

MANAGING RISK

As the industry is placed under ever-closer regulatory scrutiny, companies must ensure that their practices, and those of their employees, are above doubt

The US pharmaceutical, biotech and medical device industries are under the microscope. Federal agencies have more authority than ever before, more whistleblowers continue to finger companies for illegal promotional practice, and more policies require transparency among manufacturers. The bottom line is: risk management is paramount for everyone working in healthcare.

Driver 1: More FDA regulatory authority

As required by the Food and Drug Administration Amendments Act (FDAAA), drug and biotech manufacturers must submit a Risk Evaluation and Mitigation Strategy (REMS) to FDA prior to product approval, or possibly after the product is marketed. REMS require companies to monitor and proactively manage safety risks as part of a New Drug Application (NDA) or Biologic Licence Application (BLA) submission, or at other stages in the product's life cycle. FDA can delay approval if it deems the submitted REMS to be insufficient, or declare the product misbranded (and thus ineligible for marketing) if the company fails to follow the approved REMS.

Implications

- Companies need to be increasingly transparent with safety concerns
- More available product information opens industry to greater scrutiny
- Informed drug development requires multi-disciplinary collaboration
- Regulatory, legal, medical, marketing, policy and communications professionals need to sit at the same table
- Patient outcomes more likely to be improved
- Safety problems could be discovered earlier so companies can provide tools that mitigate risks.

The FDA has also signalled its willingness to hold corporate officials accountable through increased use of misdemeanour prosecutions. Corporate officials will be personally exposed to Park Liability, also known as Responsible Corporate Official (RCO) liability. This is in response to Congressional queries and continued industry violations.

In 2007, the former president and CEO, executive vice president and chief medical officer, and executive vice president and chief legal counsel of Purdue Pharma pleaded guilty as RCOs with a total of \$34.5m in criminal fines. In 2009, former executives of the medical device maker Synthes also pleaded guilty as RCOs.

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The story behind RCO/Park Liability actually originates outside healthcare in a case that came from the Supreme Court, called *States versus Park*. It upheld the conviction of a food chain president whose warehouses were infested with rats. The court described the behaviours expected from this RCO under the main Act governing our industry: the Food, Drug and Cosmetic Act (FDCA). Basically, it is the duty of the RCO of a specific business to be sure that its products or services do not adversely affect the health and wellbeing of the public. Even unintentional violations are punishable as a misdemeanour, carrying a penalty of up to one year in prison plus fines and forfeitures.

Implications

- Park will enable regulators to charge marketing managers, sales directors and others in 'responsible relationships' with misdemeanours, which could result in jail time and personal fines
- Experts say that it is not out of the question for promotional agencies-of-record and their staff to be targeted too, as complicit in the illegal behaviour.

Driver 2: Increased OIG/DOJ scrutiny

For the past decade, the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS), and the Department of Justice (DOJ) have pursued and settled off-label promotion cases against pharmaceutical, biotech and medical device manufacturers.

Of greatest concern to the OIG and US attorneys who are prosecuting whistleblower cases is: if a company promotes off-label, and if that leads to prescribing off-label, and if the government reimburses for that use, that is fraud against Medicare/Medicaid/Veterans Administration and others. Pharmaceutical manufacturers are not permitted to encourage off-label use of their product.

Further, consider the False Claims Act, which is a Federal law that allows anyone to file actions claiming fraud against the government. People filing such 'whistleblower' actions under the Act stand to receive a portion (25 per cent, depending on the specifics of the case) of any recovered damages.

During fiscal year 2010, the federal government won \$2bn-plus in fines, forfeitures and FDA-regulated actions, against drug firms and other FDA-regulated companies for off-label cases. There have been 25 criminal convictions. OIG is continuing to prosecute and more companies will have to enter into a Corporate Integrity Agreement (CIA), which is a negotiated settlement with the government requiring a strict plan of supervised corrective action.

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"This is a challenging time because companies are being held accountable for promotional activities that occurred several years ago. In addition, the current FDA requirements are not always clear. Companies need to have well trained staff that understand this environment and remain in compliance," said Wayne Pines, former associate commissioner of the FDA and advisory board chair of the Center for Communication Compliance (CCC).

Implications

- Industry can expect bad press as cases continue to be brought forward (200 whistleblower cases awaiting settlement)
- Every company must take aggressive steps to assure that future promotion is legal, whether or not it has a CIA
- The high cost of non-compliance underscores the importance of internal and external regulatory counsel.

Driver 3: More PhRMA commitment

The PhRMA Code revisions redefined the scope of interactions with healthcare professionals, including restricting certain relationships that were once permissible, clarifying vague areas and addressing entirely new issues. Conceptually, changes reflect a renewed effort to initiate self-reform. While compliance is a top priority for industry, government officials continue to express concern

about how companies promote their products and question whether industry is doing all that it can to ensure compliance.

PhRMA Code Implication

- No one can abdicate responsibility for compliance to promotional practices; everyone is accountable
- Companies must close compliance education gaps in every communication channel that could increase their risk
- Creating a corporate culture of compliance must be a priority.

Driver 4: Economics

Survey findings of regulatory professionals published by RxCompliance Report (May 2010) quantified the significant resource drain to companies from inadequate education among a key stakeholder group: promotional agencies.

- 76 per cent of respondents cited that three days plus per month would be saved if materials were prepared by professionals with a certified understanding of regulatory compliance
- 77 per cent of respondents said they were concerned that promotional agency programmes and materials could be a source of vulnerability in litigation.

This could cost a brand \$200,000 or more, according to the experts.

Implications

- Companies and their agencies must make compliance a business imperative; it is not just compliance and regulatory functions that bear responsibility
- There must be support at every level, including from promotional agencies, to maintain a vigilant watch over marketing practices
- Regulatory compliance training for anyone involved in drug promotion, as well as the confirmation of competency in this area via testing, must become standard practice.

The survey also found that 91 per cent of regulatory compliance professionals would be reassured if they worked with vendors certified in regulatory compliance.

- Global agencies are investing in regulatory compliance training and testing that covers both US and European regulations, including comparing the regulations in the five major markets.

"In today's complex regulatory climate, we view training and competency certification as a critical investment in our clients and staff," said Laura Schoen, president of Weber Shandwick's global healthcare practice. "By certifying our entire US and European healthcare practice, we have taken steps to ensure that all team members are fluent in the most current regulatory policy and guidelines. This enables us to continue to be an informed, efficient, and vigilant client partner in healthcare communications."

Tom Harrison, chairman and CEO of DAS, a division of Omnicom Group Inc, concluded: "Clients expect agencies to share the responsibility for developing communications with a thorough understanding of the complex regulatory environments around the world. Our overall aim is to be the first of the holding companies to achieve training and certification for all of our relevant communications agencies. This will demonstrate to our current and prospective clients, and to the industry at large, that regulatory compliance continues to be one of the highest priorities for our agencies."



The Author

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