

Role-Play Exercise: La Luna Pharmaceuticals

Directions for Instructor

1. Print copies of the role-play exercise pages (one copy of “Background” for each student in the class; one set of the roles for every five students in the class).
2. Develop teams of five students (there are five unique roles in La Luna).
3. Have each student read the “Background” as an introduction to the exercise.
4. Assign each student a role to play and provide the specific role description.
5. Indicate the desired outcome of the process (e.g., press conference, written and/or oral presentation, short-term plan, long-term plan, employee meeting, etc.) and create feedback mechanisms appropriate for the desired outcome.
6. Teams will need at least forty-five minutes to review, discuss, and prepare.
7. Link the key issues to course training and learning objectives.

Key Issues

Bribery | Price fixing | Product misrepresentation

Background

La Luna Pharmaceuticals is a fast-growing medical products and pharmaceuticals manufacturer. Headquartered in Fresno, California, and incorporated in Delaware, La Luna humbly began its operations as a low-cost producer of high-quality medical supplies and generic drugs. Today it has sales of \$11.2 billion. La Luna's production cost advantages were developed from its business strategy of locating pockets of research and manufacturing talent at out-of-the-way places around the world, each strategically located near sources of raw materials essential for manufacturing its products. An efficient user of its research and development dollars, and a high margin manufacturer, La Luna seemed to succeed spectacularly in every line of business that it entered in North America, Europe, Africa, Asia, South America, and Australia.

Competitors marveled at La Luna's success in obtaining regulatory approvals for its new drugs on every continent, but they also complained to all these regulators that La Luna seemed to win approval for its new offerings when all of its competitors had failed. La Luna spokespeople answered that the company's high energy, superior international talent, and top-quality products explained its success, but persistent accusations of questionable activity kept a large staff of regulatory and government relations professionals on the defensive. In the last four quarters, the company spent so much time and resources on regulatory and governmental issues that even its senior scientists complained that they were no longer able to focus on basic research that had been central to the company's early successes.

Rumors abounded that La Luna crossed the line in its lobbying of governments and administrative agencies across the world. Accusations emerged that La Luna officials were bribing government officials in countries such as China, Russia, and Brazil. They also pointed out that several government officials involved in the approval process of a drug were later hired by La Luna into high-level positions. In China, it has been a common practice to hire close associates or relatives of high-ranking officials involved in facilitating approval and sales of products. La Luna felt it had no choice but to engage in this common practice when the employee seemed qualified.

The Foreign Corrupt Practices Act (FCPA) is a U.S. federal law that prohibits the bribery of foreign government officials. The U.K. Bribery Act goes even further to outlaw all types of bribery and applies to any organization that has operations in the United Kingdom, whether the bribery occurred there or not. Because La Luna has operations in the United Kingdom, it is subject to this law. Therefore, proof that bribery had taken place could cost the company significantly in fines. However, every time La Luna faced these accusations, its charismatic chairwoman and vice chairman claimed that envy motivated its persistent critics who just could not duplicate La Luna's success.

La Luna made it no secret that it sought to recruit and retain the most productive scientific and professional staff throughout the world, and that it had succeeded in part because it had chosen lines of business in which it could vertically integrate from end to end. Competitors accused La Luna of poaching their employees by offering them higher

salaries and benefits if they came to work for La Luna. While this is not illegal, some claim that the main reason La Luna does this is so they can obtain trade secrets about their rivals from previous employees. La Luna denies this and says it simply wants the best talent.

Despite the integrated nature of its operations, La Luna still produced returns far above industry averages in every line of business. Business lines that did not live up to this high standard were quickly sold or dismantled before they became visible outside of the company. Rumors of internal trouble have started to trickle in. It is claimed that employees and scientists working on unprofitable lines were encouraged by managers to “make the numbers no matter what.” There are concerns that employees may be skipping corners to save their jobs. For a few lines of business outside of the United States where it seemed to be least effective, La Luna chose to operate joint ventures with other companies.

After receiving word from the General Counsel that a joint investigation is being launched against La Luna and one of its partners, the CEO has called a meeting to discuss the issue and develop a plan of action.

Diego, General Counsel

You are the General Counsel for La Luna, and you report directly to the Chief Executive Officer and Vice Chairman Alexei. You work closely with each of the company's top managers, especially with the company's Ethics and Compliance Officer, Jayden. You have just learned from a phone call from a former colleague, U.S. Attorney Dana Miller, that La Luna is the subject of a joint investigation by the Department of Justice and the European Competition Commission. Miller has invited you to meet at her office tomorrow and to bring La Luna's outside counsel for a briefing on the scope of the investigation. She said that she has also invited the General Counsel of de Beaucoux Bassault Systèmes and its French parent company to do the same. De Beaucoux Bassault Systèmes is a French company with which La Luna operates as a joint venture in France and Morocco.

Several weeks ago, you learned from Amanda, La Luna's Global Director and Vice President of Sales and Marketing, that a French pharmaceutical regulator had asked both her and her colleague at de Beaucoux Bassault Systèmes to pay a "supplemental new drug application fee." She reported that she asked the regulator to submit his request in writing so that she could review it with the U.S. and French counsel but said that her colleague at de Beaucoux Bassault Systèmes made immediate payment of \$100,000 upon receipt via wire transfer instructions.

About the same time, you learned from Chen, La Luna's Global Director and Vice President of Operations, that his peer at de Beaucoux Bassault Systèmes has proposed that their joint venture enter into an agreement with their competitors to set prices in Europe for their leading antidepressant, Cannavix. He made it clear in his telephone conversation with de Beaucoux Bassault Systèmes that La Luna would not participate in such a scheme, but his peer later copied him on an e-mail message to the competitors that said La Luna and de Beaucoux Bassault Systèmes were ready to proceed with "the plan."

You and Jayden negotiated an agreement with de Beaucoux Bassault Systèmes and its French parent to make sure that de Beaucoux Bassault Systèmes, the French parent company, and La Luna comply with the U.S. Foreign Corrupt Practices Act as well as French Law No. 2000-595 Against Corrupt Practices (FLAC). You received personal assurances from de Beaucoux Bassault Systèmes' and the French parent company's U.S. counsel that it had discontinued its practice of making additional payments that were common in France before 1997 but illegal under the FCPA. Jayden implemented a Code of Ethics and a compliance program with the help of each of La Luna's Global Directors and Vice Presidents.

Jayden, Ethics and Compliance Officer

You are the Ethics and Compliance Officer for La Luna, and you report directly to the Chief Executive Officer and Vice Chairman Alexei and the Audit Committee of the Board of Directors. You rely heavily upon La Luna's General Counsel, Diego, for advice about legal and ethical issues that affect the company. You have developed and implemented a Code of Ethics and compliance program for La Luna that the company designed to manage its most significant ethical and legal risks, particularly those that affect the firm's international operations.

You try to stay up-to-date with all areas of risk that a pharmaceutical company faces. Your company joined the Society of Corporate Compliance and Ethics, and you attend a number of their programs each year. At these meetings, you interact with ethics professionals and attend sessions to learn about effective ways of managing ethics and compliance. Most recently you attend a global compliance and ethics program that addressed topics that create the biggest challenges for global companies today.

To make sure that La Luna would not be exposed to liability for the actions of other companies that operated joint ventures with La Luna, you developed a model agreement with the General Counsel to ensure that the company's business would always be conducted ethically. In some instances, you worked with the General Counsel to add terms to the model agreement to make sure that specific risks were addressed. For instance, you worked to modify the agreement after the United Kingdom passed the U.K. Bribery Act in 2010 that enforced stricter standards against bribery and payments on companies that had operations in the United Kingdom. You also provided information about the U.S. Justice Department making the FCPA a top priority. They have determined that guidelines are important for understanding and avoiding misconduct.

To make sure that all of the company's managers and directors were familiar with legal and ethical requirements that affect La Luna's business, you conducted annual trainings for them and their subordinates, and certified completion of these trainings to the CEO and the Audit Committee.

Today you learned from La Luna's General Counsel that he had been asked to meet on Monday with U.S. Attorney Dana Miller about a joint investigation by the U.S. Department of Justice and the European Competition Commission. The company's CEO has called a meeting to discuss the investigation and has asked you to bring him up to speed on anything you believe will interest investigators. As you prepare for your meeting you learn from your assistants that Amanda, the Global Directors and Vice Presidents for Sales & Marketing, and for Global Operations, did not actually attend the trainings that you certified to the CEO Audit Committee last year, but that they sent their assistants instead.

Chen, Global Director & Vice President of Operations

You are the Vice President of Global Operations at La Luna Pharmaceuticals. You strongly believe that organizations are primarily economic entities and that increasing shareholder value should be the number one priority for growth and prosperity.

As you see things, La Luna needs more drivers like you who focus their energy on improving the company's efficiency and financial performance. You prefer not to micromanage and do not particularly care how a job is done so long as the final objectives are met.

You joined La Luna during its startup operations, and you now own 10 percent of the company's outstanding stock. In your previous job you worked as Director of Operations at a multi-billion-dollar pharmaceutical company, but you decided to leave due to some conflicts of interest and disagreements about business priorities. Power and freedom to incorporate innovative business ideas have helped you show quick results at La Luna.

You take pride in successfully launching many new products and expanding businesses in Europe, Africa, Asia, and South America. Getting government approval has been easy for you in those large markets. You have successfully test marketed products before launching them in the United States. Though you know that you have pushed hard for the timely introduction of some drugs in different countries, and initial responses of certain drugs have not been as favorable as you would have liked, your competent and highly paid employees have so far managed all business-related legal issues successfully.

You have also heard rumors of occasional bribes given to government officials. You believe that one needs to adapt to a particular business environment to be successful. As long as your employees can show strong results at the bottom line, you are not too concerned. After all, you do not have definitive proof that bribery has occurred. You have employed top-notch lawyers in these countries, and so far they have been able to handle any issues that have occurred.

Late on Friday afternoon, you receive an email message from La Luna's CEO about an emergency meeting to discuss situations in Europe, Asia, Africa, and Australia. The General Counsel, Diego, has also mentioned an investigation by the U.S. Department of Justice and the European Competition Commission. You are not sure what the Department of Justice and the European Competition Commission have to do with La Luna's operations in these parts of the world, and you have not heard of any recent government interference from your Directors in these markets.

Alexei, Chief Executive Officer and Vice Chairman

You have been with La Luna Pharmaceuticals for 18 years. You started your career at La Luna straight out of school after completing a dual degree in chemistry and biology. You loved the entrepreneurial spirit that you found at La Luna and you moved quickly up the organization. With every successful project that you completed, you were given more responsibility and greater financial rewards.

In the early days, the firm's culture was solidified as highly competitive and results-oriented. At the time, this philosophy was justified because the firm's survival depended upon competitive and sometimes aggressive business practices to compete against major rivals. The original CEO had been impressed with your hard work since the beginning and had taken you under his wing. Upon his untimely death two years ago in a plane crash, the board named you to replace him as CEO.

You find the position of CEO challenging, but the board confirmed you as CEO and named you Vice Chairman of the Board of Directors. Others at the firm questioned your ability to lead because although the previous CEO had trained you before his death, this training had been more operational in nature and not so concerned with the big picture and overall strategy. The other officers in the firm were concerned about your competitive attitude, believing it to be too aggressive. However, most employees know what is acceptable and what crosses the line, and there is an ethics officer employed at the firm, so you are not worried about unethical or illegal conduct occurring. You always direct employees to obey the law but recognize some rule-bending is necessary to do business.

Because of the increased pressure of your position, you and your wife have separated and are considering a divorce. You stand to lose more than half your current estate. This pressure, and the board's continual drive to increase earnings per share, have pushed you even harder to stress a "winner-take-all" attitude focused on results and profitability. This attitude has worked well for you in the past.

Late Friday afternoon you learned from the General Counsel, Diego, that an investigation was being launched against the company. While you view this as an unnecessary annoyance, you know from your experience in the industry that such investigations could lead to costly penalties and sanctions if they uncover activities that violate the law. Big pharmaceutical companies are targeted because they have deep pockets. You also know there can be significant fallout once the public hears of it. Also, the U.S. Justice Department is known to go after big companies to get large fines. You have heard rumors about potential bribery going on with joint ventures and salespeople but until now have not given them much consideration. You decide to call a meeting of top executives to discuss the matter and develop an action plan.

Amanda, Global Director & Vice President of Sales & Marketing

You are the Global Director & VP of Sales & Marketing at La Luna Medical and Pharmaceuticals. More than sixteen years of experience in sales management have contributed to your rapid rise in La Luna, advancing you from regional sales manager to Vice President. You have been with the company for seven years now. Most VPs of Sales & Marketing last for only three years. Your success at the company has been due in large part to your innovative ideas and ability to manage the sales force.

You work closely with the Vice President of Global Operations to launch new products and expand the business in foreign countries. Because of La Luna's business operations in other countries, legal and ethical issues are a constant concern. Salespeople have to adjust to local cultures and the way business is done.

Cannavix is La Luna's highest profit drug everywhere where the company does business. The drug has been so successful that it has prompted La Luna's competitors to copy the drug. This has led to intense rivalry among the sales representatives at La Luna and their competing firms.

Recently, you became aware that a select group of La Luna's sales representatives has been misrepresenting Cannavix and its properties to gain competitive advantages. Although you have warned the sales representatives to stop, because this drug greatly contributes to profit goals every year, you are reluctant to take additional action.

Today you received a call from the General Counsel alerting you to the misrepresentation issue. You are also told that the CEO is calling a meeting on Monday to discuss the best method of stressing the importance of ethical issues to the sales representative. Among other things, he wants you to think of ways to "fix" the damage that has already been done to the La Luna image by the misrepresentation of Cannavix. You are annoyed as you feel that the issue has been highly exaggerated. You are too busy to worry about something like ethics and believe it can constrain operations by enforcing needless rules.