Life sciences compliance
The last decade

Ted Acosta, the global leader of the Life Sciences Fraud Investigation & Dispute Services team at Ernst & Young LLP, gave the keynote address at the 10th annual CBI Pharmaceutical Compliance Conference in Washington, D.C., on 29 January 2013. Mr. Acosta has been involved with the conference since its inception 10 years ago. His address looked back at 10 years of compliance developments in the pharmaceutical and medical device industries.

A look back at 10 years of compliance developments in the pharmaceutical industry

In the area of commercial compliance, the pharmaceutical industry has experienced extraordinary change over the past 10 years. Compliance organizations have been forced to emerge and evolve quite rapidly. The US Government’s focus on enforcement since 2004 has been complex and varied, and the consequences for non-compliance have increased to levels never before seen in the industry. While the future is not certain, continued change and development can surely be expected. Thus, the demands on the compliance community will continue to rise.
Compliance developments over the past 10 years

When the CBI Pharmaceutical Compliance Conference was first launched in 2003, the concept of compliance in the commercial setting was not widely understood or embraced. Compliance officers were generally attorneys in mid-level, in-house positions, and they were often uncertain about their compliance responsibilities and the role of compliance throughout their organizations. Many had not even been formally appointed to these roles. The CBI Pharmaceutical Compliance Conference was conceived to create a community forum where industry compliance professionals could share experiences, discuss compliance functions and collaborate around the new, and often difficult, areas they were confronting or thinking about. The challenges concerned the Government’s developing interest in the industry’s commercial practices and the industry’s own evolving vision on how to react and establish compliance measures.

The agenda of the first CBI Pharmaceutical Compliance Conference in 2004 offered some key building blocks for future years. Approximately 14 companies provided insightful presentations. The keynote presentation covered TAP Pharmaceutical Products’ Corporate Integrity Agreement (CIA), the first “true” CIA in the industry. Similarly, the keynote panel was “How to Integrate the OIG and PhRMA Code into a Compliance Program.” Other agenda items also focused on the foundational elements of an effective compliance program, including “How to Build a Compliance Program,” “Dealing with State Laws” and “Privacy.” However, soon after that program, a need arose for more advanced and complex topics as the industry began to change rapidly.

From that first conference in 2004 to today, the industry has experienced one of the most remarkable change management initiatives that these sophisticated companies have undergone in the commercial setting. Government enforcement advanced quickly. Compliance officers were challenged to navigate complex regulations in the US and around the world, with various aspects of their companies’ go-to-market strategies constantly under challenge and in continuous development.

- By 2008, the conference topics had matured to include such items as how to create a culture of compliance and value-based programs, among others. Although not mandated, these efforts were seen as necessary to run an effective compliance program.
- In 2009, the focus broadened to an international scale because companies were voicing global concern with respect to the Foreign Corrupt Practices Act (FCPA), and the Department of Justice announced that the pharmaceutical industry would be a focus of its FCPA enforcement efforts. At this time, many compliance professionals were dealing with new or unfamiliar statutes, including FCPA and competition laws from around the world, at the same time learning that their companies were expanding into emerging markets. While emerging markets represented business and growth opportunities, they also heightened compliance risk. Although many compliance officers did not have sufficient experience with international issues, these were now within their scope, and they had to execute their new responsibilities with little, if any, additional resources.
- In 2010, the focus turned back to the US, still the largest market and the one with the strongest enforcement culture, to discuss the Physician Payment Sunshine Act. The Sunshine Act required companies to report payments to physicians by September 2013. These disclosures will be searchable on a public database. Educating business leaders on these new compliance areas became a major task, especially in light of their perceived effect on business and the fact that the initiatives were centered on US laws that seemed foreign, if not irrelevant, to them.

Throughout this change management process, the compliance officer function has been elevated. Compliance officers have evolved to become “agents of change,” and, more recently, have been named members of senior management who report directly to CEOs and present to the boards of directors. Companies now have a greater understanding of the importance of compliance and the specific role it plays within an organization.

The non-compliance penalties have also evolved over this period. In 2004, CIAs were just starting to be issued. Today, companies are receiving CIA extensions, and some are on their second or third CIA. Moreover, the fines have escalated from US$90 million to US$100 million, which at the beginning seemed incomprehensibly large, to those of today, when settlements and fines are in the billions.

The past 10 years have been an arduous journey and a great undertaking. Regardless of its size, every company has undergone some change, whether voluntary or involuntary. Today, only 8 of the 14 companies that presented at the 2004 conference currently exist as the entities they were at that time.

Since 2004, among other developments:

- Clinical trial registries have been established, as well as other obligations to publish trials
- The FBI has conducted sting operations
- Compliance has been expanded into supply and distribution channels
- Prosecutions have escalated from charges and convictions of sales representatives to executives and compliance officers, in-house counsel and doctors
- Compliance obligations have expanded through statutes unrelated to the industry, like the Dodd-Frank Act

And now we are facing health care reform.
Present and future compliance developments

Throughout all of the change in the past decade, one item has remained in focus: “off-label promotion.” Off-label promotion has been on every conference agenda to date, not necessarily because the issue hasn’t been resolved satisfactorily, but rather because it is complex and continues to evolve, affected by scientific developments and changes in therapy and medical practice. As recently as December 2012, in the Caronia decision, a federal appellate court reversed an off-label marketing conviction on grounds of First Amendment protection, which is a drastic alteration in legal interpretation. While no one knows exactly what the future holds, it is safe to say that off-label promotion will continue to be a recurring theme.

Much of the enforcement developments now and in future years will likely be through data analytics. Rightly or not, the Government expects companies to analyze data effectively to identify and track issues, and as part of the investigative process, government agencies are now issuing subpoenas for data to formulate theories and identify issues and patterns. The Government will look at data to understand what is happening throughout an organization, or at least to get a better perspective. Life sciences companies must use the available data themselves to understand their organization’s behavior and patterns or they could fall behind. If data is not used proactively, companies might have to answer very difficult questions regarding why they didn’t monitor data if it was available, or why their monitoring techniques did not detect problems.

What else is out there can be answered by looking at your business model, understanding the supply chain, and asking “Who are the actors on your behalf?” Some additional items to consider are as follows:

- With the rapid acquisitions and joint ventures over the past 10 years, most companies should be involved in due diligence in the US and overseas to understand what risks an acquisition target presents. Due diligence is expected to continue and possibly expand because, from the Government’s perspective, when you acquire something, you are responsible for it.
- Pharmaceutical and medical device companies around the world are looking into developments around patient access, customized, personalized medicine and telemedicine. These areas will eventually increase the scope of the compliance department’s responsibility because they generally affect the company’s overall risk profile.
- Finally, medical device companies should start to consider the compliance around certifications required to purchase certain minerals. Section 1502 of the Dodd-Frank Act regulates the use of “conflict minerals” in the supply chain, which creates additional compliance elements.

In sum, over the past 10 years, the pharmaceutical industry has experienced significant alteration, requiring compliance departments to evolve and develop quickly in an increasingly complex environment. While the industry and regulatory environment will certainly continue to change into the coming decade, the CBI Pharmaceutical Compliance Conference will remain strong and support this vital profession.

Congratulations to the pioneers and visionaries who were at the CBI Pharmaceutical Compliance Conference in 2004 and to the next generation of compliance officers, professionals, legal counsels and consultants working in this dynamic environment. Thank you for your commitment over the past 10 years and for helping to build and develop the CBI Pharmaceutical Compliance community.
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SCORE No. WW0310
1309-1135287
ED None

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