

Eli Lilly: developing cymbalta

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Eli Lilly and company is a pharmaceutical company that was established in 1876 by Colonel Eli Lilly, who had served in the union army during the Civil War. One of the products the company developed includes the antidepressant drug Prozac, which has been a legendary product for the company and has generated billions of dollars since its launch. As Prozac's patent expiration date approached, thereby allowing the sale of generic versions in the U. S. , the company decided to pursue a product to replace Prozac, named Cymbalta.

John Kaiser, the marketing director at Eli Lilly and member of a cross-functional R&D team, new anti-depressant team (NAT), has been tasked to lead this effort. Kaiser prepared a presentation about the potential successor, Cymbalta, and convened a meeting with the NAT members to discuss its future potential. The goal of the meeting was to thoroughly analyze and discuss the pros and cons about Cymbalta's development and strategic opportunities based on the different options of use. This paper will identify the strategic issues and problems the NAT faced in developing the new product.

The paper will then analyze and evaluate the industry and market behavior by using a SWOT analysis. Finally, this paper will offer a set of recommendations based on the surrounding circumstances and options available to the Eli Lilly team. Identification of the strategic issues and problems: Eli Lilly and company's NAT members began the process of searching for a successful replacement to Prozac by looking into the strategic choices, possibilities, and successful launch of a replacement shortly after the expiration of Prozac's patent.

Cymbalta was considered as a viable successor to Prozac because it seemed a) to be as good as or better than existing antidepressants, b) to show no signs of safety precautions or toxicity issues, c) to meet previous unmet patient needs, and d) to show promising signs of development as a product to also treat pain, especially if it did not cause special side effects. However, when Lilly developed Cymbalta back in the early 1990's, for the major depressive disorder (MDD) market, the product failed to show satisfactory levels of efficacy for treating MDD in phase 2 trials in 1993.

Additionally, Lilly had so little experience in the therapeutic area. Moreover, there were variances in the opinions of Neurologists and Psychiatrists related to the symptoms of pain, such as chronic back pain or recurring headache tied to depression. Those variances could peril the decision making process from the top management. Also, since there were no clear guidelines from the Food and Drug Administration (FDA), for the development of pain indications associated to depression, the likelihood of FDA approval was very slim.

Kaiser and the team also encountered several constraints. The team had to decide how to prioritize the clinical trials for Cymbalta within the range of \$25 to \$50 million and a time frame of 15 to 18 months to design, enroll patients for trial, and then analyze and document results for the clinical trial. Each study was a major task for the NAT members and the team had the opportunity to submit only one objective to the FDA for marketing approval.

On the other hand, since Cymbalta had been tested with twice daily dosages of 20 mg, 30 mg, and 40 mg, NAT members also looked into the option of

conducting a new set of clinical trials to establish once-a-day dosage of 60 mg of Cymbalta to treat Major Depressive Disorder (MDD). The new option would provide more expedient dosing for patients and would also put the product on par with the major competitors. Analysis and Evaluation: The U. S. pharmaceutical industry is complex and dynamic.

It's an industry that is characterized by high-tech research and development (R&D) expenditures and extensive regulation of its products, especially in comparison with other manufacturing sectors. The U. S. Food and Drug Administration (FDA) oversees policies that produce faster review and approval times for drugs. The agency carefully evaluates the safety of any new drug and its efficacy. Such policies result in extended periods during which companies can exclusively market their pharmaceutical products.

Longer periods of market exclusivity for pharmaceuticals then increase sales revenues, and increased sales revenues in turn lead to greater profits and potentially more funding for R&D. Treatment of depression is one area that the U. S. pharmaceutical industry has heavily invested in. The total sales of U. S. antidepressants reached close to \$9 billion in the year 2000.

Companies such as Eli Lilly capitalized on this opportunity and became a leading force in the antidepressant market with its Prozac drug.

Antidepressant product development companies invest heavily in Research and Development (R&D), and patent it.

With each successful launch of a product, they enjoy its patent rights for quite a long period of time and enjoy the exclusive rights to produce and sell that product resulting in enormous profits for the company. Thus, drug

companies continuously attempt to differentiate their product from competitors and bundle in such a way that is more tailored to segment of the market where they can realize higher profits.

SWOT Analysis:

Strengths:

- Potential successor to a highly successful brand – Prozac from a well-established company in the pharmaceutical industry. Part of the selective serotonin reuptake inhibitors (SSRI) group of drugs, which is popular and had fewer side effects than tricyclic anti-depressant (TCA) and monoamine oxidase inhibitors (MAOI).
- Potential to treat both depression and chronic pain, such as headache and backache caused by depression. Weaknesses:
- Product that is not different from competitors' brands.
- Twice-a-day dosing regimen of 20-40 mg.

Threats:

- Serious market competition from competitors' brands such as Paxils and Zoloft with same efficacy. No clear concession amongst physicians as to the nature of link between depression and pain. Attempting to compare Cymbalta to existing SSRI on pain might fail to conclusively separate from competitors, thus giving rival drugs an implicit endorsement for treating pain.

Opportunities:

- Potential development of 60 mg once-a-day dosage with high efficacy.

- The possibility of pursuing patients with fibromyalgia (severe muscle pain and chronic fatigue) and Diabetic peripheral neuropathic pain or DPNP (a painful and debilitating complication of diabetes).
- According to the National Studies of Health, over 40 million Americans were unable to find relief from their pain, including patients with fibromyalgia and DPNP.

Pros and Cons of Plausible Alternatives:

If developed successfully, Cymbalta could be a unique product that has the ability to significantly reduce and improve depression and pain. Patients with fibromyalgia and DPNP could greatly benefit from Cymbalta. The pain relief may also be great for patients who suffer from depression and chronic pain like headache and backache.

The NAT's idea of pursuing the 60 mg daily dosage is also attractive if it delivers the same efficacy of current antidepressant drugs in the market. However, all of this comes with its perils. The company has to evaluate the risks and any potential side effects that the 60 mg per day dosage may have on patients. They also have to assess the feasibility of conducting a clinical trial with a 15 to 18 months' timeframe and a projected cost of \$25 to \$50 million. Additionally, they would have to convince the FDA that the new product is ready to market.

Failure of any of the aforementioned obstacles could result in loss of the antidepressant market to competitors. Recommendations: Depression and chronic pain diseases, such as fibromyalgia and DPNP, have a profound effect in society at large. Studies in scientific publications have estimated

that depression affects 10% to 25% of the population. The antidepressant market in the U. S. in 2000 totaled sales of approximately \$9 billion. Eli Lilly has positioned itself well in this market segment. The company has enjoyed a market lead with annual sales of over \$2 billion with its antidepressant drug, Prozac.

Cymbalta needs to focus on maintaining and increasing that \$2 billion dollar revenue Prozac has achieved over the past years, by building on the successful foundations Prozac has already established. It is important to develop an updated product that will undoubtedly outperform its competitors. Cymbalta might be a successful replacement because of its good efficacy or efficacy better than existing antidepressants, Cymbalta also has no apparent safety or toxicity issues, and its possibilities of meeting a previously unmet patient needs, exemplifies why Cymbalta has the potential to total higher record sales than even Prozac.