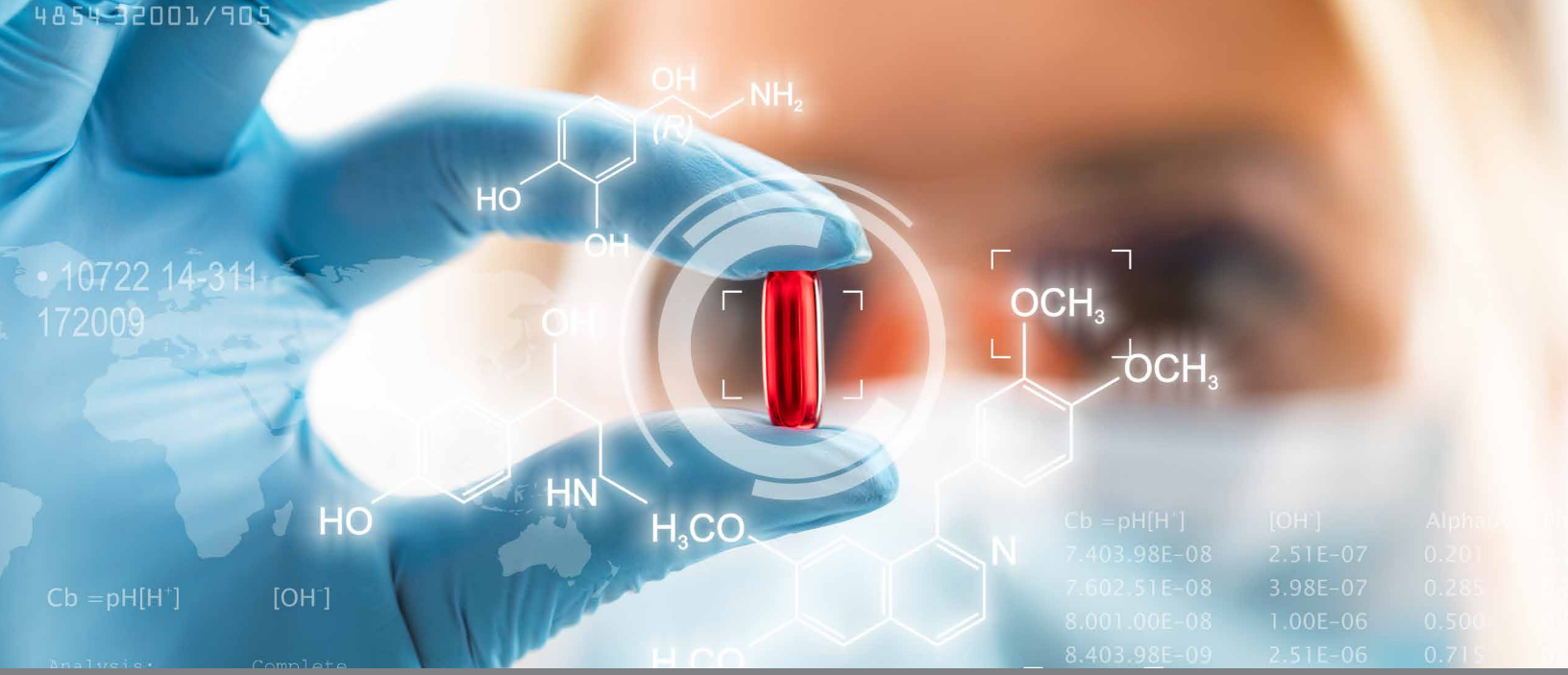

PHARMA IN FOCUS

How a healthy risk mitigation process can prevent catastrophic failure

Patient safety, clinical trial management, mergers and acquisitions, research and development, sales and marketing, and pricing structures are all areas where failure to mitigate risk effectively can lead to reputational damage, financial loss and regulatory enforcement action.

In just a couple of decades, the pharmaceuticals and life sciences industry has changed beyond recognition in response to globalization and demand for new products. What does the current risk landscape look like for pharmaceuticals and life sciences sector?

LexisNexis®

Pressure to Put People Before Profits

Ethical expectations have also had a tremendous impact on the pharmaceuticals and life sciences sector. Shareholders and consumers alike increasingly expect ethical behavior from companies. Over the last year, a campaign which opposes pharmaceutical companies that manufacture addictive opioids has mushroomed. Prominent articles in outlets like the *New Yorker* criticized some of these firms, including Purdue Pharma, a U.S.-based company that developed the prescription painkiller OxyContin.[1] Drug prices have also been an ongoing focus of consumer outrage over the rising cost of drugs ranging from EpiPens to Insulin. And *Fierce Pharma* recently reported that AARP, a U.S. advocate group for older Americans, has launched an advertising campaign aimed at lawmakers to "protect seniors, not drug company profits."[2]

Moreover, we increasingly see shareholders moving their investments away from companies they consider to be unethical and towards firms with good records on corporate social responsibility and environmental, social and governance commitments. Some shareholders are even filing class action lawsuits against pharma firms, such as the suit launched in the U.S. against nearly 20 pharma firms that produce painkillers.[3]

> "There have been three types of misconduct that we have seen arise most often in our pharma FCPA cases. One is 'Pay-to-Prescribe'; another is bribes to get drugs on the approved list or formulary; and the third is bribes disguised as charitable contributions.
>
> **ANDREW CERESNEY**
> FORMER DIRECTOR, DIVISION OF ENFORCEMENT, U.S. SEC

Increased Risk of Bribery and Corruption

Globalization and access to new markets has meant that companies now risk exposure to bribery and corruption. Effective third-party due diligence and ongoing risk monitoring are increasingly recognized as a strategic driver for sustainable business growth when moving into new and developing markets.

Fast growing markets pose significant risks to the pharmaceuticals and life sciences industry—where regulatory scrutiny and enforcement actions have increased as regulators expose supply chain and business development risks within companies' overseas operations.

Pharma must stay alert to bribery and corruption regulations globally.

U.S. Foreign Corruption Practices Act (FCPA)

Between 1977 and 2014, Pharma ranked among the top four industries subject to FCPA enforcement actions. In 2016 a pharmaceutical firm, Teva, suffered the eighth highest FCPA-related fine of all time.[4] FCPA-related investigations into pharmaceutical companies continue. For example, the U.S. firm Alexion Pharmaceuticals is currently being investigated over possible FCPA breaches in Brazil, Colombia, Japan, Russia and Turkey.

Outside the U.S., regulation continues to get stronger.

The landmark U.S. enforcement action against Teva was followed by a $22 million fine from Israel's regulatory authorities. The best way for companies to mitigate the risk of compliance failures—and to make sustainable profit—is to implement robust due diligence and third-party monitoring.

UK Bribery Act

The UK Bribery Act requires companies to conduct due diligence checks on sales agents, distributors,

joint venture partners and other third-parties—a process that regulators expect companies to put in place to show that they are serious about preventing bribery.

France's Sapin II

Sapin II requires that companies develop a map of corruption risks and assess third parties based on this risk map.

Sapin II also introduced a CJIP, which has been seen as equivalent to Deferred Prosecution Agreements (DPAs) available under the FCPA and UK Bribery Act. Companies can avoid an admission of guilt if they meet conditions including the implementation of a compliance program.

In addition, other governments' anti-bribery and corruption regimes look favorably on companies that take proactive measures to mitigate third-party risk and implement due diligence processes.

"In the fight against corruption, France cannot just satisfy itself with the existing situation."

— Michel Sapin
Former French Minister of Finance, July 2015

Costs of Breaches Escalate

In such a high-risk industry, exhaustive due diligence and ongoing monitoring are of critical importance. Yet examples of failures to implement such measures litter recent history with large fines and regulatory penalties meted out to companies that have transgressed.

Bristol-Myers Squibb

2015 Pharmaceutical manufacturer Bristol-Myers Squibb agreed to pay more than $14 million in fines to settle charges that its joint venture in China paid cash and other benefits to state-owned hospitals in exchange for prescription sales.[5] In addition, it specifies the importance of the tone from the top when it comes to establishing an anti-bribery and corruption compliance program.

Teva Pharmaceutical

Teva paid $519 million in 2016 to settle charges from the U.S. DOJ and SEC, and an additional $22 million to Israel's prosecutor. The U.S. regulators said Teva bribed government doctors in Mexico, paid a government official as a consultant in Ukraine and did business with a company owned by Russia's Ministry of Health. This is the eighth biggest FCPA-related enforcement action of all time. Teva is based in Israel, which shows that the FCPA's reach is much wider than the U.S. In fact, firms outside the U.S. have been on the receiving end of eight of the top ten FCPA enforcement actions.[6]

Novartis

In April 2017, Novartis was fined $48.3 million for offering "rebates" to doctors to boost drug sales. In March 2016 it paid $25 million to settle the SEC's claims that it bribed health professionals in China to increase sales. In 2015 it paid $390 million over bribes paid to pharmacies in the U.S. to recommend certain prescriptions to patients.[7]

Sanofi

In September 2018, the French pharmaceutical firm Sanofi agreed to pay more than $25 million to settle FEC charges that its Kazakhstan and Middle East subsidiaries made corrupt payments to win business.[8]

Pharma Risk Mitigation Checklist

What does an effective anti-bribery and corruption program include?

1. Ensure senior management understand company's anti-bribery & corruption obligations and endorse policy process
2. Prepare company policy & procedures, including disclosure requirements
3. Communicate policy & procedures to employees and third-parties (e.g. Contractors, sales agents etc.)
4. Implement regular training to ensure staff and third parties understand obligations and procedures
5. Implement a third-party due diligence process appropriate to the nature, size and risk of the company's business
6. Align due diligence process to associated third-party screening procedures
7. Ensure due diligence and third-party risk monitoring are carried out on an ongoing basis.
8. Establish escalation contacts for anti-bribery & corruption enquiries and to report violations
9. Audit and regularly review policy & procedures, training and compliance systems
10. Reinforce policy & procedures with independent audits and testing

Regulators Offer Guidance on Risk Mitigation

Regulators expect companies to have a risk-based due diligence process in place as a means of preventing bribery risk, but newer guidance has expanded to address a wider scope for risk mitigation—from establishing compliance expectations from the top to engaging in ongoing monitoring after due diligence is complete to better address emerging threats.

Having a risk-appropriate compliance process in place can also reduce the legal impact on a company when compliance failures take place. Consideration for DPAs and CJIPs hinges on whether a company has reasonable procedures in place to mitigate bribery and corruption risk.

> Pharmaceutical representatives have regular contact with doctors, pharmacists, and administrators from public hospitals in foreign countries. Those people often are classified as foreign officials for purposes of the FCPA, and they often decide what products public hospitals or pharmacies will purchase. This influence over the awarding of contracts is true for virtually every country around the globe.[9]
>
> **ANDREW CERESNEY**
> **FORMER DIRECTOR, DIVISION OF ENFORCEMENT, U.S. SEC**

About LexisNexis®

LexisNexis offers flexible solutions to help companies take a more comprehensive approach to risk mitigation.

Nexis Diligence™

With an unmatched, global content collection, and an easy to use search interface, Nexis Diligence helps companies reduce the time and expense of conducting comprehensive due diligence on individuals and entities with whom they do business.

Nexis® Entity Insight

Designed as a cost-effective, self-service risk monitoring solution, Nexis Entity Insight uses a PESTLE-analysis framework, which can be customized to companies' unique risk considerations, to identify emerging risks and enable more proactive, data-driven decisions.

Nexis® Solutions, a division of LexisNexis, empowers companies to identify, establish, and manage trusted relationships with the customers, partners, suppliers and other third parties that are critical to achieving your business goals. With a more comprehensive view of risk, you gain valuable insights to support informed decision-making.

Because good profit comes from making the right strategic decisions.

FOR MORE INFORMATION

Due Diligence Solutions:
LexisNexis.com/Lexis-Diligence

Risk Monitoring Solutions:
LexisNexis.com/Entity-Insight

@NexisSolutions

Business Blog

1-888-466-3947

1 Keefe, Patrick Radden. "The family that built an empire of pain." The New Yorker. October 30 2017. Accessed at: https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

2 Bulik, Beth Snyder. "Step off our 'doughnut hole' deal: AARP ads take on Big Pharma lobbying," Fierce Pharma. November 21, 2018. Accessed at: https://www.fiercepharma.com/marketing/step-off-our-donut-hole-deal-aarp-ads-urge-politicians-to-resist-pharma-pressure-to

3 Ellis, Jonathan. "Big Pharma accused of driving up health costs with opioid scourge." Argus Leader. October 29 2018. Accessed at: https://eu.argusleader.com/story/news/2018/10/24/big-pharma-accused-driving-up-health-costs-opioid-scourge/1743924002/

4 Gelfand, Chaim. "Teva Pharmaceuticals resolves bribery case with Israel authorities." The FCPA Blog. January 15 2018. Accessed at: http://www.fcpablog.com/blog/2018/1/15/tevapharmaceuticals-resolves-bribery-case-with-israel-autho.html

5 Wildau, Gabriel. "Bristol-Myers to pay SEC $14m to settle China bribery claim." Financial Times. October 6 2015. Accessed at: https://www.ft.com/content/3ec26b68-6bdd-11e5-8171-ba1968cf791a

6 Cassin, Richard L. "Petrobras smashes the top ten list (and we explain why)." The FCPA Blog. September 28 2018. Accessed at: http://www.fcpablog.com/blog/2018/9/28/petrobras-smashes-the-top-ten-list-and-we-explain-why.html

7 Androsova, Ulyana. "Novartis bribery allegations highlight compliance risks in pharma." LexisNexis Biz Blog. November 23 2017. Accessed at: https://www.lexisnexis.com/communities/lexisnexis_biz/b/bizblog/archive/2017/05/23/novartis-bribery-allegations-highlight-compliance-risks-in-pharma.aspx

8 "Sanofi to pay more than $25 million to resolve corruption charges: SEC." Reuters. September 4 2018. Accessed at: https://www.reuters.com/article/us-sanofi-fr-sec/sanofi-to-pay-more-than-25-million-to-resolve-corruption-charges-sec-idUSKCN1LK207

9 Ceresney, Andrew. "FCPA, Disclosure, and Internal Controls Issues Arising in the Pharmaceutical Industry," U.S. Securities and Exchange Commission. March 3, 2015. Accessed at: https://www.sec.gov/news/speech/2015-spch030315ajc.html

LexisNexis®