4 Lessons Learned from Corporate Integrity Agreements: A Roadmap to Effective Compliance
Not so long ago, headline news from the Life Science industry celebrated new medical treatments and discoveries. But in the past few years, and notably in more recent times, these headlines have focused on fraud and abuse. Swirling around them all were acronyms (most notably FDA, SEC, DOJ, FCPA and FCA) and allegations that stretched from off-label marketing and kickbacks to defrauding government-run health plans. There is zero likelihood that enforcement agencies will lose their appetite for investigating the Life Science industry.

Those attending a recent Pharma Congress heard Assistant US Attorney General Lanny Breuer promise a laser focus on the industry. He pointed out that the United States and international enforcement agencies were building a united front against bribery and corruption through shared information and investigations. He didn’t stop there. The US Department of Justice’s (DOJ) interest in the Pharmaceutical industry, according to Breuer, extended beyond its early target areas of illegal payments to regulators for approvals, to government employed doctors and hospital committees for drug/device purchases, and to sales agents for illegal sales. The DOJ will continue to investigate and prosecute those old standbys, but the newest, and potentially greatest trigger for DOJ attention centers on payments by the industry to foreign doctors conducting clinical trials abroad.

To outside observers, the fines and penalties represent the most significant feature of settlement agreements. From inside the industry, the accompanying Corporate Integrity Agreement (CIA) or Deferred Prosecution Agreement (DPA) presents as much, or more, of a challenge. A typical five-year CIA imposes high costs, oftentimes the presence of an outside monitor, compliance demands that permeate every aspect of a company’s operation and 24/7 vigilance.

Key provisions of recent CIAs create a road map to compliance before violations or enforcement actions occur. In this paper, we look at four of the most frequent provisions – and what companies should implement as core elements of a robust compliance program.

4 Lessons Learned from Corporate Integrity Agreements: A Roadmap to Effective Compliance

By Ellen Leinfuss, SVP, Life Science, UL EduNeering
1: Understand the Term “Covered Person”

The idea that companies are responsible only for the actions of their employees has been dismissed by CIAs, reinforcing the familiar admonition repeated by the FDA and other enforcement agencies: “Ultimately, the brand company is responsible ...” While proposed legislation and the FDA's current risk-based approach emphasize the role of the supply chain in product quality and regulatory compliance, CIAs have taken a hard edge to defining the individuals who are responsible for establishing and maintaining an effective compliance program across the entire enterprise.

CIAs typically designate officers, directors and employees as “covered persons” but recent agreements for Life Science companies have significantly expanded the definition of covered persons. In addition to the routine designation of employees inside the United States as covered persons, recent CIAs specifically included employees based outside the US who have responsibilities relating to promotional functions or product-related functions. Additional categories of covered persons point to the critical liabilities Life Science companies have from “third parties.” One recent CIA provides unambiguous clarification of these covered third parties:

- “Third party personnel” means personnel of the entities with whom the company has or may in the future enter into agreements to co-sell or market a “government-reimbursed product” in the United States or to engage in joint sales and marketing activities in the US.
- “Arrangements covered parties” includes each covered person involved with the development, approval, management or review of the company’s arrangements. “Arrangements” means every arrangement or transaction entered into, by or on behalf of the company that involves, directly or indirectly, the offer, payment, solicitation or receipt of anything of value and is between the company and any actual or potential source of US Health Care business. Among those “sources” any US Health Care Provider, Health Care institution, physician, contractor, vendor or agent.

Effective Actions:

Companies should develop, distribute, test and document training for all “covered persons” targeted to their specific job functions, responsibilities and compliance requirements. As the DOJ and Securities Exchange Commission (SEC) increase prosecution of individuals for actions committed by people “under their control,” the pressure is on senior and middle managers to fully understand and fulfill their compliance responsibilities.

Overall, companies must conduct risk assessments to determine where their compliance liabilities are (whether in their interactions with Health Care Professionals (HCPs) or in the oversight of subsidiary compliance) and address these vulnerabilities to demonstrate appropriate effort to assure compliance of all covered persons. Even though most CIAs identify “covered persons” by their areas of responsibility (for example, advertising, promotion and financial recordkeeping), companies should take the opportunity to review all compliance programs and target specific training or compliance remediation to specific roles based on risk assessment criteria.

LESSONS LEARNED:

Realistically, no company can guarantee complete compliance throughout its entire enterprise and supply chain, but it can establish robust supports for compliance: the policies; auditing and risk mitigation structure; and the all-important tone, not only at the top but also throughout the middle ranks.

The compliance challenge is heightened by global operations, lengthy supply chains, outsourced business functions and complex corporate relationships. The DOJ is now using additional tools, from tax evasion and mail fraud to the 50-year old Travel Act. It is important for Life Science companies to recognize that the Food, Drug and Cosmetic Act (FD&C) is only one of the compliance risks affecting the industry. In fact, the largest settlements in 2010 where to resolve False Claims Act charges, not the underlying FD&C violations.
Established compliance programs often fail to empower the CCO with the authority, responsibilities and resources to develop and manage an effective compliance program. Equally important, they fail to create an infrastructure that enables corporate officers to fulfill their responsibilities for compliance oversight. Simply designating a CCO is insufficient.

The CCO must have clearly defined responsibilities; the authority to interact directly with corporate officers; and the resources to develop, implement, monitor and report on all corporate compliance activities.

**2: Establish a Corporate Structure for Compliance Responsibility**

Even though many companies will have appointed Chief Compliance Officers (CCOs) prior to entering a CIA, provisions of the agreement are likely to require a greater specificity about the position. In a recent CIA, a company describes the CCO as a member of senior management who reports on compliance directly to the Chief Executive Officer, reports to the Board of Directors or a Committee of the Board at least quarterly, and retains authority to report on related matters to the CEO and Board at any time. “The Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer.” In addition, any noncompliance job responsibilities of the CCO must be limited and not interfere with his or her ability to perform duties outlined in the CIA. Responsibilities of the CCO include:

- Oversee compliance of the company’s operations with federal health care program and FDA requirements as well as all requirements of the CIA;
- Develop and implement policies, procedures and practices to ensure compliance;
- Monitor day-to-day compliance activities and any CIA required reporting obligations.

The CIA also requires a US Compliance Committee be established that includes, at a minimum, the CCO and other members of senior management. The CCO will chair the committee, which will support the CCO in fulfilling his or her responsibilities under the CIA. For example, the committee will assist in the analysis of the organization’s risk areas and oversee monitoring to maintain compliance.

**Effective Actions:**

Companies should review the job responsibilities and authority assigned to the CCO position, ensuring that he or she has direct access to the CEO and Board of Directors, that the CCO is provided with adequate resources to develop and implement an effective compliance program, and that the CCO establishes a system for mandated recordkeeping and reporting of compliance activities.

The CCO should oversee or have dotted-line responsibility for other compliance functions, such as quality, supply chain, clinical and sales. This span of control is of increasing importance in managing global compliance functions, which should be grounded in consistent policies and procedures, localized where appropriate.

Recently, some CIAs have designated Board members, CEOs, Executive Vice Presidents of specified business units, Chief Medical Officers and Directors of business units and departments as “certifying employees,” meaning they must all certify in writing that they believe their business units or organizations comply with all compliance requirements. All “certifying employees” must be trained on these compliance requirements and assure that their staff is trained and performing their jobs in a compliant manner.
3: Rewrite, Renew and Reinforce Your Company’s Code of Ethics

Most companies claim to have strong Codes of Conduct or Codes of Ethics, some of them recognized as industry standards. Yet, CIAs routinely commit companies to “develop, implement and distribute a revised written Code of Conduct that reflects the most recent health care compliance requirements.”

These new codes typically must include the following provisions:

- The company’s commitment to full compliance with all applicable regulations and requirements (including those contained in the CIA);
- The company’s expectation that any suspected violation of regulations and the company’s policies and procedures be reported to the appropriate individual;
- The company’s assurance of confidentiality and anonymity (“as appropriate”) related to reports of potential violation and its commitment to nonretaliation.

These provisions are not unusual or unexpected, but some companies are required to go beyond them. In addition to making the Code available and requiring new employees to certify their receipt and understanding of the Code, one company agreed to make the promotion of “…adherence to the Code of Conduct an element in evaluating the performance…” of all covered employees. The company’s revised Code will also emphasize the “potential consequence” to the company and covered persons from the failure to comply with regulations and the company’s own policies and procedures — including the failure to report such noncompliance.

A parallel provision in most CIAs is the development and distribution of policies and procedures for compliance with applicable regulations. Typically, the provision will emphasize policies and procedures in business areas that were investigated by the DOJ. More recently, CIAs have required a long list of policies, ranging from distribution of marketing materials to guidelines for hiring HCPs, funding for third party education and sponsorship of grants and charitable deductions. Many organizations now use their Learning Management System (LMS) to manage and distribute HCC policies, similar to how they manage manufacturing SOPs.

Effective Actions:

Building a stronger ethical culture within your company is an ongoing and multi-faceted process. This requires a new skill set with concepts that must be taught, awareness levels that must be met, and competencies that must be measured and sustained throughout the organization. Adoption of these new skills is best accomplished through a multi-year program anchored in the revised Code of Conduct and deepened through topics such as Raising and Resolving Ethical Issues and Ethical Decision-Making.

Companies should review their existing Codes and revise them when necessary to ensure they adequately express the company’s commitment to ethics and compliance, establish a zero-tolerance policy to ethical misconduct, set

(continued...)
The described CIA highlights several important lessons. First, training follows a stepped approach, with each segment building on the foundation of the knowledge gained in earlier courses. Second, training is ongoing, which allows continual reinforcement along with increased knowledge. Third, the requirements and expectations of each training segment are clearly defined, giving managers clear tools in determining its effectiveness or inadequacies. Finally, training targets the specific knowledge needs of individual groups of learners (role-based training).

As a result, employees receive relevant training, maximizing the effective use of corporate resources and minimizing the potential for employees to “tune out” of training that has little applicability to their jobs or knowledge needs.

Effective Actions (continued):

expectations that potential violations will be reported, and prohibit all retaliation for reporting. All contracts should be reviewed to ensure that they reflect the principles and requirements contained in the company’s revised Code. Training on the Code should be conducted for employees and third parties. Companies should remember: once is not enough and limited new-hire training is inadequate to produce enterprise-wide compliance with high ethical standards. Finally, Code of Conduct training must be continually reinforced through follow-up training, regular communications and visible actions at all management levels.

4. Implement Robust Training Programs for Employees and Third Parties

Training is a common denominator of all CIAs, but not all CIAs contain the same requirements. In fact, recent CIAs show a growing trend of expanding training requirements, both general and specific. One recent CIA illustrates the evolving thinking of enforcement agencies and regulators toward settlement requirements. The company entered into a nonprosecution agreement with the DOJ to resolve issues related to the import of products and post-market studies. In a separate action, the company entered into a civil settlement agreement related to a separate federal investigation. The resulting CIA has a significant training requirement that showcases a growing enforcement trend.

Components of the training program include:

- At least two hours of general training to covered persons that explains, at a minimum, requirements of the CIA and the company’s compliance program, including the Code of Conduct and policies and provisions as they relate to general compliance issues.
- At least four hours of training for covered persons involved in promotional and product services-related functions, with topics targeting the relevant federal health care program and FDA requirements; the company’s policies and procedures; the personal obligation of each individual to comply with regulatory and company requirements; the legal sanctions for violations of the federal health care program and FDA requirements, the False Claims Act (FCA) and the Anti-Kickback Statute; examples of proper and improper practices; and the possible consequences to the company and individual from failure to comply with all relevant regulations (and failure to report such noncompliance). After this initial training, each relevant covered person will take at least three hours of specific promotional and product services-related training in each reporting period.
- At least four hours of specific clinical investigation and reporting training for all relevant clinical investigations and reporting covered persons in addition to the general training. After this four hours of initial training, all relevant covered persons
are required to take at least three hours of specific clinical investigation and reporting training in each subsequent reporting period.

• Following training, each covered person must certify in writing or electronic format that he or she has received the required training, specifying the type of training and date received.

An interesting aspect of the company’s CIA is the requirement that the work of a newly designated covered person (whether new hire or current employee) must be reviewed by an individual who has successfully completed the relevant training – until the new person completes the required training. This system of checks-and-balances not only ensures compliant work but also promotes a culture of mutual accountability for the compliance of the group, facility or company.

Avoiding Costly Lessons

Companies under corporate integrity agreements are already experiencing the consequence of failed compliance policies, programs and procedures. For at least the period of the CIA, they will be subject to oversight by monitors, scrutiny by regulators and often, suspicion by the public. Those same CIAs offer the rest of the industry guidance about enforcement trends, regulatory expectations for effective compliance and industry-wide risk areas. The price of the guidance is already being paid by the company shouldering the CIA. Other Life Science companies can avoid paying the same price by heeding the lessons learned from recent CIAs.

**Effective Actions:**

Companies should review their training programs and make changes where necessary. Questions that need to be asked – and answered – in a useful review process include the following:

- **YN** Are training courses and materials up to date, reflecting the most current regulatory and company requirements?
- **YN** Do online courses use effective instructional techniques that engage learners and promote learning?
- **YN** Do tests accurately measure the learner’s knowledge about the subject matter?
- **YN** Are courses sequential, each one increasing knowledge by building on previous courses?
- **YN** Is content relevant to the end user?
- **YN** Training should be targeted to specific user groups, segmented by job function, location, skill set, and most important, compliance risk. Do trainers (including online training contractors) have a depth of understanding about the topic, particularly current regulatory standards and requirements?
- **YN** Is there an effective recordkeeping system that documents the courses taken by each individual; certification from the covered person; real-time status of each employee’s training and any potential problem areas, such as frequent failures of employees in one facility or department to pass required tests in the first attempt? Remedial training should be readily available for distribution upon recognition of any sign of inadequate training effectiveness.
- **YN** Is the training producing the required behavior change? In other words, is it effective? Is there increased reporting of potential misconduct? Has communication improved between the CCO and company officers? Are there fewer complaints from customers or clinical study participants? Are employees and third parties getting the message that noncompliance will not be tolerated – and are they showing improved compliance with the standards, regulations and expectations of the company?
About UL EduNeering

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