Health Care Compliance Communiqué

Amarin/FDA Settlement: Opportunity or Risk?

On March 8, 2016 the US Food and Drug Administration (FDA) entered into a settlement agreement with Ireland-based Amarin Pharma, Inc., about the company's off-label marketing of its drug Vascepa®.

The settlement followed a decision by US District Judge Paul Engelmayer who ruled that Amarin could promote Vascepa beyond the narrow uses approved by the FDA as long as the information it gives to providers is "truthful and non-misleading."

The court's Amarin decision was the second successful challenge to FDA's long-standing rule toward off-label marketing. In 2014, an appeals court in the Second Circuit ruled that Alfred Caronia, a sales representative with Orphan Medical, could not be prosecuted for promoting one of his company's drugs for an off-label use as long as the statements he gave to providers were true. The challenge was on the grounds of FDA's ruling being a violation of Mr. Caronia's First Amendment rights to free speech. The Caronia case, however, applied to an individual while the Amarin ruling applied to the entire company.

Initial reactions in the pharmaceutical community to news of the Amarin ruling were positive bordering on celebratory. While the ruling opens the door to more off-label marketing of drugs, it does not offer opportunity without risk to companies that choose to promote their products for uses not approved by FDA. The settlement is specifically between Amarin and the FDA. While the ruling and subsequent settlement are unlikely to be the last call in the off-label challenge, it is important to understand key provisions of the settlement and the guidelines they may provide for future court decisions and FDA guidelines on off-label marketing. Some of the most significant provisions include:

- FDA agrees to "... be bound by the Court's conclusion that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa ... and under Caronia, such speech may not form the basis of a prosecution for misbranding."

- Amarin carries responsibility for assuring that its communications to doctors regarding off-label use of Vascepa remain "... truthful and non-misleading."

- FDA agrees to be bound by the Court's conclusion that (based on information known as of the ruling), the combination of statements and disclosures that Amarin proposes to make to doctors to treat persons with persistently high triglycerides is truthful and non-misleading.

- FDA and Amarin agree to a timetable for Amarin's submission of two proposed communications per calendar year about off-label uses of Vascepa, FDA's return comments about any concerns, and resolution of any dispute.

- Nothing in the settlement shall "... be construed to prevent FDA from communicating with doctors through whatever channels FDA deems appropriate after identification of a dispute ..." covered in the settlement.

Managing the Risk

Even though pharmaceutical companies justifiably greeted the Amarin decision with enthusiasm, care should be taken to avoid running afoul of FDA. First, the decision and settlement apply to Amarin only and cannot be used as justification by other companies to implement similar marketing policies absent new guidelines set by FDA or company-specific court cases and settlements.

Amarin bears responsibility for assuring that its communications to doctors regarding the off-label use of its drug are truthful and non-misleading.

Going forward, companies will undoubtedly be held to the same standard.

Second, the overriding condition of the ruling and settlement is that all communications must be "truthful and non-misleading." In the settlement, Amarin bears responsibility for assuring that its communications to doctors regarding the off-label use of its drug are truthful and non-misleading. Going forward, companies will undoubtedly be held to the same standard.

Third, until FDA issues new guidelines – which it has signaled it intends to do sooner rather than later – about off-label marketing, companies are held to the current standard of off-label marketing. Deviations from the current FDA requirements will continue to constitute misbranding, leaving companies at risk of product recalls and regulatory violations. Effective and consistent training of sales personnel remains critically important under FDA's existing standards but it will be equally important if and when those guidelines change to allow some type of off-label communication to doctors.

Certainly, the trend has been established by the two court cases and FDA settlement with Amarin but a trend is not set in stone. Until FDA changes its guidelines, companies should watch the trend – and remain vigilant that their policies, procedures and training comply with current requirements.

Compliance Beyond Borders

Given the number and complexity of regulatory requirements facing compliance officers of global life sciences companies, compliance officers could be excused for not looking outside the industry to track regulatory developments not specific to the life sciences industry.

Because regulatory and enforcement trends may be evident first in other industries, compliance professionals with the resources to look "beyond our industry" may gain early insight into how those trends might affect the life sciences industry – and their own companies.

In remarks at the American Bar Association's 30th Annual National Institute on White Collar Crime in March 2016, US Assistant Attorney General Leslie R. Caldwell spoke about the policies, resources and achievements of the DOJ's Criminal Division. AG Caldwell emphasized the international nature of the Division's work and focused specifically on the challenges associated with international investigations in the area of corporate fraud. Pointing to the Division's involvement in increasingly deep coalitions of international regulatory and enforcement partners, he used several examples to illustrate the evolving approach and subsequent successes. Although his examples did not involve life sciences companies, they demonstrate the potential for criminal activity and

enforcement under multiple laws and jurisdictions by global companies in any industry, particularly those with complex corporate structures and supply chains. Thorough, properly resourced attention is required by any Life Sciences company seeking to avoid headlines as the "next Target" breach.

A Global Effort

One of Caldwell's examples involved VimpelCom and its wholly-owned Uzbek subsidiary, Unitel. The cases against the two corporate entities were made, according to Caldwell, "... by the tracing of illicit funds through various countries around the world. Without the assistance of other countries in obtaining documentary evidence, such as bank records, and executing search warrants, the prosecution wouldn't have been possible."

He credited agencies in multiple countries including the Netherlands, Sweden, Switzerland and Latvia, and law enforcement teams in Belgium, France, Ireland, Luxembourg, Norway and the UK.

Caldwell admitted the difficulty of FCPA enforcement internationally, explaining "... corrupt officials who receive bribes often are beyond the reach of US law enforcement..." He continued, "But just because we cannot get our hands on bribe recipients doesn't mean we can't try to get our hands on bribe proceeds if they enter the US banking system."

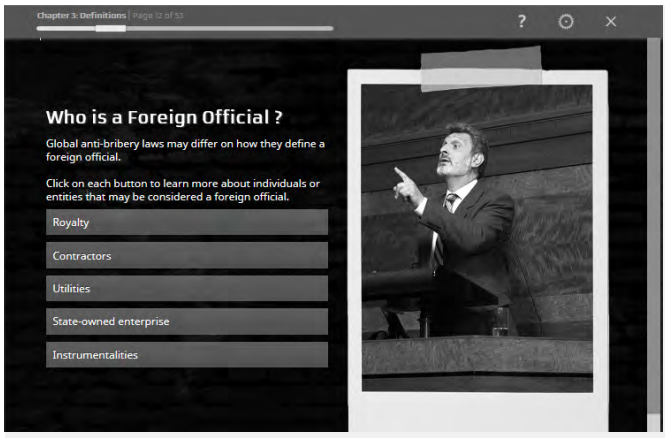
Ultimately, VimpelCom admitted that from 2006 to 2012, they paid $114 million in bribes to that official, falsified their books and records, and attempted to conceal the bribery scheme by reclassifying payments as equity transactions, consulting and repudiation and reseller transactions. In the end, VimpelCom agreed to pay a total of approximately $795 million in penalties (divided among various foreign and domestic law enforcement and regulatory agencies), a criminal penalty of $230 million to the US including $40 million in criminal forfeiture, an equal criminal penalty to the Public Prosecution Service of the Netherlands, and an additional $375 million in civil penalties divided between the US Securities and Exchange Commission and the Netherlands.

DOJ's Expanding Global Presence

DOJ has attachés in eight countries stationed at US embassies in Bangkok, Bogota, Brussels, London, Manilla, Mexico City, Paris and Rome. An additional 60 resident legal advisors and 45 intermittent legal advisors are located around the globe.

Criminal Division prosecutors have been placed with Eurojust in The Hague and INTERPOL in France, and DOJ is exploring the possibility of embedding prosecutors with other foreign law enforcement agencies.

With life sciences companies historically at the center of attention for corporate misconduct, Caldwell's remarks and examples serve as cautionary tales about the future of global anti-corruption enforcement.



Take Our Global Anti-Bribery Course

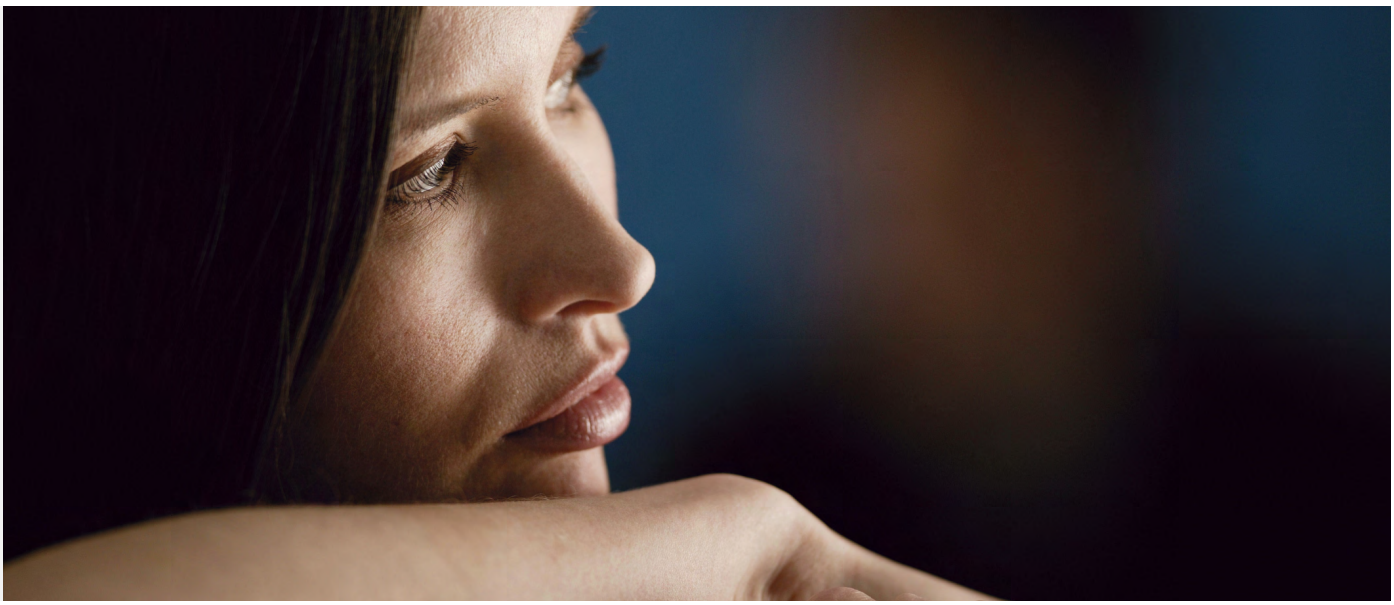
UL provides a 40-minute, self-paced Global Anti-Bribery course that is available in 11 languages. After completing this course, sales and business development professionals will be able to identify the two main provisions of the Foreign Corrupt Practices Act (FCPA) and common components of many anti-bribery laws around the world.

They will also be able to recognize a foreign official, and when to report a violation and the consequences for violating an anti-bribery law. The course can be taken via any learning management system that supports either AICC or SCORM.

To view the Global Anti-Bribery course for 15 days, contact Pat Thunell at pat.thunell@ul.com.

Human Trafficking and Forced Labor

The term "human trafficking" typically triggers images of children and women being coerced, bought and sold into lives of sexual slavery. Tragically, that picture is true; and just as tragically, it is incomplete.



The International Labor Organization estimates as many as 21 million people are victims of human trafficking, forced labor and slavery. Men, women and children have been lured into forced labor through fraud or force – and have been kept in forced labor through debt manipulation, contract fraud, document confiscation, threats to family members or blatant physical constraint. Forced labor is not just a moral issue; for global companies with extensive supply chains, it can be an issue of legal compliance as well as basic human rights.

Who Are the Traffickers?

Global companies rarely have direct involvement with human trafficking and forced labor but they cannot escape responsibility for the actions of their third-party entities in their supply chains. In its 2015 Trafficking in Persons Report, the US Department of State writes about trafficking, "The fluid nature of the crime means traffickers can target vulnerable workers anywhere to fill labor shortages everywhere along a supply chain." The report cautions, "Risks are present in the service sector as well as in the production of goods."

Where are a global company's greatest vulnerabilities? The Department of State report explains, "Practices that lead to human trafficking often occur in the recruitment process before employment begins, whether through misrepresentation of contract terms, the imposition of recruitment fees, the confiscation of identity documents, or a combination of these. The involvement of intermediaries (for example, labor brokers, middlemen, employment agencies, or recruiters) creates additional layers in the supply chain and positions these individuals to either assist or exploit."

The exploitation of workers can occur in multiple ways including the following, according to the report:

- Debt manipulation, in which workers borrow large sums of money to cover the costs of recruitment or "job placement" fees that can run anywhere from several hundreds to tens of thousands of dollars, leading to longer periods of time, sometimes years, of forced labor.

- Contract fraud or switching is another technique used by labor recruiters to entrap workers, many of them illiterate or unable to read the language in which the contracts are written.
- Document confiscation and threatening workers with job loss; recruiters and employers can force workers to remain in their "employment."

Fraud, bribery and corruption are inherently linked to trafficking, posing yet another risk for the companies that rely on third parties that participate in or benefit from forced labor. These third parties often give bribes to government officials to "look the other way" or actively participate in recruiting, transporting or promoting forced labor.

What are the Laws?

Human trafficking and forced labor are illegal in most countries but enforcing anti-trafficking laws in individual countries is inconsistent at best and ignored in others. It is up to the companies themselves to ensure compliance with laws against trafficking, forced labor and slavery everywhere throughout their enterprises.

New laws and regulations are being enacted and increasingly enforced in countries including the US.

Companies should be aware of the following in the US:

- The joint DOJ/SEC FCPA guidelines include trafficking as an element of corruption. The risk of bribery of government officials in positions covering customs to labor permits and human rights protections may place the global company under FCPA liability.
- California Transparency in Supply Chains Act, one of the first laws in the US that specifically addresses human trafficking, forced labor and slavery in the supply chain. Companies with $100 million in gross worldwide revenues that do business in California are required to disclose their efforts to eliminate human trafficking, forced labor and slavery from their direct supply chains.
- An executive order signed by President Obama ("Strengthening Protections Against Trafficking in Persons in Federal Contracts") requires government contractors and subcontractors to have compliance plans for the prevention, detection and monitoring of human trafficking in their supply chains. The resulting Federal Acquisition Regulations took effect in March 2015, mandating that all federal contractors follow required steps to prevent, detect, address, monitor and disclose actions related to trafficking anywhere in their supply chains.
- An amendment to the US Tariff Act of 1930 was signed into law in February 2016. It bans imports that were made by forced labor, giving US Customs and Border Protection agents the authority to seize shipments that are suspected of being made with forced labor.
- A proposed law is the Business Supply Chain Transparency on Trafficking and Slavery Act of 2014, which would require any public or private company required to submit annual reports to the US Securities and Exchange Commission to disclose whether they have taken appropriate measures to identify and address human trafficking, forced and child labor, and slavery in their supply chains.

Laws enacted outside the US create an added layer of responsibility for global companies. These laws and regulations include:

- The UK Slavery Act requires any company operating in the UK to disclose a statement detailing the steps they have taken to ensure that slavery and human trafficking do not exist in their business operations – or to disclose a statement admitting that the business has taken no steps to address those issues.
- A number of national laws and international policies and directives have been enacted or are under review that would require companies to take active measures to prevent, detect and address human trafficking and forced labor in their supply chains. Because the status of these laws, regulations and directives are evolving rapidly, it is essential that global companies investigate the current and anticipated risks they face in the countries in which they operate.

How Companies Can Reduce Risk

No global company can guarantee that every member of its supply chain, whether subcontractor or third-party intermediary – complies with the company's policies and compliance program requirements against human trafficking and forced labor. Companies can, however, take steps to minimize their liability for violating one or multiple laws that address human trafficking and forced labor.

These steps range from extensive due diligence and focused audits of their supply chains to expanded training among the company's employees based on identified vulnerabilities to bribery, fraud and human trafficking risks. Subcontractors and business operations in locations with high levels of human trafficking and forced labor as identified by organizations including the International Labor Organization and the US State Department should be scrutinized. In addition, Individuals who participate in business functions including procurement, supply chain management, transport, import control and product delivery, and compliance may represent particular vulnerability.

Specialized training and continual reinforcement should include straightforward understanding of the laws and regulations governing human trafficking and forced labor but they should also enable employees to identify and report potential human rights abuses. Diligent efforts by companies are essential.

The cost – to people and eventually the company – are far too great for anything less than a passionate commitment by the company and diligence in preventing and eliminating the cause of such human misery.

About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

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