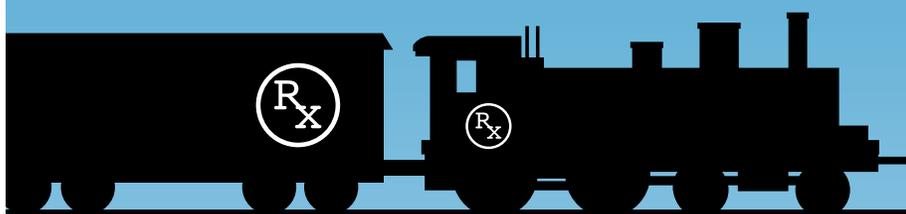


# AVOIDING MISTAKES THAT CAN DERAIL COMPLIANCE TRAINING

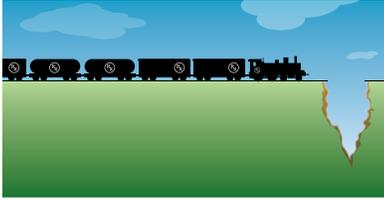
*By Mary Holloway and Dee Mahoney*



**A**s regulatory authorities continue to increase their scrutiny of off-label promotion, pharmaceutical, biotechnology and device companies are finding themselves in a challenging position; working to not only understand evolving regulatory policies, but bridging a significant gap between these policies and compliant field conduct. Government prosecutors have voiced their concern that compliance education and training programs are not translating to appropriate field conduct. Bridging this “gap” is one of the greatest challenges facing companies today.

*Illustration by Frederick Knapp*

## GOVERNMENT IMPACT



# AVOIDING MISTAKES THAT CAN DERAIL COMPLIANCE TRAINING

The increased scrutiny on the industry shows no sign of slowing down. The government and consumer groups are voicing their concerns that there continues to be violations despite record fines levied against companies. The government fears that these large company fines have been attributed to the cost of doing business and are not making enough impact to deter off-label promotion. One of the government's solutions to this concern is to hold individuals accountable for corporate misdeeds. To date over 30 individuals, ranging in title from sales representative to CEO, have been prosecuted or are awaiting sentencing for alleged misconduct.

### A NEW ENFORCEMENT ARSENAL

At the 11th Annual Pharmaceutical Regulatory and Compliance Congress in October 2010, there was much discussion regarding the government's enhanced enforcement arsenal. This arsenal includes powerful and novel penalties for both corporations and individuals. These tools will further intensify today's challenging enforcement environment.

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#### 1. Increased Scope of Corporate Penalties

One of the most powerful weapons in the government's arsenal is the option to exclude companies that engage in misconduct from conducting business with federal healthcare programs, including Medicare and Medicaid.

While this option poses a large threat to a company's viability, it also would have a negative impact on patients, which made it hard to impose. In an unprecedented move, the Office of Inspector General (OIG) has forced a company to divest itself of a subsidiary to avoid exclusion from federal healthcare programs.

Mary Riordan, Senior Counsel, Office of Counsel to the Inspector General, US Department of Health and Human Resources (HHS), spoke at the Congress about the criminal plea in the medical device company Synthes case in which

Synthes was ordered to sell one of its subsidiaries, Norian, as part of its Corporate Integrity Agreement, to an unrelated third party. This move is in addition to the prosecution of four top officers who are awaiting sentencing. Following sentencing these officers face potential individual exclusion.

#### 2. Focus on Individual Accountability Through the Exclusion Provision

Ms. Riordan also announced new guidance on the permissive exclusion of officers and managers following a corporate plea. This guidance includes both individuals that knew of or should have known of the wrongdoing. Exclusion is a method that the OIG uses to ban individuals from participating in federal healthcare programs such as Medicare and Medicaid. In layman's terms, if an individual is excluded it would significantly limit their ability to work in the health care field.

#### 3. Physicians as Informants

The US Food & Drug Administration (FDA) launched a new program, Bad Ad, which is designed to educate health care providers about their role in ensuring that sales promotion by drug companies is truthful, and not misleading. The Bad Ad Program will help health care providers recognize misleading promotion and provide them with an easy way to report this activity to the FDA. The program specifically target sales reps' pitches to health care providers, but medical professionals can also report false and misleading ads.

## TRANSFER OF LEARNING TO FIELD CONDUCT

It is clear that there has never been a more important time for companies to improve the quality and impact of their compliance training. Trainers have to be sure that the methods they are using are resulting in a successful transfer of training to field conduct. The most common factors that inhibit successful transfer of learning are climate, delivery, design and learner motivation.

The climate of the organization has to be one in which compliant behavior is encouraged, modeled and reinforced by leaders at all levels of the company. Leaders must support and promote compliant behavior in words as well as actions.

Training design and delivery must move from remote legalese education and mock scenarios to real-world training that is relevant and practical to the individual being trained. A discussion of the false claims act is not one that particularly resonates with individuals. Training case studies, examples and simulations have to be in a language that commercial teams will understand and identify with. Learners must identify with the personal and professional relevance of the topic to help them understand the impact of the current regulatory environment as it relates to them and their specific function.

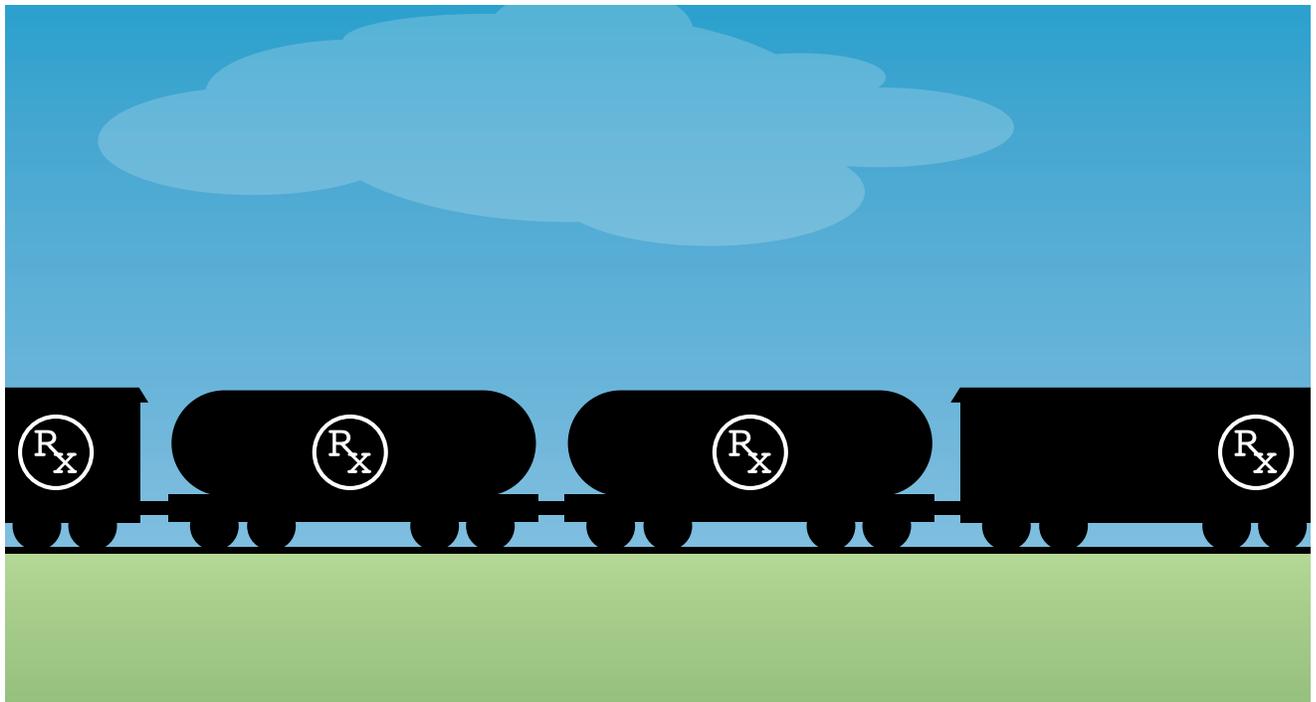
Trainers also have to keep up to date on the subtle selling skills that may now be considered violative. What training and sales professionals once considered “compare and win”

or “guerrilla” selling may be considered misleading promotion in the eyes of the government. It is the responsibility of all training and sales professionals to ensure they understand the rules and laws that govern off-label promotion, and the subtle behaviors that are considered violative, especially as they pertain to their products.

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Lastly compliance training can't be a once a year, click the link activity, it has to be viewed as an integral part of daily business. New hire training, phase training, and leadership training should be updated to keep up with industry compliance trends. There has never been a more important time for companies to maximize the impact of their compliance training.

*Mary Holloway and Dee Mahoney are co-founders of DMH BioPharm Advisors LLC and the COMPLY training model. They can be reached at [info@dmbbiopharm.com](mailto:info@dmbbiopharm.com)*



## Who We Are

DMH is a consulting and training firm specializing in behavioral-based commercial compliance training. Our services include developing commercial compliance learning solutions and building, delivering and licensing customized commercial training curriculum, sustainability tools and workshops.

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## Our Services

### Compliance Training That Won't "Paralyze" Your Commercial Organization

With over 46 years of combined biopharmaceutical commercial experience, DMH understands the need to deliver revenue growth while maintaining a culture of compliance. Our training programs are focused on minimizing the risk of unlawful promotion while maximizing sales performance.

DMH has developed the COMPLY Compliance Training Program which is designed to change individuals beliefs regarding the importance of engaging in effective and ethical promotion. COMPLY's content, unique workshops and thought-provoking activities are customized for every level of your organization and are delivered in a language that your commercial teams will understand.

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### Compliant Communication Training

Organizations create numerous written documents every day. Many of these documents are hastily written, poorly worded and may not be consistent with the laws that govern promotion. As a result, these documents may pose a significant compliance risk for your organization. Our "Compliant Communication Training Workshop" will help participants see firsthand how their communications may be taken out-of-context and how they may create compliance challenges.

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### Reinforcing and Sustaining Compliance Training Tools

DMH has developed several sustainability tools and programs that will help ensure learnings are applied into daily activities. These tools include turnkey workshops, and thought provoking activities that provide on-going skill application, skill development, as well as leadership and coaching strategies

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## To Contact Us

To learn how DMH can help minimize your organization's risk of unlawful promotion while maximizing your performance, contact us today at: **1-866-964-8555** or **info@dmhbiopharm.com**

