVICES COMPLIANCE RESOURCES, <https://oig.hhs.gov/compliance/compliance-resource-portal/> (last visited (Aug. 25, 2018)).

¹⁰⁶ See HCCA-OIG Resource Guide, *supra* note 6.

¹⁰⁷ See *id.* at 11.

¹⁰⁸ Leslie R. Caldwell, Assistant Attorney Gen. for the Criminal Div., Remarks at the 22nd Annual Ethics and Compliance Conference (Oct. 1, 2014), <http://www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-22nd-annual-ethics>.

¹⁰⁹ EVALUATION OF COMPLIANCE PROGRAMS, *supra* note 8.

¹¹⁰ *Id.* at 2.

¹¹¹ *Id.* at 3.

¹¹² See Memorandum from Sally Quillian Yates, Deputy Attorney Gen., U.S. Dep’t of Justice, to the Assistant Attorney Gen., Antitrust Div., et al. (Sept. 9, 2015), <https://www.justice.gov/archives/dag/file/769036/download> (“One of the

most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.”).

¹¹³ See HCCA-OIG Resource Guide, *supra* note 6, at 2.

¹¹⁴ See Griffith, *supra* note 4, at 2099 (“...firms in some industries--most notably financial services, pharmaceuticals, and defense/aerospace--are often seen as having more highly developed compliance functions.”).

¹¹⁵ See, e.g., Deloitte, *Navigating the Year Ahead: 2018 Life Sciences Regulatory Outlook* (2017), <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/regulatory/us-regulatory-2018-life-sciences-industry-outlook.pdf>; PwC, *Getting ahead of the watchdogs: Real-time compliance management*, 2018 State of Compliance (2018), <https://www.pwc.com/us/en/risk-assurance/state-of-compliance-study/assets/pwc-2018-state-of-compliance.pdf> (53% of respondents expect an increase in online training over the next three years; 52% of compliance leaders intend to increase dynamic training triggered by compliance monitoring practices); Deloitte, *supra* note 11, at 7 (60% of respondents “expected their total compliance budget to increase” and 48% “expect budgets to increase by as much as 10%, another 8% expect increases of 11%-20%, while only 4% expect increases by more than 20%.”); PWC State of Compliance Study 2016, *supra* note 12 (discussing increased scope of compliance and ethics programs).

¹¹⁶ See Griffith, *supra* note 4, at 2104 (explaining that the differences in compliance programs among varying industries are seen as the “differences in ‘maturity’” of the function of compliance within those industries, which center around common values, for example, “when Wal-Mart came under investigation by federal authorities for paying bribes to foreign officials, it designed an expansive compliance infrastructure similar to that of financial institutions”).

¹¹⁷ See Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Olympus Corp. of the Americas. (Feb. 29, 2016), https://oig.hhs.gov/fraud/cia/agreements/Olympus_Corporation_of_the_Americas_02292016.pdf; U.S. DEP’T OF HEALTH & HUMAN SERV., Corp. Integrity Agreement between the Office of Inspector Gen. of the Dep’t of Health & Human Servs. & Aegerion Pharm., *supra* note 28.

¹¹⁸ See Griffith, *supra* note 4.

¹¹⁹ See Bird & Park, *supra* note 1.

¹²⁰ See *id.* at 205 (explaining one side of the compliance debate, which states that CLOs can present the danger of taking on an “excessively legalistic” approach to the compliance function that would “devalue the role of firm culture that impacts employee behavior.”); see also Philip A. Wellner, Note, *Effective Compliance Programs and Corporate Criminal Prosecutions*, 27 CARDOZO L. REV. 497, 512 (2005) (explaining that the Sentencing Guidelines could lead corporations to implement “window-dressing” compliance programs that allow them to receive reduced criminal sentencing instead of adopting truly effective programs).

¹²¹ See Code of Ethics for Senior Financial Officers, 15 U.S.C. § 7264 (2011).

¹²² See U.S. SENTENCING GUIDELINES MANUAL §8B2.1 (U.S. SENTENCING COMM’N 2004), <https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2004/manual/gl2004.pdf>.

¹²³ See, e.g. PRACTICAL GUIDANCE, *supra* note 6 (explaining that health care boards should take advantage of educational programs that describe how effective compliance and ethics programs operate); see also 68 Fed. Reg. at 23733 (“Although a clear statement of detailed and substantive policies and procedures is at the core of a compliance program, the OIG recommends that pharmaceutical manufacturers also develop a general corporate statement of ethical and compliance principles that will guide the company’s operations.”).

¹²⁴ See HCCA-OIG Resource Guide, *supra* note 6, at 2.

¹²⁵ See *id.* at 2; see also Bird & Park, *supra* note 1; see also Griffith, *supra* note 3 at 2093-94 (“...authorities have recently emphasized the development of policies and procedures that go beyond narrowly applicable rules and regulations and that are designed more broadly to promote a ‘culture’ of compliance.”).

¹²⁶ See, e.g., Lynn Sharp Paine, *Managing for Organizational Integrity*, HARV. BUS. REV., Mar.-Apr. 1994, at 106-117.

¹²⁷ See, e.g., DeStefano, *supra* note 1, at 92 (surveying the literature).

¹²⁸ See generally LRN, *supra* note 12, at 12; see also LRN, *Ethics and Compliance Effectiveness Report* (2016) [hereinafter LRN (2016)] (discussing how the survey and other literature make clear the advantages of a values-based approach).

¹²⁹ See Bird & Park, *supra*, note 1 at 205.

¹³⁰ See Doron Levin, *Volkswagen’s New CEO Must Tackle the “Culture of Arrogance”* FORTUNE, Sept. 27, 2016, <http://fortune.com/2015/09/27/volkswagen-culture-scandal/>; see also Jon Picoult, *What Went Awry at Wells Fargo?*

The Beaten Path of a Toxic Culture, N.Y. TIMES, Oct. 8, 2016, <https://www.nytimes.com/2016/10/09/jobs/what-went-awry-at-wells-fargo-the-beaten-path-of-a-toxic-culture.html>.

¹³¹ See generally, LRN (2016), *supra* note 128 (discussing the advantages of a values-based approach and best practices for implementation).