

## ***Field Force Monitoring and Targeted Off-Label Investigations***

# **New Data-Driven Methodology Focuses Audits on High-Risk Field Interactions**

*By Andy Bender and Christina Keller*

**F**ew pharmaceutical compliance officers are entirely comfortable with the controls they have in place to monitor field interactions with physicians and the subsequent risks of off-label promotion. The traditional tools of auditing and monitoring are not always effective in identifying the bad actions of a few or the occasional bad actions of the many. Moreover, inappropriate off-label promotion by a large segment of the field force presents an increasingly attractive target for both prosecutors and *qui tam* relators.

The compliance landscape is now shifting in response to state off-label investigations. Most notably, vast amounts of data and new analytical tools are being used to identify off-label prescribing. Prosecutors have begun to employ sophisticated data mining technology to identify and quantify potential off-label violations. In fact, State Attorneys General are using these data to build off-label promotion cases against pharmaceutical companies (*see related story, p. 10*).

To staunch the tide of escalating settlements, and keep pace with government enforcement efforts, pharmaceutical compliance departments must embrace new technology and harness the granular-level prescription and diagnosis data that is now available for analysis. Rather than relying on historical data and anecdotes from audits to deliver snapshots of compliance efforts and violations, sometimes years after they have occurred, the new data-driven methodology described in this article can provide frequent updates on promotional activities and real-time assessment of risk.

The new methodology is not intended to replace audits, but to make them more effective. It is meant to complement audits by identifying certain areas of interest, thereby allowing for more targeted audits after the data has been analyzed. What this means for compliance is that audits may now be used to validate findings from data runs that analyze prescribing patterns for every physician in the country, rather than using audits to discover new evidence at the outset.

Until now, compliance officers have not had a

reliable analytical tool at their disposal to conduct comprehensive data-driven audits that measure the effectiveness of a company's policies and procedures. Because of time and budget constraints, and the

logistics of field audits, it has been impossible to review every single transaction across all sales territories and deliver a complete assessment of compliance. The data that is currently available allows compliance to review the prescribing behavior of all physicians prescribing off-label and to analyze whether this prescribing should be of concern to the company. Using this new methodology, the company can identify whether a physician is prescribing off-label relatively more

frequently than other physicians with a similar patient population, location or therapeutic area.

### **Need for Enhanced Audits**

Compliance currently relies on stratified sampling to select three or four populations for annual audits, out of thousands of sales reps. The resulting spot checks reflect anecdotes and interpretation of ride-alongs, questionnaires, interviews, and observations. Given those parameters, it proves difficult to discern nationwide promotion patterns. The recent Cephalon investigation, for example, focused on interviews with staff members who had direct contact with healthcare providers, including sales representatives and medical science liaisons;

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review of call notes; review of requests for medical information and articles, and recall requests from physicians. Such labor-intensive audits are limited in reach and scope, and present only a snapshot of sales reps' behavior during an audit.

The narrow perspective of piecemeal auditing has made it difficult to determine whether findings indicate a systemic problem or anomalous instances of one-off behaviors. Most pharmaceutical companies have gone to great lengths to establish policies and procedures to guard against off-label promotion, abiding by the seven elements of the Office of Inspector General, the PhRMA code and other regulations. They have conducted staff training and subsequently performed audits to ensure the training and policies have been taken seriously. Yet, because of the limitations of audits, compliance has had no assurance that employees are complying with stated policies and procedures.

### **Methodology: Superior Data Analysis**

The new data driven methodology matches prescription and diagnosis data at the physician level. Prescription data is readily available and has been used for years by the industry. However, the availability of large volumes of diagnosis data is relatively recent, and the ability to link, process and compare the two sets of data is a completely new development. State prosecutors are already accessing similar data, and drawing conclusions about off-label activities. By linking large volumes of prescription and diagnosis data, the new data-driven methodology can instantly identify instances of off-label usage.

The analysis can then normalize physician findings, controlling for patient populations, therapeutic area, volumes they are prescribing, and geographic area. By plotting outliers, the analysis can detect clusters of off-label prescribing, and discern potential patterns of prescribing behavior. Analysis can then filter for attendance at certain speaker programs or articles received.

In the hands of prosecutors, such analysis can quickly bolster an off-label case. But within the compliance department, the data analysis can form the basis for an audit that specifically targets those physicians or sales territories identified as over prescribing for off-label indications before they become a regulatory or systemic problem. With such laser-sharp focus, an audit will be much more likely to root out reasons for off-label prescribing, and identify trends and potential problem areas to be

monitored over time, giving compliance a much-needed preventive tool.

Using this data will increase the cost of conducting audits, as the data needs to be purchased and analyzed to identify the areas of concern, which can then be analyzed through spot audits. However, the data-rich analysis makes the audits much more effective and ultimately reduces the number of audits over time. The overall cost remains far below that of a potential government settlement in an off-label promotion case, as evidenced by recent settlements.

Once the investment has been made, and a given company or particular drug's analytical models have been developed, the numbers can be crunched every three, six, or twelve months. For other pharmaceutical companies that may not be focused on patterns of off-label promotion, the data may instead be used to identify patterns of potential fraud, abuse and diversion. By filtering patient demographic data, analyses can include, for example, the number of prescriptions filled by a patient in one week and the number of prescriptions paid for in cash. Data analysis can also identify patients traveling long distances to fill prescriptions.

### **Risk vs. Reward**

In the past, pharmaceutical companies may have been reluctant to employ such data-driven techniques to conduct deep analysis because

of a fear of what they might find. Such a comprehensive review could potentially open a Pandora's box of off-label activities that must then be addressed. Any anomaly could become discoverable through a subpoena, and companies would be compelled to initiate internal investigations that would drain precious time and money.

So why take the risk? Because there has been a paradigm shift in off-label promotion enforcement, and if compliance officers do not take a more proactive role in monitoring, government officials

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might be a step ahead of them.

To be sure, the government looks more favorably on companies that have identified a problem and demonstrated they are taking steps to solve it. According to recent corporate integrity agreements (CIA) with Lilly and Cephalon, corporate compliance officers will be expected to demonstrate they have done everything within their power and position, to the best of their ability, to root out violations in their organizations. For example, the Cephalon CIA states that chief compliance officers are responsible for monitoring all day-to-day compliance activities and for meeting all reporting obligations. Beyond establishing a sound monitoring program and conducting audits, compliance officers may now be held responsible, as individuals, for violations and gaps in the program.

### Preparation as a Defense

By establishing a systematic approach to monitoring off-label trends, and making audits more effective by first identifying areas of concern, the data-driven analysis provides companies with a powerful tool. This methodology can periodically test the efficacy of the organization's policies, a key step towards lasting change in entrenched organizational culture and behavior. With its ability to match drivers of off-label prescriptions with tactics used in annual sales and marketing plans, the methodology can target physicians and sales territories. It can also deliver rapid feedback, since prescription and diagnosis data is typically available 90 days after a patient fills a prescription.

Preparation is a key defense against aggressive prosecutors. State prosecutors have already begun to mine this data as their Medicaid Fraud Control Units work to isolate incidents of off-label marketing. In this changing compliance landscape, pharmaceutical companies must start using the data and analytics that are available, and they must have advanced technology to implement the most comprehensive monitoring possible. Data-driven analysis provides a very powerful tool against off-label risks. ■

■ **Andy Bender**, President, Polaris Management Partners, New York, NY, [abender@polarismanagement.com](mailto:abender@polarismanagement.com)

## Novel method for analyzing off-label data carries potential risks and benefits

One of the most significant recent developments in pharma fraud enforcement is the development of a new methodology by state prosecutors to use Medicaid claims data to help investigate and settle off-label cases. In fact, according to Delaware Deputy Attorney General **Dan Miller**, data claims analysis has become central to investigating off-label cases.

The methodology outlined by Miller is hardly just a theory, however. When Cephalon's \$475 million off-label case was settled last year, *qui tam* attorney **Peter Chatfield** was quick to point out that the investigation represented the first instance in which the new methodology was employed. Chatfield predicted that use of this methodology in dozens of ongoing investigations would help reduce the backlog of off-label cases now that prosecutors have a more systematic way of analyzing data.

### Risks and benefits

According to one veteran attorney, the practice of analyzing off-label data outlined in the preceding article carries many of positive features, including making compliance audits "more objective," in part, because it would allow companies to examine data in context. The key to using resources effectively from monitoring perspective, he says, is to understand the underlying issues. That can only be accomplished by viewing data points in context, he explains.

The attorney concurs with the Polaris experts, however, that the practice also has some risk associated with it, because the context that is revealed could turn out to be negative from a compliance perspective. It also raises fundamental issues about how to collect data and what to do with it, and how to maximize and minimize litigation risk, he adds.

Moreover, there are ways of mining these data for reimbursement and business purposes, separate from compliance, that may not be viewed as legitimate in some quarters. This means a fundamental question facing companies is who will have access to the data.

In short, before companies analyze their off-label data, they basically have to clean up their act, the attorney warns, because there is less risk if it is used to validate changes as opposed to figuring out what changes need to be made.