In August of 2008, pharmaceutical giant Eli Lilly announced that it would be acquiring Monsanto’s rBGH division for $300 million. Recombinant bovine growth hormone, or rBGH, is an artificial growth hormone that is injected into dairy cows in order to increase their milk production. Eli Lilly was already the exclusive international seller of Posilac, Monsanto’s brand name for rBGH, in the decade preceding the acquisition.\(^1\) RBGH is sold in 20 countries,\(^2\) including South Africa, Brazil, Colombia, Honduras, Kenya and Mexico.\(^3\) Posilac and its supporting operations became part of Eli Lilly’s Elanco division, which handles animal health and nutrition.\(^4\) Among other things, Elanco sells antibiotics that are used to treat mastitis in dairy cows,\(^5\) and an increased rate of mastitis is one of the more common side effects of using rBGH.\(^6\) Lilly’s Elanco division was also one of the four companies that originally submitted rBGH drugs to the FDA for approval (along with Monsanto, American Cyanamid and Upjohn), but only Monsanto’s Posilac was approved.\(^7\)

It is easy to understand why Monsanto would sell its rBGH business. The hormone is already banned in Canada and parts of the European Union. Kroger and Starbucks refuse to use milk that was produced with rBGH,\(^8\) and Dean Foods, the largest milk distributor in the United States,\(^9\) states that virtually all of its milk is sourced from cows not treated with the hormone.\(^10\) Even Wal-Mart now uses rBGH-free sources for its private-label milk.\(^11\) In fact, Monsanto’s stock went up 4.63 percent on the day it became news that it was eliminating rBGH from its portfolio. It was not immediately clear why Eli Lilly decided to acquire the rBGH operations at this point in time, and in fact, Lilly’s stock declined that same day.\(^12\)

In its quarterly conference call following the acquisition, Lilly touted the decision as part of a strategy to build its global business.\(^13\) The company did not elaborate further, but given the supposed benefits of the product and the current status of the international food system, it is possi-
ble that Lilly will market rBGH to developing countries as a tool for increasing domestic milk production. Whether Eli Lilly will be promoting this product ethically, however, remains to be seen, as Eli Lilly has been involved in a number of controversies over its questionable business and marketing practices.

On January 15, 2009, Lilly agreed to settle an “off-label” promotion case with the U.S. Justice Department for a record-setting $1.42 billion. Off-label refers to the practice of using drugs for purposes that have not been approved by the FDA. While doctors have discretion to prescribe medications for non-approved purposes, it is illegal for drug companies to promote and market the drugs for these uses. This was the largest-ever sum for both a corporate whistleblower claim and the largest criminal fine ever imposed by the U.S. upon a single company. Lilly faced criminal and civil charges for violating the Food, Drug and Cosmetic Act, and was accused of engaging in a multiple-year long scheme to persuade doctors to prescribe its anti-psychotic drug Zyprexa for use in two groups of patients for whom the drug was particularly risky and not approved, children and the elderly. As part of the settlement, Lilly agreed to plead guilty to one misdemeanor charge of illegally marketing the drug for use in treating the elderly for various symptoms of dementia. The company paid a $615 million penalty for the criminal charges and also paid $800 million to stop the civil investigation from proceeding further. In addition, Lilly agreed to be monitored for five years by a federal review organization that will assess and report on the company’s practices, policies and procedures.

Zyprexa is by far the largest source of revenue for Lilly, with more than $4.7 billion in sales in 2007 alone, which is more than double the amount of the next largest source. Zyprexa has potentially dangerous side effects that are more likely to occur than in competing drugs, including severe weight gain and changes in cholesterol and insulin levels that can increase the risk of diabetes. This raises some questions of impropriety, given that Eli Lilly also makes drugs for treating diabetes.

Lilly had already settled claims for improperly marketing Zyprexa prior to this latest agreement. In October of 2008, Lilly paid out $62 million to 33 states for improperly marketing the drug, this time setting a record for the largest sum in a state consumer protection claim. The company was accused of the same illegal behavior, which was promoting the drug for uses that were not approved by the FDA and urging doctors to prescribe it for those uses.

In addition, in 2005 Lilly pled guilty to similar charges of illegal off-label promotion of its drug Evista. Evista was only approved for the prevention and treatment of osteoporosis in post-menopausal women. However, Lilly was allegedly promoting the drug for the unapproved uses of reducing the risk of cardiovascular disease as well as for reducing the risk of breast cancer, a use that FDA had specifically rejected. Lilly also markets another drug, Gemzar, which is approved by FDA for treating metastatic breast cancer. Lilly agreed to pay a $36 million to settle the Evista case with the U.S. government. It needs to be questioned whether Lilly knows that cows injected with rBGH show elevated levels of another
hormone, IGF-1, in their milk, and that this hormone is possibly linked to increased rates of breast cancer in humans.  

Coincidentally, the very same day that the $1.42 billion federal settlement regarding Zyprexa was announced in January of 2009, FDA issued guidance permitting pharmaceutical companies to bypass the prohibition of marketing off-label uses of drugs, allowing them to pass out medical journal articles that discuss these non-approved uses.  

The House Oversight and Government Reform Committee had discovered the initial proposal back in November, and began an investigation into FDA’s decision-making process regarding this policy.  

As a result of the investigation, it came out that in April of 2007, lobbyists from the pharmaceutical industry had met with FDA and requested that FDA draft guidance allowing this form of off-label marketing.  

Unsurprisingly, the firm that lobbied FDA to get this guidance passed is the same firm that is used by Ely Lilly, Monsanto and a number of other pharmaceutical giants.

In addition to its illegal off-label marketing campaigns, Eli Lilly has also engaged in other questionable forms of drug promotion.  

In 2006, an article appearing in the peer-reviewed New England Journal of Medicine criticized Lilly’s marketing tactics for the drug Xigris, which is used to treat sepsis, otherwise known as blood poisoning.  

FDA approved the drug in 2001, although not without some controversy since it was based on a single problematic trial of the drug, and half of the FDA advisory panel voted to require another confirmation trial before approval.  

While not accusing Lilly of illegal activity, the NEJM article did shed light on what it considered to be particularly unethical marketing strategies.

When initial Xigris sales were lower than expected, Lilly hired a public relations firm to help boost sales of the drug.  

Since Xigris was expensive, the company spread rumors that the drug was being rationed at hospitals, and doctors were being “systematically forced” to decide who would receive the drug and therefore who would live or die.  

Lilly then formed a special “task force” that would address the ethical issues raised by the supposed rationing of this drug.  

The company also engaged in several other questionable tactics, including starting a publicity campaign on “surviving sepsis” as well as attempting to create treatment guidelines for sepsis (with Xigris, of course) using third-party groups with financial ties to Lilly.

During the period that this PR campaign was taking place, issues continued to arise over the safety and effectiveness of the drug, with increasing calls for further testing of the product.  

As a result of Lilly’s actions, the NEJM article called for a system of creating drug use guidelines that prohibited pharmaceutical companies from funding or influencing these developments.

Lilly has repeatedly engaged in illegal and unethical marketing of its drugs to doctors and has paid millions of dollars in fines and settlements for doing so.  

The company has also used marketing and promotion to increase the sale of drugs suspected of having ill effects.  

The money lost settling lawsuits does not seem to have deterred Lilly from continuing its behavior; the company appears to have accepted the fines as just another cost of doing business.  

It would seem then that Eli Lilly is an excellent choice to take over the reins of a such a controversial product as rBGH, as the company has demonstrated a willingness to engage in illegal marketing to sell its products and may very well continue to use unethical tactics to sell rBGH to unsuspecting nations and peoples around the world.
Endnotes

6. Available at: http://www.elanco.us/products/posilac.htm
8. Available at: http://www.lilly.com/products/

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