Managing regulatory and financial compliance risk:

What life science organizations need to know

Today's life sciences companies operate in a highly regulated industry where the guidelines aren't always clear, and the risks of financial corruption loom large. Staying on top of evolving laws, global watchlists and sanctions is no easy feat, but the penalties for non-compliance are too severe to ignore.

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Financial organizations have long been vigilant about regulatory compliance, but they're not the only ones that must tread with care. Increasing regulatory scrutiny means businesses in all sectors are now vulnerable to compliance actions including financial penalties and criminal charges. Companies in life sciences—medical device manufacturers, biotech firms, blood and tissue centers, and laboratories—are among those in the crosshairs.

The Feds get serious

The number of United States Department of Justice investigations into big pharma corruption practices has been on the rise.

Charles Cain, FCPA Unit Chief, SEC Enforcement Division, stated, "Bribery in connection with pharmaceutical sales remains as a significant problem despite numerous prior enforcement actions involving the industry and life sciences more generally. While bribery risk can impact any industry, this matter illustrates that more work needs to be done to address the particular risks posed in the pharmaceutical industry."

As a result, the U.S. Attorney's office has been paying attention to the pharmaceutical companies, especially the ones that focus on specialty and orphan drugs.[1]

$2.65 Billion

In 2019 a record $2.65B in FCPA fines[2] were imposed for anti-bribery and corruption failures, and the range of non-financial companies now scrutinized for anti-money laundering measures has grown.

$231 Million

A German-based provider of kidney failure products was ordered to pay FCPA violations spanning across multiple countries and lasted over a decade.[3]

$25 Million

A large U.S.-based technology company offering healthcare IT solutions was ordered to pay $25M for bribing foreign officials.[2]

For life sciences companies, these statements should be a loud wake-up call. **The message is clear: A check-the-box compliance program is no longer adequate to safeguard against money laundering and terrorist financing** that could result in severe regulatory and financial penalties.

Due diligence is a necessity

Maintaining oversight over third parties and subcontractors is one of the major challenges facing life sciences companies. Regulatory agencies expect them to take responsibility for every entity and individual conducting business on their behalf.

That includes sales agents, marketers, distributors, contract manufacturers, clinical researchers and physicians. That responsibility also extends to suppliers and vendors. Life sciences companies must develop robust due diligence programs to evaluate and monitor all parties with which they are connected.

Creating an audit trail

A due diligence program allows life sciences companies to address corruption risks proactively. They can identify bad actors before they become involved in business with them. The program also satisfies another purpose. In case of a corruption breach, due diligence serves as an audit trail that proves to investigators the measures taken to manage such risks, which demonstrates an earnest intent to comply. This could result in a slap on the wrist rather than a significant punitive fine.

Understanding the threat

No industry is immune to the impact of a compliance enforcement. With an increasing and expanding focus on bribery and corruption from governments in major global markets, the threat facing life sciences companies is real. An investigation can cut into business performance, productivity and profitability for years.

Global events such as a novel coronavirus lead to disruptions in the global supply chain of every industry. As *The Wall Street Journal* noted, "the coronavirus epidemic is upending the carefully calibrated logistics of global shipping."[4] Hit especially hard is the healthcare supply chain (devices, pharmaceuticals, surgery supplies, etc.) as the supply of life saving supplies dwindles and jeopardizes the public's health. These risks exacerbate the need to diversify the healthcare supply chain to prevent future shortages.

The U.S. government has urged all healthcare manufacturers to start exploring more sustainable domestic production models to further prevent shortages of critical supplies such as masks, surgical gowns, and ventilators.[5] As healthcare organizations look to bring production back to the U.S. or expand into new global regions, there is the urgent need to properly vet potential suppliers and partners to prevent fraud, terrorist financing and other corruption risks. Now, more than ever, is the time to produce lifesaving supplies and drugs. It is also time to build greater visibility into diversified supply chain management by vetting potential suppliers and partners against domestic and global watchlists to help healthcare organizations get ready to face whatever risk comes next.

Punitive Regulation Fines

Penalties for non-compliance can cost tens of millions of dollars, far more than proactive screening and monitoring would ever cost.

Leadership Attrition

Violations can result in key individuals being fired or resigning from an organization. Replacing them can be costly. For the individuals, the potential for personal liability or jail time also exists.

Legal Fees

Fees associated with outside counsel and consultants needed to resolve the matter and bring a company into compliance quickly add up.

Reputation Damage

An enforcement can negatively impact industry relationships, new business growth, and employee recruitment and retention for years. It can also erode market value and stock prices.

Three Compliance Barriers for Life Sciences Companies

One way that life sciences companies maintain compliance or conformance with regulations is to check sanctions and enforcement watchlists. **There are dozens of watchlists to monitor**, including:

- The Government Service Administration's Excluded Parties List System (EPLS)
- The Office of the Inspector General's List of Excluded Individuals and Entities (LEIE)
- Lists created by the U.S. Treasury's Office of Foreign Assets Control (OFAC)
- State Medicaid Exclusions Lists

These lists and more help organizations identify problematic businesses and people that may be excluded from participation in certain government programs, prevent and detect suspicious activity such as terrorist operations, or assess risk associated with doing business with certain entities.

In addition to screening individuals and businesses around the globe, life sciences companies must also be vigilant about their domestic partners and ensure that doctors and other third parties they do business with within the United States are not excluded by states to receive federal healthcare dollars.

State Medicaid Exclusions Lists help protect life sciences companies from costly civil monetary penalties for doing business with companies and individuals who are excluded by the state from participating in federal- or state-funded healthcare programs.

Checking watchlists seems simple, right? Compare one list of people and organizations to another list. How complex could that be?

Checking watchlists may seem simple, but that is far from the truth. A closer inspection reveals the complexity and three common barriers to watchlist screening:

1. Different department needs
2. Document and due diligence maintenance challenges
3. False positives

1 *Different department needs*

Departments within a health system have different timetables for screening watchlists. Compliance departments conduct regular screenings to meet various laws; Procurement may search their active vendors on an annual basis; and Corporate Security may search people or organizations as needed during investigations. Since each of these groups check watchlists on a different schedule, each group may independently update the watchlists from each source. Errors can enter the screening process when a screener thought they were using the most updated version of a watchlist only to find during an audit later that it was outdated. The specific watchlists that each department checks may also be different. There are hundreds of lists worldwide, and each may be used to comply with or conform to a different regulation or program need. Each department may have different programs of interest and different watchlists to support those programs, whether that be federal healthcare program exclusions, Customer Identification Programs, Anti-Bribery and Corruption, or investigations.

A flexible compliance screening platform allows departments to select the watchlists they want to monitor, automatically update the watchlists, and then screen lists according to a schedule or when they have real-time needs.

2 *Document and due diligence maintenance challenges*

As departments conduct periodic watchlist screening, they need to document that the compliance screenings were completed along with identifying possible matches and any follow-up actions they took regarding the possible matches. If departments keep separate documentation, then documentation from one group may not be accessible to other groups. Because of this, duplication of effort can happen, and time may be wasted. Each department may also have different tools available to conduct due diligence, or their lack of access to due diligence tools may stymie them altogether.

An advanced compliance screening platform consolidates case documentation into an enterprise repository and provides a suite of due diligence tools for follow-up research.

3 *False positives*

As each department conducts screening, the “investigator” compares a list of individuals and/or organizations to each watchlist. This matching process is difficult because of common names, misspellings, transposed digits and missing attributes. An investigator that visually compares the two lists or uses unsophisticated “exact match” technology for the comparison could create a mountain of false positives — and subsequently an enormous time burden for due diligence. With so many false positives, investigators may be programmatically desensitized and mistake true positives as false positives.

Watchlist screening platforms that use advanced fuzzy matching technology are critical for reducing false positives and the cost of due diligence.

The added value of enhanced watchlist screening

With complexity and process variations come more opportunities for error, more duplication of effort, and reduced value of a watchlist screening program. Life sciences organizations are complex entities with numerous compliance needs. Having a consolidated compliance process, standardized controls across the enterprise, and high-quality and consistent tools can make a compliance program easier to manage and more valuable.

Employing the right strategy

Every company has different needs in meeting regulatory compliance. A data partner that offers a full suite of robust identity and screening solutions can tailor a program to an organization's activities and workflow. Using one trusted solution provider keeps things simple.

A robust compliance system allows life science companies to stay on top of regulations in a proactive, budgeted and controlled fashion. It facilitates compliance without hindering operational efficiency or diverting significant resources away from the company's primary objectives. Most importantly, it provides peace of mind through enterprise-wide protection against regulatory and reputation risks.

As healthcare leaders consider how to address their enterprise compliance needs, LexisNexis® Bridger Insight® XG can be part of the solution with a fully-integrated compliance platform that uses advanced linking technology to compare identities submitted in batch or real-time with numerous watchlists. Because of its flexible design, Bridger Insight® XG can be used by departments to automate sanctioned and enforcement watchlist screens, conduct due diligence, and provide an enterprise-wide repository for life sciences organizations. — and LexisNexis® World Compliance can provide access to global watchlists through the Bridger Insight XG tool.

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For more information about compliance risk solutions for life sciences, call 866.396.7703 or visit risk.lexisnexis.com/healthcare

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Our healthcare solutions combine proprietary analytics, data science and technology with the industry's leading sources of provider, member, claims and public records information to deliver insights that improve cost savings, health outcomes, data quality and compliance.

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