

Risk Management: A Key Regulatory Theme for 2009



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The pharma, 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 practices and more policies require transparency among manufacturers. Bottom line: Risk management will be front and center for the industry in 2009.

Driver #1: Increased FDA Regulatory Authority

The Food and Drug Administration Amendments Act (FDAAA) increased the agency's regulatory muscle. Drug and biotech manufacturers are now required to submit a Risk Evaluation and Mitigation Strategy (REMS) to the FDA prior to product approval or possibly after the product is marketed. REMS expects companies to monitor and proactively manage safety risks as part of NDA and BLA submissions and life-cycle management. 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.

REMS Implications

- Companies will need to be increasingly transparent, especially with safety concerns.
 - More product information and data available from manufacturers opens industry to greater scrutiny.
- Informed drug development will require multi-disciplinary collaboration.
 - Diverse disciplines need to sit at the same table (e.g., regulatory, legal, medical, marketing, policy and communications professionals).
- Role of communications is critical as healthcare professionals, media, patients and general public should

understand REMS value.

- Avoids drug being positioned as deficit.
- Patient outcomes may likely be improved.
 - Safety problems could be discovered earlier so companies can provide tools that mitigate risks.

Driver #2: Increased OIG/DOJ Scrutiny

For the last decade, the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS) and the DOJ have pursued and settled off-label promotion cases against pharmaceutical, biotech and medical device manufacturers. Virtually all of these cases originated as whistleblower cases. While use of a drug or device off label is legal and may be the best course of treatment available, companies are not permitted to encourage off-label uses of products. If Medicare/Medicaid/VA reimburses for that use, the practice is defined as fraud under the False Claims Act. The industries have paid well over \$8 billion in the last five years for cases brought by the government. DOJ's recent Lilly settlement for Zyprexa is the largest ever in any industry at \$1.4 billion.

False Claims Act Implications

- Industry can expect bad press as cases continue to be brought forward (200 whistleblower cases currently awaiting settlement).
- Every company must take aggressive steps to assure that future promotion is legal, whether or not it has a Corporate Integrity Agreement (CIA).
- High cost of noncompliance redefines importance of internal and external regulatory counsel.

Driver #3: Increased PhRMA Commitment to Compliance

The recent PhRMA and AdvaMed Code revisions redefine the scope of interactions with healthcare professionals, including restricting certain relationships that were

once permissible, clarifying vague areas and addressing entirely new issues. Conceptually, the changes reflect a renewed effort to initiate self-reform on behalf of companies to "stanch the tsunami of legislative, enforcement, litigation and public policy pressures weighing on the (pharma) industry's current marketing paradigm." (McDermott Will Emory report) While compliance is a top priority for industry, government officials continue to express concern about how companies are promoting 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. For the first time, Code:
 - addresses promotional materials explicitly, stating that materials should be accurate, not misleading, and consistent with regulations; and
 - language makes any person or organization engaged in drug promotion accountable, including vendors providing communication services to industry.
- Companies must face literacy gaps in every communication channel that could increase their risk.
 - Public relations is in the spotlight. You have to look at what you are telling your company to do with your releases.
- Creating a corporate culture of compliance must be a priority.
 - Regulatory compliance training for anyone involved in drug promotion, as well as the confirmation of competency in this area, will become de rigeur.

Ilyssa Levins is president and founder of the Center for Communication Compliance (CCC), the only resource, training and certification portal solely dedicated to enhancing regulatory compliance among healthcare communicators.