Increased Scrutiny Leads to Renewed Focus on the Essentials of Compliance

June 28, 2013
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A couple months ago the United States Department of Justice and the U.S. Attorney's Office for the Southern District of New York filed separate lawsuits against an international pharmaceutical manufacturer for violations of federal anti-kickback statutes and the False Claims Act. While these lawsuits allege illegal actions by the pharmaceutical firm's sales and marketing teams — providing cash incentives to pharmacies for switching patients to its products and providing lavish meals and other non-educational activities to healthcare providers — almost every function of the pharmaceutical industry is under increased compliance scrutiny these days. Lawsuits like these should serve as a wake-up call, not just to pharmaceutical sales and marketing teams, but to anyone involved in quality assurance and compliance programs for the pharmaceutical and medical device industries. Firms engaged in inadequate quality management and compliance programs could just as easily find themselves facing federal charges.

Regardless of the outcomes of the lawsuits, the cost of defending them and the reputational damage caused by them will be significant. If that's not enough to get your attention, consider this: Individual employees of the firm — senior executives and mid-level managers alike — could face criminal charges. As we said, it's a wake-up call for the industry and those of us who work in it.

The Essentials of Compliance

In this environment of increased scrutiny, now is a good time to refocus our efforts on quality assurance and compliance. The best place to start is with guidance published by the U.S. Department of Health & Human Services Office of Inspector General (OIG) more than 10 years ago. The guidance published in May 2003 established the seven essential elements of an effective pharmaceutical and medical device compliance program. These elements are:

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 detected problems and undertaking corrective actions.

The OIG recognized that not all companies have the same resources available to them and establishing the above systems is more difficult for some organizations. According to the 2003 guidance, "Some pharmaceutical manufacturers are small and may have limited resources to devote to compliance measures. The compliance measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience)."

The above systems, as well as a clear message of an expectation of compliant behavior from the board of directors and executive team, should reduce risk of inappropriate behavior at all levels of the organization without impeding an entrepreneurial spirit. Nevertheless, it is possible that rogue behavior may occur in spite of a firm's best efforts. The OIG guidance document "recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer. However, a good faith effort by the company to comply with applicable statutes and regulations as well as federal health care program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties."

Beyond Compliance

While the OIG's seven essentials of an effective compliance program are critical to understand, creating systems on paper is the easy part. Bringing those systems to life in our organizations is the real challenge. The best designed, most sophisticated quality and compliance systems can be subverted by employee behaviors driven by an organizational culture that is not aligned with a quality doctrine. In some cases, undesirable behaviors are unknowingly encouraged by the organization's own policies and programs. As an example, we have seen bonus plans that reward employees for meeting regulatory market clearance and product launch milestones. When these milestones are met, everyone celebrates and employees are duly rewarded. Yet, there is no accountability when the new product has to be recalled six months later because of a design or manufacturing defect. This communicates a powerful message about the company's true priorities: Obtaining market clearance is more important than assuring product quality. Other

personnel practices such a salary adjustments, promotions, and informal recognitions can provide similar incentives for inappropriate behaviors.

While understanding the essential elements of an effective compliance program are a good foundation, leadership behavior speaks volumes in communicating the company's real values and, in turn, creating the company's culture. And employee behaviors inspired by the corporate culture almost always trump the best designed quality and compliance systems.

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