Life & Health

Health Care Compliance Communiqué

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FALSE CLAIMS ACT: 2013 PATTERNS SET 2014 TRENDS

For Health Care companies, Fiscal Year 2013 was a year of record-setting fines and settlements under the False Claims Act. According to the US Department of Justice (DOJ), the government recovered $3.8 billion under the Act, leading the Assistant Attorney General for DOJ's Civil Division to describe 2013 as a "banner year for civil fraud recoveries." The $3.8 billion number is on the low side due to several massive settlements entered during 2013 but after the DOJ's fiscal year cutoff. Perhaps the best example is J&J's jaw-dropping $2.2 billion settlement, which occurred in November 2013.

Not all of 2013's FCA recoveries were related to the Health Care industries – but more than two-thirds of the recoveries were, with a hefty portion attributed to Pharmaceutical and Medical Device companies. That trend is likely to continue, with DOJ and state governments signaling their ongoing appetite for investigating and prosecuting False Claims Act violations in the industry. Inevitably, those settlements will be accompanied by third party and class action litigation likely to tack on millions or even billions of dollars to the government's settlement agreement.

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FALSE CLAIMS ACT: 2013 PATTERNS SET 2014 TRENDS *(Continued)*

Top Risk Areas

The main risk areas for Pharmaceutical and Medical Device companies have not changed substantially but the vigor with which DOJ now prosecutes its cases has. Here are the main danger zones:

- Misbranding: A 2012 court decision seemed to give greater leeway to Life Science companies and their employees in promoting their products. It's important to recognize that the court decision focused on the first amendment rights of a salesperson who made truthful, non-misleading statements about off-label uses of a drug. The court overturned an earlier conviction but the ruling may have very little to do with liability for misbranding. As a rule, the government's position on misbranding is that the drug is prescribed for the FDA-approved indication and that if reimbursement for the drug does not fall under a category CMS has agreed to reimburse (including approved use), the claim is false. Consider that settlements were made related to misbranded drugs with Wyeth, J&J and ISTA Pharmaceuticals among others. Consider also that the Wyeth settlement, which was the largest misbranding settlement to that date, centered on the government's argument that the misbranded drugs were introduced into interstate commerce.
- Good Manufacturing Practice (GMP) violations follow DOJ's thinking that runs alongside the misbranding approach. DOJ holds that manufacturers that have failed to meet GMP requirements for safety, quality and purity are liable under FCA. The underlying theory is that there is an implied certification by manufacturers that their products are in compliance with FDA requirements including GMPs. To date, the theory has produced notable results, most notably the 2013 Ranbaxy Laboratories case that cost the company $500 million in civil and criminal penalties. It is unlikely that the settlement will be the last, either for Ranbaxy or for other companies in the industry.

FCA Going Forward

It's tempting to anticipate "more of the same" in 2014. Certainly, investigation and cooperation with other government agencies on AKS and GMP violations leading to subsequent FCA charges are not likely to slacken. In fact, there are a few points that are likely to intensify the FCA-related liability and risk for Life Science companies. Among them:

- District Attorneys General have become aggressive in their investigations and prosecutions of FCA violations. Important health care cases have been brought and settled by the US Attorney's office for the Western District of New York, the Northern District of Georgia, the Eastern District of Pennsylvania, the District of Kansas, the District of Maryland, the Middle District of Florida and the Northern District of California.
- State FCAs are stretching the borders of the Federal FCA as a result of the Deficit Reduction Act's (DRA) push for states to join the fight against Medicaid fraud. The incentive was substantial: 10% of the federal share of recovered Medicaid funds would go to the states. Not surprisingly, many states jumped on board. In 2013, eleven states became certified as DRA-compliant. Other states have fallen into several categories, with several already DRA-compliant and others amending their FCAs. In a number of states without their own FCAs, legislation was proposed in 2012 or is pending. The trend is clear: liability exists on the federal and state level, not only under the FCA but on laws that are being used to trigger FCA charges, including GMP violations and the AKS.
- New, tighter Corporate Integrity Agreements (CIA) became evident in the recent GSK CIA, which included provisions for certification by management, use of compliance experts and outside consultants and, perhaps most important, executive clawback provisions.
- Finally, the ACA requires any supplier or provider seeking reimbursement from Medicare or Medicaid to establish a minimum compliance program that expands the provisions contained in the Federal Sentencing Guidelines. The provision causing the greatest discussion is that regulated organizations report probable violations of law to an appropriate law enforcement agency. The requirement changes the compliance game considerably and should be taken into account when companies design, oversee and operate their compliance programs.

INVESTIGATOR-INITIATED RESEARCH: RESPONSIBILITIES AND RISKS

Increasingly, Pharmaceutical and Medical Device companies are recognizing the value of investigator-initiated clinical research (IIR), also known as investigator-initiated trials (IIT). IITs serve an important function in the development and use of drugs and devices. Even though a drug or device company may commit more than a decade and $1 billion to bringing a new product to regulatory approval and patient use, there is no way to fully understand all the potential risks and uses of a product until it is in the general population. Traditional clinical trials cannot be designed to answer those questions. As a result, companies are turning to IITs to expand their knowledge about safety and additional uses that can improve the health of additional patients.

Many drug and device companies have designed their own in-house programs to manage requests by investigators for support. Pfizer, for example, lists the types of research it considers eligible for support. These candidates reflect similar categories for consideration by other large Pharmaceutical companies and include:

- Clinical studies of approved and unapproved uses involving approved or unapproved Pfizer therapies;
- Observational studies including epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease;
- Other types of independent research on disease states, including novel diagnostic screening tools and surveys where Pfizer has no direct commercial interest.

In some cases, companies may provide product to the IIT or grants to assist in funding the research. Without proper planning and execution, legal and compliance risk can attach to the company as well as the IIT.

Sponsor and Investigator

In an IIT, the investigator is also the sponsor of the trial, responsible for compliance with all regulatory requirements. While that would seem to insulate the company from any liability, it is important that companies understand their roles in IITs and how to avoid potential, unnecessary risks.

By definition, IITs are unsolicited by the company. Companies may, however, choose to support the study through drug product, grant or administrative assistance. Independent investigators submit preliminary proposals to the

INVESTIGATOR-INITIATED RESEARCH: RESPONSIBILITIES AND RISKS *(Continued)*

company, typically through the company's IIT program or its research division. The proposal will identify the resources sought by the investigator, which can form the company's products to study funding or management assistance. The driver for the investigator may be a straightforward interest in advancing medical knowledge or, in the case of a physician investigator, it may be for the benefit of patients or support of a new use for the approved product. For the company, the same drivers may hold true.

The Company's Risks

For the company to move forward, several provisions should be in place.

- A predefined set of criteria for reviewing research requests from independent investigators;
- An established group that will evaluate the proposal. Evaluations should be conducted by medical, R&D and clinical personnel – not marketing people;
- Know what your company's role is in the investigation. Especially important, know how the investigator will document adverse events, reporting and compliance requirements;
- The FDA has increased its scrutiny of clinical trials, including in the areas of fraud and abuse. IITs are subject to the same laws as company-initiated compliance in areas such as protection of subjects, informed consent, Sunshine laws, the Anti-Kickback Statute, anti-corruption laws and even the False Claims Act. Scrutiny may be especially keen for trials that receive assistance or any funding from the company. Recognizing this, both AdvaMed and PhRMA have developed guidelines for investigator-initiated trials;
- Have and follow a written agreement that clarifies the company's role in the trial. Questions that should be answered: Who owns the research data? Who is responsible for monitoring the trial to ensure the written agreement is followed? Who is providing which (if any) specific resources for the trial? The agreement must protect the company in cases such as poor data generation, misleading reporting and violations of anti-corruption laws, both domestic and foreign.

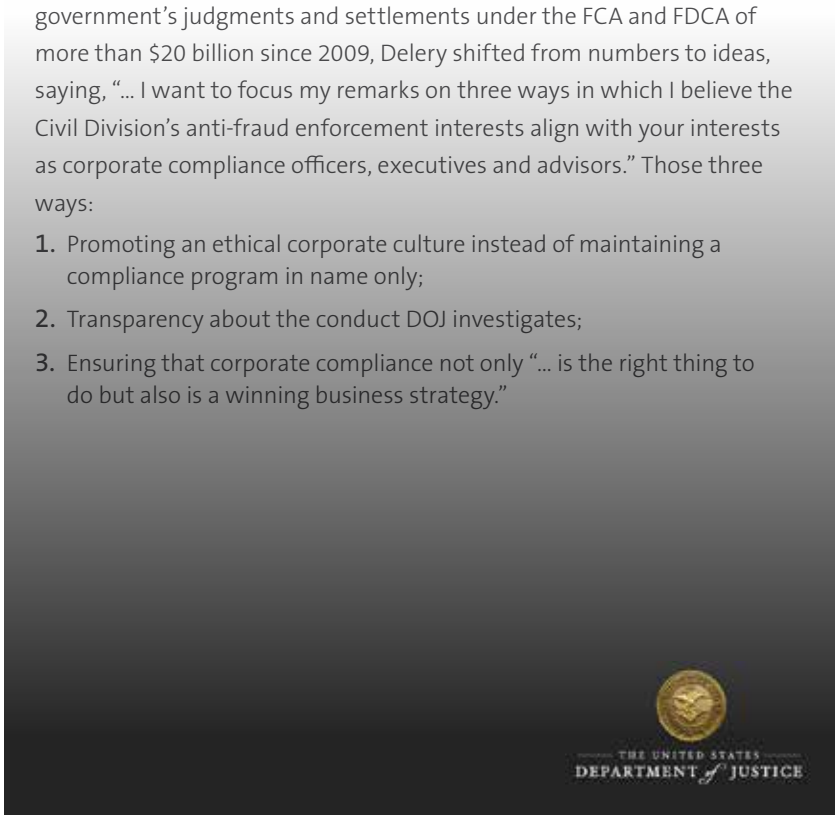
For a growing number of companies, the risks of IITs are far outweighed by the potential benefits, especially in identifying new uses for approved products and additional safety information for discrete patient populations. Despite this positive balance, however, companies must take the necessary steps to ensure that investigator-initiated research is reviewed, approved, and conducted in compliance with all regulatory requirements and company policies.

FDA, ENFORCEMENT AND BUSINESS

In late January 2014, Assistant Attorney General Stuart F. Delery spoke at the CBI Pharmaceutical Compliance Conference, clearly identifying FDA's expectations for the Life Science community and its own enforcement perspective. The speech serves all Life Science companies for its substance and tone.

AAG Delery set the stage in his opening remarks, stating, "...one of my top priorities is the work the Civil Division does to enforce the Food, Drug, and Cosmetic Act; the False Claims Act; and other laws protecting the safety and well-being of patients and the general public." After noting the government's judgments and settlements under the FCA and FDCA of more than $20 billion since 2009, Delery shifted from numbers to ideas, saying, "... I want to focus my remarks on three ways in which I believe the Civil Division's anti-fraud enforcement interests align with your interests as corporate compliance officers, executives and advisors." Those three ways:

1. Promoting an ethical corporate culture instead of maintaining a compliance program in name only;
2. Transparency about the conduct DOJ investigates;
3. Ensuring that corporate compliance not only "... is the right thing to do but also is a winning business strategy."



Promoting an Ethical Culture

The importance of an ethical culture isn't news to Corporate Compliance Officers, but Delery drilled into the topic, saying, "People must have the right incentives to see, report and fix problems. A common thread in many of our cases is that numerous individuals – ranging from executives to safety technicians – saw signs that misconduct was taking place and did not act." He went on to describe the events leading up to the guilty plea to felony charges relating to producing and distributing adulterated drugs from two Ranbaxy facilities in India. A second example was an agreement with Abbott Laboratories for conduct relating to its drug Depakote. In both cases, monetary settlements were huge but Delery explained, "...we have put a renewed emphasis on identifying non-monetary measures that will help us to prevent the recurrence of misconduct." He continued, "... we are not interested in merely collecting a large fine and moving on to the next case. We strive to give companies the incentives – and the tools – to craft better compliance practices in the future." Among the non-monetary measures related to Abbott, for example, was a resolution designed to ensure high-level accountability by imposing a term of probation that requires the company to report any probable violations of the FDCA and requires that its CEO personally certify compliance with this reporting requirement.

FDA, ENFORCEMENT AND BUSINESS *(Continued)*

Transparency About Investigations

Delery's second common interest between government and industry was transparency about the conduct DOJ investigates. His rationale for transparency goes beyond any single company or enforcement action. "Each victory we achieve in fighting a single instance of fraud helps to deter others from following the same path." Delery focused specifically on misbranding issues such as Janssen Pharmaceuticals' distribution of the antipsychotic drug Risperdal to elderly patients in nursing homes, children and individuals with mental disabilities. None of these uses has been approved by FDA. He said, "... we recognize the value of giving doctors the freedom to decide, in consultation with their patients, what treatments to use." Then he continued, "That said, where a company crosses the line and distributes its products intending them to be used in ways that are not approved as safe and effective by the FDA, we will act aggressively."

A Winning Business Strategy

Delery explained, "... we have a common interest in ensuring that corporate compliance not only is the right thing to do but also is a winning business strategy. That means pursuing companies that seek an unfair advantage by breaking the law." He continued, "We want to ensure that companies that are committed to doing things right have the opportunity to compete on a level playing field." To do that, Delery noted that companies should be rewarded for doing the right thing. "Rewarding compliance ... means acknowledging when companies and individuals do the right thing and voluntarily disclose wrongdoing." Specifically, "when a company or individual acts responsibly by timely and voluntarily disclosing unlawful conduct, we will give serious consideration to that disclosure in deciding whether or how to charge or resolve the matter. Likewise, we will credit actions taken once the government has started to investigate."

Notwithstanding his emphasis on cooperation with the industry, Delery was clear about DOJ's aggressive enforcement strategy. "We reject the pernicious idea that a company can succeed by violating the law and treating health care fraud enforcement as a cost of doing business. We continue to insist on resolutions that eliminate any economic incentive to engage in and attempt to conceal unlawful conduct. We continue to see criminal penalties, against both companies and individuals, under appropriate circumstances. We continue to demand accountability by vigilantly enforcing federal laws against those who seek an unfair advantage at the expense of patients and taxpayers."

EFFECTIVE THIRD PARTY SALES AND MARKETING COMPLIANCE

When building a compliance program for third party agents and distributors, what are the most significant risks to consider? That was the key issue discussed during a February 12th UL EduNeering webinar, Elements of an Effective Third Party Sales and Marketing Compliance Program, featuring Denise Pedulla and Peter Katz from Berkeley Research Group (BRG).

BRG is a respected multi-disciplined team of professionals who specialize in serving the Life Sciences and Health Care industries in resolving complex regulatory and compliance challenges. BRG also serves as a trusted Subject Matter Expert (SME) to UL EduNeering, and recently wrote a new UL course on Third Party Compliance, which is available to subscribers of UL's Sales and Marketing library.

Denise and Peter approach the topics of compliance from two different perspectives, providing a creative balance of insight and experience. Denise is a career health care attorney who formerly served as an SVP and Chief Compliance Officer for an international Medical Device company. Peter, alternately, comes from the enforcement world, having served 17 years as a state and federal prosecutor and as a supervisor of the Federal Medicare Fraud Strike Force. Driven by these two individuals and UL EduNeering's Rob Sims, who served as moderator, the conversation moved to the roles and risks of third parties, the expectations of regulators for compliance, and the challenges faced by practicing compliance professionals.

The Role of Third Parties

Third parties represent essential resources for global life science. They serve as company agents and intermediaries for sales and marketing activities, consultants, representatives, distributors, teaming partners, contractors and suppliers and joint venture partners. In fact, a Sales and Marketing Intermediary (SMI) can be virtually any individual or entity engaged in sales and marketing activities inside or outside the US.

Not surprisingly given their roles in corporate operations, SMIs represent significant risk areas. Why and when? Companies contract with SMIs to assist in sales and marketing and product distribution in foreign jurisdictions and high-risk areas. SMIs are required to collaborate with health care professionals to promote product development, training and safe and effective product use. Health care professionals, if employed by the government or other public institution outside the US, may be considered "government officials" under anti-bribery and anti-corruption law compliance.

So, what are the three greatest SMI corruption risks? Bribery and corruption, fraud and abuse, and transparency/disclosure/permissions. While regulators have indicated their general expectations, they have not been specific about how those expectations are developed into a coherent, cohesive program. The question, then, is what prosecutors look for in compliance programs to determine their effectiveness.

Here are some of the main expectations, according to Peter and Denise:

1. Prosecutors want to see a high level of commitment, not just in statements and policies but also in the resources allocated and the degree to which the company is prepared to implement its policies. A clear, written policy is essential – but it must be enforced by the company. It must also be translated into languages used by various groups in the company, applied to third parties, developed in response to the risks for corruption by employees and third parties, and reviewed/updated as necessary. In other words, it has to be dynamic, responsive and funded.
2. Regulators look for accurate, thorough risk assessments that have been conducted in good faith. They must be scalable and appropriate to the company's size, product mix, locations and workforce.
3. Regulators look for due diligence. Peter and Denise emphasized that regulators do not define HOW to conduct due diligence but only what should be accomplished. Effective due diligence can be risk-based for third parties and should be able to identify red flags of potential risks or misconduct, such as rapidly rising expense and offshore accounts, and low thresholds for assessing performance by third parties.

EFFECTIVE THIRD PARTY SALES AND MARKETING COMPLIANCE *(Continued)*

Audience Shares Most Critical Compliance Challenges

The webinar also included a few interactive, real-time polls with attendees about some of their toughest third party compliance challenges. The responses held a few surprises from real-world practitioners of corporate compliance programs.

A. The greatest challenge to SMI compliance was voted as auditing/monitoring. Denise offered several insights about addressing that challenge, noting the importance of inventorying all third parties (and knowing who is doing what where), confirming that they have written arrangements, organizing those arrangements according to country and corruption risk with additional risks added as needed, and analyzing the resulting data to determine both compliance and ongoing risk. Especially noteworthy "red flags" include inaccessibility to an SMI's compliance data, a lack of clarity of the auditing rights of the sponsor company, and noncompliance of the SMI with annual certifications of compliance. "Usually," said Denise," if the SMI is compliant, they have no problem opening up their records and cooperating with you."

B. Books and records represent the second greatest challenge, receiving 47% of the votes. Books and records have emerged as a point of increasing scrutiny by investigators. SMIs who are unable or unwilling to stay current and accurate with books and records requirements pose particular risk to the company and must be addressed.

C. Voters were asked what was most helpful in measuring compliance program effectiveness. The response was two ends of the compliance challenge. First, metrics were the most effective resource, but use of metrics was followed closely by declined compliance from regulatory investigators. The challenge with metrics is not having the numbers but selecting and organizing them in a way that is both useful and defensible.

Click here to view the complete webinar and slides.

The webinar and slides are available for download from the UL EduNeering website, along with other resources for establishing and documenting effective compliance. As a key subject matter expert and consultant to our clients, the Berkeley Group adds another element to the full arsenal of resources provided by UL EduNeering to clients in the Life Science and Health Care communities for effective compliance. **If you want to learn more about our new Third Party Compliance course, or view a demo of the course, contact your Account Director or e-mail Pat Thunell at pat.thunell@ul.com.**

About UL EduNeering

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UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.