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Compliance on the Road: Government and Industry Efforts to Monitor Field Force Compliance

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The use of field representatives is a crucial component of pharmaceutical sales models. Yet interactions between field representatives and healthcare practitioners (HCPs) often pose compliance risks for pharmaceutical manufacturers, such as the risk of off-label promotion and the provision of perceived kickbacks. Monitoring, both retrospectively and in real-time, identifies the risks inherent in these interactions and serves as part of a risk mitigation strategy. This article will examine monitoring techniques imposed by the federal government and by industry to address compliance risks during field interactions with HCPs, and provides a framework for addressing observed non-compliant behavior by the field force.

Compliance Risks – A Closer Look

Field force interactions with HCPs pose two major compliance risks – off-label promotion in violation of the Food, Drug and Cosmetic Act,[1] and the provision of kickbacks as prohibited by the federal Anti-Kickback Statute.[2]

Off-Label Promotion. Although HCPs may prescribe products for reasons other than their intended use, the Food, Drug and Cosmetic Act prohibits manufacturers from promoting products for uses outside the approved product labeling. Off-label promotion in the context of field interactions can take on many forms, including:

- Proactive off-label discussions by field representatives during HCP office visits
- Field representative responses to off-label questions posed by the HCP, made in lieu of forwarding the HCP's inquiry to the manufacturer's medical information department
- Modifications to pre-approved publications that highlight off-label information
- Use of HCPs as speakers or consultants to deliver off-label messages during peer-to-peer interactions
- Field representative call plans which include HCPs with inappropriate specialties (e.g., specialties that are not aligned with approved uses of the drug, or that are aligned with known off-label uses)

The government has become increasingly wary of interactions by field representatives with HCPs, especially when HCPs are paid by industry to discuss products in a peer-to-peer format. Accordingly, many life sciences companies have started to monitor these interactions in order to evaluate and measure risk.

Kickbacks. While off-label promotion poses the greatest risk in interactions between field representatives and HCPs,[3] certain behaviors by field representatives may also pose risks under

the Anti-Kickback Statute. Consider the following scenario:

- Rep A, a field representative of Pharma X, is visiting the office of an HCP who regularly prescribes Pharma X's most successful product. Rep A is aware that the HCP is seeking funding from Pharma X for an Investigator-Initiated Trial (IIT).[4] Rep A tells the HCP that Pharma X is currently funding IITs on similar topics and of similar scope. Rep A then goes on to state that Pharma X will surely look favorably on the HCP's IIT proposal, since the HCP is a loyal prescriber.

While the majority of Rep A's behavior would be compliant with most companies' policies, the rep's promise of favorable treatment for the HCP should raise red flags under a company's compliance program.

The Federal Government's Most Effective Tool: Corporate Integrity Agreements

Corporate Integrity Agreements (CIAs) function as one of the government's favored tools for reducing off-label promotion and kickbacks in the pharmaceutical industry. Recent CIAs have imposed extensive monitoring requirements on pharmaceutical companies to address interactions between field representatives and HCPs. The most common monitoring requirements include:

- *Speaker Program Reviews* : Company personnel or a third party (e.g., consultant) attends the speaker program to monitor for compliance issues. Monitors evaluate activities and statements made by field representatives before, during and after the program, in addition to reviewing HCP speaker statements and materials used during the program (such as PowerPoint slide presentations and hard copy materials).
- *Field Observations (Ride Alongs)* : Similar to Speaker Program Reviews, Field Observations may be conducted by company personnel or a third party. The monitor "rides along" with the field representative and attends all interactions with HCPs, including, most commonly, visits to physician offices. Field representative behavior is assessed against company policies, and instances of off-label promotion or other inappropriate conduct is noted and reported to the company.
- *Records Reviews* : A review of records related to field representative interactions with HCPs is conducted internally or by a third party. The review generally focuses on time and expense (T&E) records, requests for medical information, field representative call notes, emails drafted by the field representative, and documented results of Field Observations. Records from message recall studies may also be included. A specific volume of records is not stipulated in the CIA; however, companies must typically conduct Records Reviews on three or more Government Reimbursed Products.

The first two forms of monitoring are conducted "live" – monitors attend each program or ride along and record observations in real time. Records Reviews are retrospective, examining past behavior.

Corporate Integrity Agreement Monitoring Requirements (for Select CIAs)

CIA Term	Lilly[1]	Pfizer [2]	AstraZeneca[3]	Allergan[4]
Field Force Monitoring Program: Observations	Yes (50)	Yes (60)	Yes (75)	Yes (30)
Field Force Monitoring Program: Records Review - Interactions w/ HCPs	Detailing Activities Only	Yes, 3 products with elevated risk levels	Yes, 3 products	Yes, 3 products
Field Force Monitoring Program: Speaker Program Monitoring	No	Yes (200)	Yes (250)	Yes (75)
Other Internal Monitoring: Consultant Monitoring Program	No	Yes (50)	Yes (70)	Yes (30)
Other Internal Monitoring: Publication Monitoring Program	No	Yes (30)	Yes (50)	Yes (25)
Other Internal Monitoring: Grant Monitoring Program	No	Yes (60)	Yes (60)	Yes (30)
Other Internal Monitoring: Researcher Monitoring Program	No	No	Yes (30)	Yes (20)
External Monitoring	Yes (IRO)	Yes (IRO + External)	Yes (IRO)	Yes (IRO)

1. Eli Lilly and Company CIA, http://oig.hhs.gov/fraud/cia/agreements/eli_lilly_and_company_01142009.pdf
2. Pfizer Inc, http://oig.hhs.gov/fraud/cia/agreements/pfizer_inc_08312009.pdf
3. AstraZeneca Pharmaceuticals LP, http://oig.hhs.gov/fraud/cia/agreements/astrazeneca_04272010.pdf
4. Allergan Inc, http://oig.hhs.gov/fraud/cia/agreements/Allerga_Executed_CIA_with_Appendices.pdf

Corporate Integrity Agreements – A Floor, Not A Ceiling

Although CIAs apply only to specific organizations, many pharmaceutical companies have started to embrace their provisions, using CIAs as a guideline for developing and refining company compliance efforts. Many of these companies have also chosen to treat CIA requirements as a floor, proactively building additional requirements into their monitoring programs. These enhanced requirements often include:

- Monitoring field interactions with HCPs at conferences/congresses, including events that may take place in close proximity to these events, such as dinners or Advisory Boards
- Review of training metrics to determine field representatives' understanding of compliance requirements
- Review of Sales Training materials to ensure proper instruction is provided
- Monitoring field interactions with HCPs and patients at consumer events
- Review of sampling practices
- Review of requests for Off Label Information

A Framework for Addressing Non-Compliance

Results generated from monitoring efforts provide insight into trends in compliant and non-compliant behavior; training effectiveness; and impact of company responses to non-compliant behavior.

While this information can be highly beneficial to a company, the knowledge this data provides often necessitates taking action, especially when instances of non-compliance have been identified.

Before acting, companies must take several steps to determine the appropriate action to address the observation. The first step in determining appropriate action is to categorize the monitoring observations by type:

- Isolated versus systemic
- Active versus passive (commission or omission)
- First offense versus recidivist
- Individual versus organizational
- Magnitude of the problem (frequency, size, impact)

Second, companies must determine the type of control gap that has led to the observation:

- Gap in policies or procedures
- Lack of organizational support / buy-in
- Ineffective training
- Technology gap
- Lack of company response to violations

Finally, companies must determine how they will respond:

- Individual disciplinary action
- Individual re-training
- Broader re-training (division or company-wide)
- Re-drafting internal guidance documents, policies or procedures
- Communication of senior level expectations regarding compliant behavior
- Evaluating adequacy of current technology solutions employed by the organization

Utilizing this framework will help companies to respond to observed instances of non-compliance in a manner that is both appropriate for, and proportional to, the type of non-compliant behavior observed.

Monitoring: An Easy Drive or a Bump in the Road?

Monitoring, whether mandated by a CIA or proactively incorporated as part of a company's compliance program, poses challenges and provides benefits for life sciences companies. Robust monitoring programs are typically time and resource intensive, requiring significant investment on the part of companies. However, these programs can also provide a wealth of information, often close to or in real-time, that allows companies to swiftly address observed compliance concerns – a benefit not realized through quarterly or annual audits. Therefore, companies should consider implementing or enhancing their monitoring efforts to complement their existing compliance program.

**Opinions expressed herein are attributable to the authors and are not those of Polaris Management Partners or Bayer HealthCare LLC.*

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1 21 U.S.C. §301 et seq

42 U.S.C. § 1320a-7b(b)

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3 The Food and Drug Administration (FDA) has recognized the risks associated with off-label promotion that may occur during interactions between field representatives and HCPs. In response, the FDA created the Bad Ad Program to encourage HCPs to report instances of off-label promotion by field representatives or other company personnel. Information regarding the FDA's Bad Ad Program may be accessed at this link.

4 Investigator-Initiated Trials (IITs), also known as Investigator-Initiated Studies (IIS), Investigator-Sponsored Studies (ISS), or Investigator Initiated-Sponsored Research (IISR), are trials in which the investigator serves in both his or her traditional role (as an investigator) and as the trial's sponsor. This differs from clinical trials and post-market studies and trials, in which the pharmaceutical manufacturer serves as the trial sponsor.
