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Separating compliance and legal: Part 1, Best practices for defining expectations and responsibilities

By Jack A. Rovner

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Part 1 of this article presents cautionary tales that expose how conflicting expectations and responsibilities can reap adverse consequences for the CLO, the CCEO, and the organizations employing them.

Part 2 of this article will review practical considerations why a compliance function separate and independent from legal can and does serve corporate interests and is the “best practice” for an effective corporate compliance program. Part 2 will appear in the February 2020 issue of Compliance Today.

The good reasons are many for keeping the compliance department separate from the legal department and employing a chief compliance and ethics officer (CCEO) as a member of senior management to lead the compliance function independent of the organization’s chief legal officer (CLO) and the legal function. Among the most important reasons are the distinct expectations and responsibilities associated with these functions. The CCEO is expected to be the corporate conscience—vigilant against company officers and employees straying from the ethical; prompt to correct compliance transgressions; and champion of self-disclosure to government regulators, if not to the public. The CLO is the organization’s confidential adviser, expected within the bounds of professional ethics to defend the corporate interest and mitigate corporate exposure to government regulators and the public. Indeed, lawyers’ ethical obligation is to zealously represent their clients’ interests within the bounds of the law.

These distinct expectations and responsibilities, if combined, are fraught with potential conflict. The CLO’s role and responsibilities include furnishing legal advice and guidance to the organization—processes protectable by the attorney-client privilege and focused on minimizing, if not avoiding, organizational risk to legal liability. The CCEO’s role and responsibilities encompass implementing, managing, and overseeing an effective compliance program throughout the organization, and identifying and remediating compliance deficiencies—processes outside the attorney-client privilege that may not be subject to any privilege from disclosure. To avoid conflicting expectations and responsibilities, compliance program “best practice” separates compliance from legal.

The Sulzbach parable—hats clashing

Christi Sulzbach was among the first compliance officers in the healthcare industry. She was also the

associate general counsel—and ultimately the general counsel—of the organization that she was supposed to monitor for compliance. That organization was Tenet Healthcare Corporation, a publicly traded hospital company.

In September 2007, the U.S. attorney in Miami, Florida, sued Sulzbach personally for violating the civil False Claims Act (FCA).^[1] The complaint charged that Sulzbach gave false attestations in 1997 and 1998 that Tenet was in substantial compliance with a corporate integrity agreement.

Sulzbach, as Tenet’s associate general counsel, had negotiated that corporate integrity agreement for Tenet in 1994 to settle government criminal and civil fraud and abuse charges. That 1994 corporate integrity agreement required Tenet to create the compliance officer position that Sulzbach filled.

According to the government’s complaint, Sulzbach received an internal memorandum in February 1997 from a Tenet executive questioning the legality of contracts between a Tenet hospital in Florida and a dozen physicians. The internal memorandum expressed the concern that the hospital’s payments to these physicians appeared to be based on their volume of laboratory referrals to the hospital, in violation of the Stark Law. The Stark Law prohibits a hospital, as a provider of “designated health services,” from billing Medicare or any other payer for services furnished to a Medicare beneficiary referred by a physician with a financial relationship with the hospital, unless an exception applies.^[2] Sulzbach engaged an outside law firm to analyze the hospital’s contracts with these physicians.

The law firm delivered its draft analysis to Sulzbach on June 23, 1997. The law firm opined that the hospital’s payments did not reflect fair market value for the physicians’ services without regard for their laboratory referrals and thus appeared to violate the Stark Law. Four days later—on June 27, 1997—Sulzbach submitted her attestation to the government of Tenet’s substantial compliance with all applicable federal laws, including the Stark Law. This annual attestation from Sulzbach, as Tenet’s compliance officer, was required by the corporate integrity agreement. On June 30, 1997—three days after submitting her attestation to the government—Sulzbach directed Tenet executives to fix the illegal physician contracts. The government’s complaint charged that, though Tenet did not terminate the illegal physician contracts until November 1999, Sulzbach submitted an additional attestation of Tenet’s substantial compliance with all applicable federal laws to the government in June 1998.

Unclear and unspecified in the government’s complaint is whether Sulzbach, in addressing the legally questionable physician contracts in 1997, wore the hat of Tenet’s associate general counsel—within the attorney-client privilege and responsible for developing solutions to mitigate Tenet’s legal exposure, or the hat of Tenet’s compliance officer—outside the attorney-client privilege and responsible for expeditiously correcting and potentially self-reporting Tenet’s compliance problem.

In February 1999, Sulzbach was promoted to Tenet’s general counsel. She remained Tenet’s compliance officer. The corporate integrity agreement expired in mid-1999.

New compliance problems emerged to vex Tenet and Sulzbach. In 2002, the FBI raided Tenet’s hospital in Redding, California, which was under investigation for allegedly performing unnecessary cardiac procedures and surgeries on healthy patients. As general counsel, Sulzbach negotiated resolution of that investigation, with Tenet paying a \$54 million fine. As compliance officer, Sulzbach was supposed to enforce a compliance program to prevent unnecessary procedures and surgeries for profit.

Also in 2002, a stock analyst exposed Tenet management's scheme to inflate earnings by manipulating hospital billings to maximize Medicare "outlier" payments, which are additional payments to Medicare-participating hospitals to cover "extraordinary high cost" care for Medicare beneficiaries.^[3] As general counsel, Sulzbach was responsible for ensuring that Tenet satisfied all Securities and Exchange Commission (SEC) reporting rules and, accordingly, participated in the preparation of Tenet's financial reports and SEC filings. As compliance officer, Sulzbach was responsible for ensuring the accuracy and integrity of Tenet's internal financial data collection and maintenance processes and procedures so that Tenet's financial data and management's description of those data, as reported in Tenet's financial statements and SEC filings, were reliable, complete, and truthful. As holder of substantial Tenet stock options, Sulzbach had financial self-interest in ensuring that Tenet's financial reports and SEC filings enhanced the company's stock market value.

The notoriety of Tenet's multiplying compliance problems resulted in a Senate Finance Committee investigation of Tenet's corporate governance practices with respect to federal healthcare programs. Senator Charles Grassley of Iowa, as Committee Chair, made a document demand on Tenet by letter, dated September 5, 2003. Senator Grassley's letter pointedly questioned the propriety of Sulzbach "wearing two hats as Tenet's general counsel and chief compliance officer." According to Senator Grassley, "It doesn't take a pig farmer from Iowa to smell the stench of conflict in that arrangement."^[4]

Sulzbach resigned from Tenet shortly after Tenet received Senator Grassley's letter. Meanwhile, a *qui tam* FCA action filed in 2000, before Sulzbach's resignation, asserted that the physician contracts of Tenet's hospital in Florida violated the Stark Law. The government intervened and took extensive discovery. Claiming attorney-client privilege, Tenet—under the direction of Sulzbach as its general counsel and compliance officer— withheld from discovery the analysis of its outside law firm that questioned the legality of those physician contracts.

By 2006, new management was running Tenet. The new management included a compliance officer who had been chief counsel for the U.S. Department of Health and Human Services Office of Inspector General. Tenet settled the *qui tam* action with the government, waiving the attorney-client privilege in the process. The analysis of Tenet's outside law firm about the Florida hospital contracts was turned over to the government. The government's FCA case against Sulzbach followed, though too late to avoid dismissal as barred because of the applicable statute of limitations.

The Sulzbach parable is based on the allegations in the government's complaint, filed on September 18, 2007, in the United States District Court for the Southern District of Florida, and on the Order and Opinion of that District Court, entered on April 16, 2010, in *United States v. Sulzbach*, No. 0:07-cv-61329-KAM. The Order and Opinion granted summary judgment dismissing the government's complaint as time barred by the applicable statute of limitations. Hence, the validity of the government's allegations was never tested by trial.

The Sulzbach parable presents a sharp picture of the tensions between the differing roles, responsibilities, and ethical obligations of the CLO versus the CCEO. When Sulzbach engaged the outside law firm to investigate the Florida hospital contracts, what hat was she wearing—CCEO or CLO? Sulzbach (wearing a compliance officer hat in receiving the internal memorandum about her company's potential Stark Law violations) was obligated to investigate, implement corrective action, and press senior management, up to the board, to disclose the legally questionable arrangements pursuant at least to the corporate integrity agreement then in place at Tenet. Sulzbach (wearing a corporate counsel hat in receiving that internal memorandum) was obligated to

maintain the confidentiality of this client communication and of her advice on ways within the bounds of the law for Tenet to mitigate its exposure. That advice would include the legal risks inherent in Tenet making a privilege waiver and corporate disclosure. Trying simultaneously to wear both a legal and a compliance hat did not fit Sulzbach nor suit Tenet.

The Challenger disaster—unmatched hats

Clashing hats can compromise more than legal, compliance, and ethics. The temperature at Cape Canaveral plunged below freezing on January 27, 1986, the eve of the Challenger space shuttle launch. Morton Thiokol Engineering Vice President Bob Lund was reluctant to approve the launch, because Morton Thiokol's O-rings had not been tested in freezing conditions. As an engineer, Lund was subject to a professional code of ethics that directs an engineer to "hold paramount the safety, health, and welfare of the public."^[5] As a corporate executive, Lund had to consider, among other things, the financial, contractual, and performance implications for his company and the national space program of delaying the launch.

Morton Thiokol Senior Vice President Jerry Mason pressed Lund for a decision. Mason asked Lund to "take off your engineering hat and put on your management hat." One Morton Thiokol engineer present at the launch decision meeting summed up the atmosphere as "a meeting where the determination was to launch, and it was up to us [engineers] to prove beyond a shadow of a doubt that it was not safe to do so, [which] is a total reverse to what the position usually is in a preflight conversation or a flight readiness review."^[6]

Lund put on his management hat and approved the launch. The Challenger disintegrated shortly after take-off, killing the seven astronauts aboard. An O-ring in the right solid rocket booster failed.

The Balla bind—more clashing hats

Roger Balla, an attorney, wore many hats for his employer, Gambro Inc., a kidney dialysis equipment distributor. Balla simultaneously served as Gambro's director of administration/personnel, manager of regulatory affairs, and general counsel. As manager of regulatory affairs, Balla was "responsible for ensuring awareness of and compliance with federal, state, and local laws and regulations affecting the company's operations and products."^[7] That effectively made him the company's CCEO.

Balla told Gambro's president to reject a shipment of defective dialyzers from the company's German parent company that did not comply with Food and Drug Administration (FDA) regulations. The president agreed, but a week later reversed that agreement and accepted the shipment of defective dialyzers, because he could sell them "to a unit that is not currently our customer but who buys only on price."

Upon discovering the president's conduct, Balla told the president that he would "do whatever [was] necessary to stop the sale of the dialyzers." The president fired him. Undeterred, Balla informed the FDA about the defective dialyzers. Balla also sued the company for retaliatory discharge. That's when Balla's legal hat got in the way of his retaliatory discharge claim.

The Illinois Supreme Court stressed that Balla, as an attorney, was ethically "required under the

Rules of Professional Conduct to report [to the FDA] Gambro's intention to sell the 'misbranded and/or adulterated dialyzers'" to protect the public from "death or serious bodily harm to patients." Nonetheless, given that Balla "was not just an employee of Gambro, but also general counsel of Gambro," the Court dismissed his claim, because it declined to apply "the tort of retaliatory discharge to in-house counsel."

Balla may have had the personal and professional satisfaction of acting ethically, but his many hats cost him his job without recourse for acting ethically. Would the situation have been different if Balla had only been Gambro's manager of regulatory affairs, a position previously held by a non-lawyer? Perhaps, though the Court did not address that question. According to the Court, Balla's "two roles...were so intertwined and inextricably bound," there was no way that Balla "was not performing his general counsel functions in this matter."

That Balla's retaliatory discharge claim may have survived if he served only the non-lawyer function of manager of regulatory affairs is suggested by the dissent; the dissenter stressed, "where doing 'the right thing' will often result in termination by an employer bent on doing the 'wrong thing,'...the incentive needed is recognition of a cause of action for retaliatory discharge." If Balla served only as the compliance officer, with the substantial threat of a valid retaliatory discharge claim if his employer fired him for doing his compliance job, just maybe the wayward president, rather than the ethical Balla, would have been the one to lose his job.

Wayward compliance—right hat worn wrongly

Wearing one hat won't bring compliance, but it may encourage the compliance officer to do the job and, unlike corporate counsel, have legal recourse if that brings resistance or retaliation. That's because compliance serves a public policy function and implements an organization's pledge of ethical business conduct without the muddle of the ethical principles that apply to lawyers. As explained by the federal judge, who sentenced a compliance officer to six years' imprisonment for failing to do his compliance job:

[C]ompliance officers are very much today's corporate "fire personnel." They are often the company's "first responders" and must focus on both proactive and reactive efforts to be effective. Proactive efforts need to emphasize the complimentary goals of crime prevention and corporate ethical behavior. Reactive efforts measure how well a corporation reacts when it learns that questionable and potentially illegal corporate conduct has occurred.^[8]

That compliance officer was found wanting in monitoring the compliance of the company—a medical device manufacturer—with its obligation to report untoward outcomes to the FDA. The compliance officer capitulated to management pressure, that there was insufficient evidence that the company's device may be causing patient injuries, despite mounting contrary reports from hospitals.

Corporate counsel may legitimately be able to interpret and advise management that the FDA reporting rules allow the company to withhold information regarding untoward outcomes until there is "sufficient" evidence to establish that the company's device was the cause, and to have that interpretation and advice cloaked in privilege. But a compliance officer—at least as one court sees it—is tasked with pressing for reporting, because erring on the side of patient safety is "the right thing to do" that overrides legal niceties. Indeed, the Code of Ethics for Health Care Compliance Professionals—and this wayward compliance officer was indeed a healthcare compliance

professional—directed that he resist management’s pressure to the point of resignation, followed by report “to public officials when required by law,” because the CCEO’s duty “goes beyond other professionals,” being a “duty to the public [that] includes prevention of organizational misconduct.”^[9]

If this medical device manufacturer had had a CLO of Balla’s integrity, perhaps the manufacturer’s CCEO would have taken comfort and cover under that integrity to stand up to management “bent on doing the ‘wrong thing.’” Then with compliance and legal working together for the “right thing,” management, too, may have felt no option but to also do the “right thing.”

Part 2 of this article will appear in the February 2020 issue of Compliance Today.

Takeaways

- Compliance “best practice” separates an organization’s compliance function from its legal function.
- Real world cautionary tales show why to avoid the inherent conflict between the roles, responsibilities, and expectations of compliance versus legal.
- Compliance serves a public function, favoring transparency in enforcing an organization’s pledge of ethical business conduct.
- Legal serves a private function, operating under the obligation to maintain client confidences in protecting the organization’s interests within the bounds of the law.
- Compliance and legal must cooperate, coordinate, and complement each other to work in tandem for the best benefit of the organization they serve.

131 U.S.C. §§ 3729-3733.

242 U.S.C. § 1395nn.

3 Reed Abelson, “Tenet Faces Agency Audit of Payments for Medicare,” *The New York Times*, November 7, 2002, <https://nyti.ms/2NgLm6a>.

4 “Grassley Investigates Tenet Healthcare’s Use of Federal Tax Dollars,” news release, September 7, 2003, <https://bit.ly/345hiB6>.

5 National Society of Professional Engineers, “Fundamental Canon: 1,” *Code of Ethics for Engineers*, July 2019, <https://bit.ly/2PqDAcD>.

6 NASA, *Report of the Presidential Commission on the Space Shuttle Challenger Accident*, Ch. V, p. 93 (testimony of Morton Thiokol Engineer Robert Boisjoly), 1986, <https://go.nasa.gov/2PrrXlR>.

7 Balla v. Gambro, Inc., 145 Ill.2d 492, 496, 584 N.E.2d 104, 106 (1991).

8 United States v. Caputo, 456 F. Supp. 2d 970, 985 (N.D. Ill. 2006), affirmed in part, vacated on restitution amount, 517 F.3d 935 (7th Cir. 2008).

9 SCCE & HCCA, *Code of Ethics for Health Care Professionals*, R1.4 and Commentary, <https://bit.ly/2NjIwNN>.

Compliance Today – February 2020

Separating compliance and legal, Part 2: Best practices for an effective compliance program

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Part 1 of this article (published in the January 2020 issue of *Compliance Today*) explored cautionary tales that illustrate the peril to effective compliance programs of assigning the compliance function to the organization's chief legal officer (CLO), instead of engaging an independent chief compliance and ethics officer (CCEO) as a senior executive in charge of compliance.

Part 2 reviews practical considerations why a compliance function separate and independent from legal is the “best practice” for serving an organization's interests and success. Part 2 examines the federal health industry regulators' views on separating compliance from legal, and explains why cooperation and collaboration between separate, but equal, compliance and legal leadership put an organization on a solid foundation for legal and ethical conduct. Part 2 closes with “Murphy's List” of 10 concrete reasons for keeping compliance separate from legal. The goal is to stimulate organizations in general, and especially those operating in the healthcare sector, to give careful consideration to how best to structure their compliance and legal functions to optimize these critical components of an ethical, successful enterprise.

The government's view—Don't mix hats

The federal government, through the Centers for Medicare & Medicaid Services (CMS), operates the Medicare Advantage (MA) program as an alternative means for Medicare beneficiaries to obtain their Medicare health benefits. To make MA plans available, CMS contracts with private health insurance companies. These insurance companies, called MA organizations, are required by applicable CMS regulations to adopt and implement an effective compliance program. This Medicare regulatory mandate includes designation of “a compliance officer...who report[s] directly and [is] accountable to the organization's chief executive officer or other senior management.”^[1]

CMS guidance for MA organizations expresses strong preference that the CCEO and compliance function be separate and independent from the CLO and the legal function. CMS's *Medicare Managed Care Manual* specifies that “[t]he compliance officer should be independent [and] not serve in both compliance and operational areas (e.g., where the compliance officer is also the CFO, COO or GC)”;^[2] the reason is to avoid “self-policing in the operational area(s),” which can create “conflict of interest.”^[2]

To be clear, neither CMS regulations nor guidance directs that the mandated CCEO cannot be, or be

subordinate to, an MA organization's CLO. CMS guidance acknowledges that, although an MA organization "must ensure that reports from the compliance officer reach the [organization's] senior-most leaders (typically the CEO or president)," that "direct reporting relationship between the compliance officer and the senior-most leadership refers to the direct reporting of information, not necessarily to a supervisory reporting relationship"; consequently, the required direct reporting "can be accomplished through a dotted line or matrix reporting."^[3]

These comments reflect government recognition that "one size won't fit all" and, hence, there is no one "correct" compliance structure. What matters is that the compliance structure adopted and implemented be "effective" and have "measures that prevent, detect, and correct non-compliance with CMS's program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse."^[4]

Perhaps for smaller or more resource-constrained organizations, combining compliance with legal may be the only practicable solution. But if the organization has the resources, there appears to be a better choice. As CMS sees it, the compliance officer "must have express authority to provide unfiltered, in-person reports to the sponsor's senior-most leader [without first being] routed...through operational management such as the COO, CFO, GC...or other executives responsible for operational areas." To protect that authority, CMS argues that "best practice [will] allow the compliance officer to meet in Executive Session with the [organization's] governing body [i.e., the board]."^[5]

CMS's preference for compliance independent from legal has been implemented by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. In corporate integrity agreements (CIAs) that resolve federal fraud and abuse and False Claims Act cases, OIG has shown willingness to impose the separation of compliance from legal. In the 2009 CIA with drug-maker Pfizer, which settled (for \$2.3 billion) fraud and abuse and False Claims Act charges of illegal off-label prescription drug promotion, OIG required that Pfizer have an executive-level "Chief Compliance Officer [who] shall not be, or be subordinate to, the General Counsel or Chief Financial Officer." The requirement that the "Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer" has generally become the standard for OIG's CIAs.^[6]

OIG's chief counsel at the time of the Pfizer CIA explained that this CIA requirement, which removed Pfizer's compliance function from under its general counsel, was "intended to eliminate conflicts of interest, and prevent Pfizer's in-house lawyers from reviewing or editing reports required by" the CIA. The reason for this separation is that "lawyers tell you whether you can do something, and compliance tells you whether you should."^[7]

OIG's CIAs also generally mandate that the "Chief Compliance Officer shall be a member of senior management..., shall report directly to the Chief Executive Officer..., shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors..., and shall be authorized to report on such matters to the Audit Committee at any time."^[8] The OIG CIAs mandate that the CCEO be "a member of senior management" reporting directly to the CEO and the board, which mirrors CMS guidance for MA organizations that "[i]t is best practice for the compliance officer to be a member of senior management" so that the chief compliance officer can "raise compliance issues without fear of retaliation."^[9] No Balla Bind here (for definition, see Part 1 of this article).

Compliance best practice—Collaborating hats

The CCEO and the compliance function should—indeed, must—work in close, constructive collaboration with the CLO and the legal function. That collaboration can enable the CCEO to enlist the investigative aid and tools of the organization’s legal function to gather evidence to determine whether there has been a compliance deficiency. The CCEO will then have the facts to decide whether and how to report and remedy the issue.

Separately, the investigative capabilities of the legal function can enable the CLO to advise the organization’s senior management and board of directors within the scope of the attorney-client privilege of potential legal liability exposure and the means to manage and mitigate that exposure. Among the benefit of separating the compliance and legal functions is that, when advising management and the board, there should be no ambiguity that the CLO is acting as the organization’s attorney providing privileged advice, and not as the organization’s CCEO reporting compliance deficiencies and their remediation outside the attorney-client privilege. Put differently, it avoids the Balla Bind and the Sulzbach Parable (see Part 1 of this article) and frees the compliance officer to do the compliance job, secure in legal protection from retaliatory firing.

Murphy’s List—Fit the hat to the job

Long-time compliance consultant and attorney Joe Murphy^[10] provides a “top ten” list of reasons the CLO ought not also to serve as the CCEO. Joe Murphy presented this list at a meeting of the Chicago Regional Business Ethics Network on February 10, 2009. His list of reasons appears below as numbered subheads. (My explanations for these reasons are provided in plain text; I alone am responsible and accountable for the explanations.)

1. Lawyer as witness

If the CCEO is also the CLO, the company’s lawyer may have to become a company witness if the company needs to present the facts about its compliance program, its investigative process of potential compliance failures, or its corrective action. A lawyer usually cannot be both a fact witness and legal counsel for the organization that the lawyer represents. Moreover, lawyer-as-witness usually puts the attorney-client privilege at risk. The CCEO, who is not also acting as corporate attorney, can testify as an organization’s fact witness, and doing so would not put the attorney-client privilege at risk.

2. Loss of privilege

If the CCEO is also the CLO, uncertainty about the hat that person wears when investigating and advising on compliance problems could put the attorney-client privilege at risk. Consider the Sulzbach Parable and the Balla Bind—was Sulzbach’s direction to Tenet management to fix the physician contracts privileged advice of the CLO or the corrective action of the CCEO? Was Balla’s urging not to accept the defective dialyzers privileged legal advice or a nonprivileged compliance directive?

3. Mandatory “Miranda” warning

The CLO investigating compliance problems needs to be upfront in witness interviews of company officers and employees that counsel represents the company, not these individuals. The CLO may even need to caution the officer or employee to obtain the advice of a lawyer who represents the officer or employee. A CCEO faces no such obligation when conducting witness interviews, unless the CCEO is acting under the direction and on behalf of the CLO (a situation in which the CCEO is essentially carrying out a legal function). The reason is a CCEO, not acting for the CLO, provides no basis for an individual officer or employee to assume the CCEO is acting in a legal capacity or represents anyone other than the company.

4. Management skills, not legal skills

Compliance takes management skills—the ability to develop and implement policies, procedures, training, and processes that nurture a “culture of compliance” and persuade officers and employees of the value of ethics and integrity to business success. Compliance is expected to develop and execute programs of audit and oversight to monitor compliance on an ongoing basis. And compliance is ethically bound to act to correct compliance deficiencies. These are skills and roles not generally expected of lawyers. Rather, lawyers are “problem-solvers” and “risk mitigators” who give advice on how to act within the bounds of the law, rather than taking action themselves. Lawyers are expected to interpret and advise on the law and are not usually expected to be champions for “doing what’s right” versus “doing what’s legal.”

5. Just the usual legal business

Compliance is ethics, culture, and vigilance. Compliance is not just “legal stuff.” Compliance is the process of deciding the “right thing” when an issue may be in a legal grey area. The CLO could, within the bounds of legal responsibilities, explain the options for determining when, under applicable FDA regulations, the organization had “sufficient” grounds to require reporting of the Gambro’s devices’ apparent problems, but a CCEO, getting reports of patient injuries, would be ethically bound to act to get the organization to “do the right thing” and alert the FDA in case immediate remedial action may be required.

6. Ethics, not just law

Compliance is about ethics and ethos—doing the “right thing” because the “right thing to do” is the corporate culture. Compliance reflects a value judgment that ethics and integrity are good business and good for corporate prosperity. Law is about conforming conduct to statutory and regulatory rules. Legal interpretation is about line-drawing between the lawful and unlawful and divining the shades of grey in between. Compliance kicks in where law leaves off. “Law” permitted Morton Thiokol management to decide to approve the Challenger launch; “compliance,” in the form of engineering ethics, argued to scrub the launch.

7. Legalistic approaches

Lawyers are called upon to find legal means for accomplishing their clients’ objectives. This often requires interpretation of legal niceties and application of law to facts for which established legal standards do not always fit well. Compliance is about keeping an organization on the straight and narrow, sticking to its corporate ethos as captured in its code of ethical business conduct, and doing the “right thing” even when law may appear to allow other choices. When the CCEO is also the CLO, an organization may be sending confusing signals to officers and employees that compliance is just

“legal stuff.”

8. More than giving advice

The CCEO is expected to provide an ethical compass for doing “what is right.” Compliance operates hotlines/helplines as “safety valves” for corporate officers, employees, and others to anonymously seek ethical guidance and report ethical (if not legal) concerns. Compliance is expected to investigate and to act to remedy divergence from the corporate ethos. The CLO is usually expected to provide legal advice without moralistic overtones. The CLO receiving reports of legal concerns is generally obligated to disclose the reports and the reporters to the client—the company (i.e., senior management or the board)—and usually cannot assure anonymity to reporters. The CLO’s duty to the client is one of the reasons that corporate counsel should caution people who report compliance concerns that counsel represents the company and has no obligation of confidentiality to the reporters. The CCEO may want to provide the same caution, and must do so if acting on behalf of the CLO, but otherwise does not face the assertion that the person who reported compliance concerns “believed” the CCEO was acting as the reporter’s lawyer who is obligated to maintain the reporter’s confidences.

9. Not everyone calls a lawyer

Employees and others may be willing to seek compliance guidance from and disclose compliance concerns to the CCEO—particularly if the corporate code of business ethics assures anonymity. They may be reluctant to share their compliance concerns with the CLO. That’s particularly true if they understand or are properly cautioned that the CLO owes a professional duty to the client—the company—to disclose to senior management or the board a reported compliance concern and the reporter of it.

10. More than putting out fires

Legal problems usually involve discrete projects, such as commercial transactions, contract disputes and other controversies, personnel issues, or statutory and regulations construction. Legal issues all too frequently arise as emergencies, if not raging fires, that need to be contained and extinguished. Compliance is much more than firefighting and emergency response. Effective compliance is every day, every way—a continual corporate program of persistent vigilance involving ongoing training, monitoring, oversight, and process improvement.

Conclusion

Their distinctive roles and responsibilities, regulatory mandates, government guidance, and best practice borne of experience—all argue for the CCEO and compliance function to be independent of the CLO and legal function. The need for compliance independence is rooted in avoiding the potential conflict between the CLO’s duties of providing privileged legal advice on the organization’s legal obligations and potential legal exposures, and the CCEO’s duties of implementing and monitoring compliance with the organization’s code of ethical business conduct and preventing, detecting, and correcting compliance deficiencies.

Murphy’s List, the Sulzbach Parable, the Balla Bind, and the Challenger disaster—each argues for compliance separate from legal and a CCEO separate from the CLO. Assuredly, an organization’s

legal and compliance functions must be closely coordinated and work interactively. But their roles and responsibilities differ markedly. Legal is tasked with advising on what the law requires; compliance is tasked with pressing for “what is right.” Keeping these very different roles and responsibilities separate enables compliance and legal to perform their distinct functions with integrity and effectiveness—to the best benefit of the organizations they serve.

Takeaways

- Compliance “best practice” separates an organization’s compliance function from its legal function.
- Real world cautionary tales tell why—to avoid the inherent conflict between the roles, responsibilities, and expectations of compliance versus legal.
- Compliance serves a public function, favoring transparency in enforcing an organization’s pledge of ethical business conduct.
- Legal serves a private function, operating under the obligation to maintain client confidences in protecting the organization’s interests within the bounds of the law.
- Compliance and legal must cooperate, coordinate, and complement each other to work in tandem for the best benefit of the organization they serve.

¹ 42 C.F.R. § 422.503(b)(4)(vi)(B).

² CMS, *Medicare Managed Care Manual (MMCM)*, Pub. 100-16, Ch. 21 § 50.2.1 (January 11, 2013), <https://go.cms.gov/2OXuGCM>.

³ CMS, *MMCM*, Ch. 21, § 50.2.1.

⁴ 42 C.F.R. § 422.503(b)(4)(vi).

⁵ Office of Inspector General, U.S. Dep’t of Health & Human Services, Ass’n of Healthcare Internal Auditors, American Health Lawyers Ass’n & Health Care Compliance Ass’n, *Practical Guidance For Health Care Governing Boards On Compliance Oversight* 10 (April 20, 2015), <https://bit.ly/2DThYyM>.

⁶ OIG, *Corporate Integrity Agreement between OIG and Pfizer, Inc.* § III.A.1 (Aug. 31, 2009) (hereinafter *Pfizer CIA*).

⁷ Jim Edwards, “Pfizer’s Lawyers Play Musical Chairs in Wake of Bextra Settlement,” *CBS News MoneyWatch*, September 23, 2009, <https://cbsn.ws/389KEBf>.

⁸ *Pfizer CIA*, *supra* n. § III.A.1.

⁹ CMS, *MMCM*, *supra* n. 2, Ch. 21 § 50.2.1.

¹⁰ See www.joemurphyccp.com.