Embracing Corporate Social Responsibility: A Case Study on Biogen Idec

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Abstract

Pharmaceutical companies face the unique challenge of achieving an effective business model that embraces the values set in place for the organization and its complex network of stakeholders. The wide array of important issues on an internal and external level ranging from patient health and safety, regulation and business ethics pose many challenges for the healthcare industry as more and more organizations strive to embrace corporate social responsibility (CSR) initiatives. In the case of Biogen Idec, the organization faced extreme challenges during the development and withdrawal of the drug, Tysabri, which led to a series of events based on crucial decisions made by executives and management. The case calls into question the lack of a well-structured business model and the decisions made in the time leading up to adverse events. This paper aims to provide an in-depth analysis of Biogen Idec from the perspective of CSR by focusing on critiquing the organization’s business structure and proposing solutions to re-evaluate and re-organize in order to embrace corporate sustainability.
Introduction

“I’m not afraid of dying; I’m afraid of living as a burden to those I love” (Erik, 2009).

Nausea, liver damage, dizziness, low blood pressure, trouble breathing, depression, and progressive multifocal leukoencephalopathy (PML) are just a few of the side effects that can be experienced upon taking Tysabri for multiple sclerosis (MS). Side effects are not only experienced with taking medication but also with a lack of corporate social responsibility in businesses. Biogen Idec proved a burden to the stakeholders involved: the community, employees, shareholders, patients, etc. through the decisions made and the value placed on market profit. For a sustainable future, this biotechnological company should integrate corporate social responsibility in their everyday business model and organizational structure to create lasting value for the company as well as its stakeholders. In keeping side effects at a minimum, and in focusing on the overall quality and longevity of life for this corporate citizen, stakeholder engagement and proactive business strategies are essential outcomes in integrating corporate social responsibility in Biogen Idec's business model. This can be seen through the construction of core values, creation of value alignment and collaboration with the Food and Drug Administration.

Background

“Quality of life is more important to me than quantity of years lived” (Erik, 2009).

History. Biogen was founded in 1978 in Cambridge Massachusetts by two former Nobel Prize winners, Phillip Sharp and Walter Gilbert whose mission was to find altruistic scientists to create “great lab science” (Margolis, Delong & Heymann, 2007, pg. 2A). The company's revenue in the beginning stemmed from royalties of their licensed discoveries and technologies to pharmaceutical moguls as they were trying to make the transition from being primarily
associated with University research to a “profit-motivated enterprise” (Margolis et al., 2007, pg. 2A). Jim Vincent became CEO in 1985 and focused the companies’ mission on two promising drugs, Hirulog and Avonex and profits were steadily increasing. Avonex became the main focus when switching from a hepatitis therapy to that of a multiple sclerosis (MS) therapy drug when a competitor (Chiron Corporation) used a similar beta and was already making strides in MS therapy. Jim Tobin was appointed CEO for a brief amount of time and tried to acquire new drugs in their early stages of development in order to diversify Biogen's drug pipeline. He resigned for personal reasons and Vincent took his place again. This transition of research and drug development widened as Jim Mullen took over as CEO in 2000, even though Avenox held 82% of Biogen's profits.

**Merger and collaboration.** Biogen merged with Idec Corporation and together transitioned into the “third largest biotechnology company in the world” which was valued at $6.4 billion dollars (Margolis et al., 2007, pg. 4A). The fusion of immunology with that of oncology proved to be a success and not only increased their profits but allowed them to completely revamp their facilities and staff to reflect the company they were becoming since the “efficiencies of the merger would save more than $300 million in operating expenses and $175 million in capital expenditures through 2007” (Margolis et al., 2007, pg. 4A). In 2000, Elan Corporation of Ireland wanted to collaborate with Biogen Idec in hopes to partner in the development of a new MS drug called Antegren. The opportunity for Biogen Idec to collaborate with smaller biotechs was popular especially in helping them to get FDA approval where in “2001, 38% of all new drugs approved by the FDA were the result of a partnership” and in 2002 it rose to 50% (Margolis et al., 2007, pg. 5A). In 2003, shareholders approved of Genentech purchasing Idec after a class action lawsuit against Biogen Idec.
A Beacon of hope. Antregeen was labeled *a beacon of hope* to the company as well as the MS community. It was the “first of a new class of drugs called selective adhesion molecule inhibitors, designed to inhibit immune cells from leaving the bloodstream and attacking inflamed tissue” (Margolis et al., 2007, pg. 8A). This drug ended up being combined with Avonex, and it successfully moved from Phase I to Phase III trials and demonstrated safety and efficacy. Within one year of the Phase III trials this drug was able to successfully reduce “the rate of relapse by 66%” in relation to the other MS drugs on the market (Margolis et al., 2007, pg. 8A). Biogen Idec decided to take a risk and submit to the FDA prematurely even though they were short in the number of years for data collection in May 2004. With this early submission came a rise in stock prices, a mass hiring of workers for their new research facility in order to mass produce the drug, and a surge of optimism.

The FDA was willing to approve their application in November 2004 only if the company changed the name of the drug, and Biogen changed it to Tsyabri. Not only did Tysabri “[bring] a new hope for a disease that was not well understood nor well served,” it “[did] wonders for Bioden Idec's share price” (Margolis et al., 2007, pg. 2B). A year later over seven thousand patients were on Tsyabri and a serious adverse event occurred. The rare and fatal brain infection PML was seen in two separate instances. The drug was withdrawn from the market and the stock price decreased. Now the MS community was “wondering why the company was withdrawing their one ray of hope, and others in the investor community casting the company as a bunch of liars and thieves” (Margolis et al., 2007, pg. 2C).

The withdrawal of Tysabri on February 25th 2005, a supposed warrior in delaying MS came multiple struggles: employee layoffs of the mass hire that was just performed, patient record analyzation where there was one more case of PML found, patient insecurities and lack of
free choice to continue taking the therapy drug, intense criticism for the way the situation was handled, financial instability, a management reorganization due to insider trading and an investigation from the Securities Exchange Commission. Mullen however still believed that Biogen Idec is “well poised for near-term success, we believe that to continue to deliver for patients, employees, and shareholders requires a bold reshaping of the company in an effort to generate high-level, sustainable growth beyond the current decade” (Margolis et al., 2007, pg. 1D). This, along with a reorganization became difficult even though Mullen believed “ultimately it's the right decision if we are to build for the future of our patients” and of course patient safety (Margolis et al., 2007, pg. 4D).

**Biogen Idec and Elan**

“My wife didn’t have to die. If we had all the information we should have had, she’d be with us today. I cannot describe to you how broken my family’s heart is over ever having Tysabri enter our lives.” --Walter Smith, widower of Anita Smith who died from PML after taking Tysabri.

**Patient Safety and Well-being**

One of Biogen Idec’s core values in February 2004 was, “we measure our success by how well we enable people to achieve and to thrive. Patients, caregivers, shareholders and colleagues deserve our best,” (WayBack Machine). This was the only value that was directed toward patients and stated that they deserved their best. However in 2004, Biogen Idec put its patients at risk and decided to put the importance of their shareholders first. On May 25th, 2004, Biogen Idec submitted its Biologics License Application early based on interim one year results from the ongoing Phase III trials which was earlier than planned and where priority review was requested from the FDA. This expedited review reduced the process from 10 to 6 months. With less than two years of phase III research, the safety of Biogen Idec’s patients was jeopardized.

Prior to this submission, Elan Corporation merged with Biogen Idec and developed a new
MS drug named, “Antegren.” Antegren promised big things to the MS community but submitting early was still a major gamble for Biogen Idec. Stephan Reingold, Vice President for research program at the National Multiple Sclerosis Society acknowledged these promises and stated, "One hopes that the optimism this most recent announcement has generated is well considered and appropriate" (Armstrong, 2004). This collaboration made immense promises to the MS community but their major motive seemed to be the market profits. In January 2001, CEO Jim Mullen told the financial community, “Biogen’s next great challenge is to transition from being a one-product company into a multi-product company” (Delong, Heyman, & Margolis, 2007, pg. 3A). This statement in no way involves helping MS patients; instead it focuses on Biogen Idec’s financial success. At this time, Biogen Idec’s mission and core values were self-interested and unaligned. There were limited CSR initiatives and in 2004 their mission lacked direction and failed to mention their patients: “We create new standards of care in oncology and immunology through our pioneering research, and our global development, manufacturing and commercial capabilities” (WayBack Machine). Their most important stakeholders were their shareholders, investors and management executives.

Antegren showed promising results in its Phase II and Phase III trials. Neurologists and statisticians presented it to Mullen and other executives in early February 2004. Although only through one year of their proposed two-year research duration, the executives were excited and impressed by the results. No MS drug had previously been approved without two years of Phase III data but Biogen Idec and Elan decided to submit their application for approval. Although discussions with the FDA about Antegren were very positive, nothing was guaranteed and an early application to the FDA was unusual. There were also several indications at the time that the current commissioner would shortly be leaving the FDA and the replacement was unknown.
Additionally, the FDA was also involved in a controversy regarding over-the-counter contraception, (Margolis et al., 2007, pg. 3A). But even with this information, Biogen Idec believed they had the data and research to achieve approval from the FDA and submitted their application early. Many considered this a very precarious decision as not receiving approval would hurt their reputation which in return would hurt their profit and affect other stakeholders, their partnerships and employees. But the competition had gotten to Biogen Idec and Elan and their main concern was their possible future success and profit gains.

Submitting the application early was so important because, as the case study states, it would enable more MS patients to receive treatments but also the early application and approval would enable Biogen Idec and Elan to start gaining profit. As stated in this case study:

Getting a license for Antegren would also allow Biogen Idec and Elan to start realizing a return on the large investment they had both made just to get this far in the development process. On the heels of the announcement, analysts estimated between $35 and $90 million in additional Antegren sales for 2005 alone. Analysts estimated profit margins anywhere from 16% to 25% (Margolis et al., 2007, pg. 1A).

The success for Biogen Idec and Elan would be groundbreaking.

An additional risk was that receiving an early approval would require a major increase in manufacturing, distribution and reimbursement capabilities. The major challenge would be, “making enough of the drug to meet the anticipated demand. It needed to be produced in dedicated bio-reactors and it took eight weeks to produce a single batch,” (Delong, Heyman, & Margolis, 2007, pg. 10A). To ensure that proper quality requirements were always met, operators needed to be, “highly skilled and obsessive about quality,” (Margolis et al., 2007, pg. 10A). Hiring such obsessive and skilled employees and training them so quickly would be a major
undertaking. Another threat included the administering of this drug. Patients received Antegren, “through an intravenous infusion once every four weeks. Biogen Idec would therefore also need to make sure that approximately 1,000 independently run infusion centers would be functional and capable of delivering the therapy,” (Margolis et al., 2007, pg. 8A). These challenges caused two issues with patient safety. The first concern being that the administrators be fully trained and capable of ensuring proper infusion for patients with limited amounts of training time. Secondly, Biogen Idec and Elan needed to ensure that the immense amounts of infusion centers were ready if the drug was approved.

In the early 2000s, Biogen Idec’s values were unaligned and unfocused. The executives made decisions based on profit gains. Their most important stakeholder was the investors and shareholders. Biogen Idec wanted to be a multi-product company and wanted to keep up with the largest pharmaceutical competitors. Their other stakeholders, employees, patients and the MS community, should have been the number one concern. Fighting the war against MS with the proper amount of research should have been their goal. On November 24th, 2004, the FDA approved the drug’s application with a requested name change. The companies were committed to completing the two-year trial but only 3 months after FDA approval, on February 25th, 2005, Jim Mullen decided that Biogen Idec would withdraw Tysabri (previously Antegren) because a serious adverse event had occurred. One patient was near death because they had contracted Progressive Multifocal Leukoencephalopathy (PML), a brain infection, (Margolis et al., 2007, pg. 3B). The other patient was in critical condition and was suspected to have also contracted PML. On July 20th, 2005, Walter Smith sued Biogen Idec and Elan for negligence and fraud related to his wife, Anita Smith’s death. This adverse event may or may not have occurred after a full two years of research from phase III trials but many of their stakeholders will always
criticize Biogen Idec’s decision to jeopardize the safety of their patients by submitting their application early.

**Regulator or Colluder: The role of the FDA**

Anita Smith’s death and the lawsuit pursued by her husband Walter Smith, raises some important questions about the role of the Food and Drug Administration in the case of Tysabri. As mentioned earlier, there are no clear answers to what might have happened if the phase III trials were completed before Tysabri was approved and launched in the market. Would they have caught a PML case early on and perhaps delayed launch or scrapped the drug altogether?

Looking at the timeline and the repeated mention of profit projections by Biogen Idec prior to the launch of Tysabri, it is difficult to imagine a scenario where patient safety would have trumped economic gains. And thus, this brings into focus the role of the regulatory authority, in this case the FDA. As a gatekeeper regulating the pharmaceutical industry and setting standards for products produced by this sector, the FDA had a crucial role to play in the approval of Tysabri.

Biogen Idec not only sought and received expedited approval for Tysabri, they also wanted it to have *orphan drug* status.

The Orphan Drug Act (ODA) was enacted in January, 1983 to encourage research and development of drugs to treat rare diseases (Berens & Armstrong, 2013). According to the ODA a disease qualifies as an orphan (rare) disease if there are fewer than 200,000 people afflicted by the condition within the USA. According to the National Institutes of Health, there are approximately 400,000 patients suffering from Multiple Sclerosis (MS) in the USA today (Multiple Sclerosis, NIH, 2013). This number is an approximation since no law within the country makes it mandatory for physicians to report new or existing cases of MS.

Though the idea behind the development and passage of the Orphan Drug Act was noble,
there has been a wide-ranging debate about the underlying motivation for pharmaceutical companies engaged in such a niche area of research and development. On the thirtieth anniversary of the ODA, Seattle Times (Berens & Armstrong, 2013) conducted a study to assess its successes and failures. Research done by the newspaper found that prior to the passage of the Orphan Drug Act in 1983, the FDA had only approved 10 drugs for rare diseases. Whereas, since the act has come into being, 363 drugs have been approved. Similarly, the number of orphan or rare diseases requiring an orphan drug have increased to a whopping 6,428. These figures tell a story that implicates the pharmaceutical industry; are they trying to use the Orphan Drug Act to their commercial advantage?

Margolis et al. (2007) point out in the case study that Serono Pharmaceuticals of Switzerland in 1999 had applied for approval of their MS drug, Rebif. It had already been approved and was used in Europe and Latin America to “prevent disease progression in patients of relapsing remitting” MS (Margolis et al., 2007, pg. 7A). The FDA though, rejected their application on the grounds that Avonex, manufactured and marketed by Biogen, was protected under the ODA and was serving the same segment of MS patients that Rebif hoped to help. In light of this, why did the FDA go ahead to approve Tysabri when it was to be used to treat relapsing remitting MS, same as Avonex? The actions of the FDA raise questions about the competence of the leadership of the regulatory body and their motivations in providing an expedited approval for Tysabri. The gatekeeper failed in its responsibility.

It is pertinent to note here that in a study comparing the CSR approaches of U.S. and E.U. pharmaceutical companies; it was found that US companies are largely motivated by the economic benefits of engaging in the development of orphan drugs (Bruyaka, Zeitzmann, Chalamon, Wokutch & Thakur, 2013, p.61). Though producing what might be termed a basic
human need—means to good health, pharmaceutical companies, Bruyaka et al. found did not always rate their CSR higher than the economic benefits of being in the orphan drug market. This is primarily due to the fact that under the ODA, U.S. pharmaceutical firms are provided a 50% tax benefit for clinical trial expenses in addition to a seven-year period of market exclusivity (Bruyaka et. al, 2013, p 48).

Viewing the case of Biogen Idec and Elan's launch of Tysabri from this lens, it is clear that in this case too economic benefits outweighed the intended impact on patients and other stakeholders. The history of the development of Tysabri (previously Antegren) has been summarised in previous sections. The announcement of the launch of this new drug, hailed as a new development in decades, had raised patient hopes and increased the valuation of Biogen Idec's stock. Biogen Idec had also announced that the impending launch would earn it revenues around the ballpark figure of $2 billion. It is thus, no coincidence that in order to capture the market, Biogen Idec and Elan, pursued an expedited review of their Biologics License Application with the FDA.

Elan pharmaceuticals’ choice of partnering with Biogen Idec, a market leader in MS therapies, was a strategic move. As mentioned earlier, Avonex, its treatment for relapsing forms of multiple sclerosis, was already well established and held orphan drug status. Bruyaka et. al also point out that there is often a lack of understanding about a rare disease thus making the research and development process of orphan drugs lengthy and costly (2013, p. 48). But in the case of Biogen Idec and Elan, there was already in existence sufficient expertise in the field of MS treatment. This further points to the fact that corporate responsibility was missing as a motivating factor in the pursuit of Tysabri development. The idea of creating value for the community and for its stakeholders, was only limited to the creation of wealth in the form of
stock prices and sales revenues of the drug.

On November 23, 2004 the FDA approved Antegren with the condition that its name be changed. Tysabri was thus proposed and adopted. Then commissioner of the FDA, Lester Crawford, was quoted as saying, "While we eagerly await long-term results from ongoing clinical trials, we have reason to believe that Tysabri will significantly reduce relapses in MS.” Tysabri was launched in the market the following week. Biogen Idec, in preparation for the launch of Antegren hired new staff aggressively. The shortened timeline from approval to commercial launch meant it had to prepare a sales force, negotiate with insurance companies and convince physicians and patients about the efficacy of the drug. But within 3 months the drug was withdrawn from the market (Refer to Background, p.4) In retrospect, the actions of Biogen Idec, Elan and the FDA, from introduction to withdrawal of Tysabri, were to affect not just patients and their families but other crucial stakeholders such as employees, doctors, clinical trial patients, patients using Tysabri outside of trials and of course, investors and shareholders. In the plan for restructuring announced on September 8, 2005, Mullen estimated that 650 jobs approximately 17% of Biogen Idec’s workforce, would be cut worldwide in order to reign in operating expenses (Margolis et al., 2007, p.3 D). Similarly, the company had been engaged in liquidating its assets wherever possible to cut costs. Thus, the chain of events set in motion by early approval and then the withdrawal of Tysabri had far reaching impacts on the lives of all those involved, from patients to researchers to production line employees.

The actions of all three of the key decision makers shine a light on their prioritization of stakeholders. In keeping with the Neo Classical view of CSR that Milton Friedman put forth in his essay, Biogen Idec and Elan were visibly working in a framework of shareholder primacy. While one of the core values listed on the Biogen Idec website in 2004 is as follows:
“Commitment to Those We Serve: We measure our success by how well we enable people to
achieve and to thrive. Patients, caregivers, shareholders and colleagues deserve our best”
(WayBack Machine). Their actions did not display this sensitivity to patient needs and well-
being. Thus, in 2004 Biogen Idec was using a business approach that gave primacy to the
creation of equity instead of value.

A Question of Ethics: Insider Trading by Biogen Idec Executives

The withdrawal of Tysabri had repercussions for the valuation of Biogen Idec in the
market. On February 28th, 2005 the day began with Biogen Idec’s stock price at $67.28 which
dropped 43% to $38.65 after the announcement about the withdrawal of Tysabri, (Margolis et al.,
2007, p. 1C). CEO Mullen anticipated a Securities and Exchange Commission investigation
about such drastic change in stock price and prepared accordingly. Although at this point in time
he was unaware of it, there had been instances of insider trading by senior executives after the
news of PML related adverse events had been received. Biogen Idec had to deal with insider
trading in the past. In May, 2004 the company's chief scientific officer, Nabil Hanna, resigned
after being found guilty of insider trading involving another company (Margolis et al., 2007,
p.4D). Whether it was just a coincidence or sheer bad luck, Biogen Idec's executives had been
provided a pre-arranged trading window on the morning of February 18th, 2005 to exercise their
stock options. While some executives were found to have traded within the allotted trading
window, Thomas Bucknum used his knowledge of the adverse events to make a profitable trade
(Margolis et al., 2007, p.3D).

The Securities and Exchange Commission defines insider trading as both, legal and illegal. In the
case of Biogen Idec and Thomas Bucknum, the insider trading was illegal:

Illegal insider trading refers generally to buying or selling a security, in breach of a
fiduciary duty or other relationship of trust and confidence, while in possession of material, nonpublic information about the security. Insider trading violations may also include "tipping" such information, securities trading by the person "tipped," and securities trading by those who misappropriate such information." (SEC website)

His actions were not only unethical and an example of insider trading, they were also outside of the pre-arranged trading program. Korczak, Korczak & Lasfer, hypothesize that insider trading often results prior to market sensitive news announcements by companies (2010, p. 373). Though Korczak et. al. claim that insider trading is often guided by an understanding of regulatory implications of such strategic trading as well as considerations about a loss of trust; the case of Biogen Idec's Thomas Bucknum shows no such deliberation. Bucknum's actions displayed a complete disregard of the regulatory consequences of his actions for himself and the company.

The actions taken by CEO Mullen in light of the withdrawal of Tysabri and the fall of share price were done in preparedness for an impending investigation; instead if he had had the foresight to have taken preventive action, the episode of insider trading could have been avoided. The prearranged trading window that was provided to executives on February 18th, 2005 was part of a program which required enrollment, such that only the enlisted executives could trade during that time period. Knowing this arrangement, it is surprising that Mullen did not decide to clamp down and close the program as soon as he received news of the adverse events. This episode points towards a leadership that did not think and act preemptively, but rather moved in to rescue the situation. Though the move to remove Tysabri was supported by infomediaries such as New England Journal of Medicine (Margolis et al., 2007, p.2D), this reactive strategy was not an appropriate one to deploy when it came to insider trading. A proactive plan of action which
would have factored in the harm that such irresponsible and unethical behavior on behalf of executives in senior management would cost Biogen Idec, could have proved more effective. Thus, not only was there a lack of planning on behalf of the company’s leadership, there was most visibly a lack of value alignment within the organization.

**Shareholder Primacy Model: Biogen Idec’s Ordering of Stakeholders**

As Milton Friedman wrote, “There is one and only one social responsibility of business — to use its resources and engage in activities designed to increase its profits so long as it … engages in open and free competition, without deception or fraud,’” (Smith, 2003). Bigoen Idec and Jim Mullen would be in agreement with Milton Friedman and his views of shareholder theory. Biogen Idec and Elan made their decisions based on the shareholder primacy model instead of the stakeholder theory. The decisions they were making were based on market profit. Biogen Idec and Elan didn’t have aligned missions, values or visions and also didn’t incorporate corporate social responsibility in their business practices. The organization needed to integrate a corporately responsible business model and organizational structure. Biogen Idec didn’t engage all their stakeholders. The key stakeholder groups by order of importance to Biogen Idec are as follows: shareholders/investors, management/executives, partner collaborations, patients/MS community and lastly, employees.

Biogen Idec and Elan had made big promises to the MS community but their major motive seemed to be the foreseen profits. On just the announcement of Antegren, “analysts estimated profit margins anywhere from 16% to 25%,” (Margolis et al., 2007, pg. 1A). Submitting an early application and receiving an early approval from the FDA would increase optimism and stock prices. In the early 2000s, Biogen Idec’s values were unaligned and unfocused but Biogen Idec knew what they wanted. They wanted to be a major pharmaceutical multi-product
competitor. The executives seemed to make decisions based on profit gains. Therefore, their most important stakeholder was the investors and shareholders.

Management and executives were also high on Biogen Idec’s stakeholder order. In June 2003, Biogen announced that they were to merge with Idec Corporation. The merger enabled increased research, facilities, employees and a budget of over $300 million. This merger would also cut an incredible amount of costs. Yet even after this, there was speculation that the company’s merger did not include cutting costs for management and executives. “It was reported that despite Biogen Idec’s pledge to find $475 million in savings by 2007, the new company spent $5.1 million on three Boston luxury condos for executives relocating from San Diego,” (Margolis et al., 2007, pg. 5A). Keeping their management and executives happy was clearly a priority to Biogen Idec and Elan.

Collaborators and partners are also a major stakeholder in this case. One of the most important collaborations in the case study is Biogen’s collaboration with the FDA. Announcing the news on Antegren early was a strategic move on Biogen Idec’s part. The announcement, backed by the support of the FDA, would raise patient and investors’ hopes and interest which in return would increase the valuation and sales of Biogen Idec’s stocks. Additionally, Biogen requested an expedited review of their Biologics License Application from the FDA. An expedited review approval from the FDA would seriously help raise the hopes of patients and investors.

The MS patients and community should be considered the most important stakeholder but following the shareholder primacy model prevented this for Biogen Idec. In the early 2000’s, Biogen Idec’s missions, visions and values barely included the importance of health care and their patients well-being. Biogen Idec submitted its Biologics License Application early based on
interim one year of results from the ongoing Phase III trials which was one year earlier than planned. Biogen also requested priority review from the FDA which reduced their review and approval process from 10 months to 6 months. Biogen Idec management and executives decided that even though they only had one of phase III research completed, that they would go ahead and apply. They were so excited with the current results and the possible profit gains that they rushed the application. This decision put their clinical trial patients and the MS communities’ health and safety at risk. Although it did help a lot of patients, several clinical trial patients lost their lives within the first three months of Tysabri’s release.

The shareholder primacy model does not emphasize the importance of employee engagement. High levels of employee motivation, retention and emotional well-being are associated with high levels of trust and fairness in the workplace. As Richard Axelrod wrote in his book about Terms of Engagement:

It is obvious that trust lies in the hands of organizations’ leadership and management. In order to build trust within the organization it is necessary to ensure that these individuals are not only personally involved in the organization, but they also submit themselves to the same vulnerabilities and risks as their employees (Axelrod, 2000).

The management and executives of Biogen Idec and Elan did not submit themselves to the same vulnerabilities as their employees. In 1985, in an effort to transform their organization, Biogen found it appropriate to lay off 275 employees. As a result of an early submission of the BLA application for Antegren/Tysabri and an adverse event, Biogen Idec and Elan needed to reduce their workforce by 17% or approximately 650 employees. Once again, there was no trust in Biogen Idec and Elan.

In conclusion, Biogen Idec followed a shareholder primacy model rather than a
Biogen Idec focused on maximizing shareholder value and therefore put the importance of their shareholders first. This in return put the well-being of their clinical trial patients and the MS community at risk which also hurt Biogen’s reputation and valuation of stock prices. The shareholder primacy model additionally discourages employee engagement. As Jeff Smith mentions in his article, executives should consider changing their language from maximizing shareholder value to maximizing company value (Smith, 2000). In order for Biogen Idec to accomplish this, they would need to better define and communicate their organization’s values, missions and objectives while also incorporating corporate socially responsible initiatives.

**Critiquing Biogen Idec’s Communication Plan and Business Model**

“I have three exes. Three medications I allowed to enter my body because I believed they would stand up for me against my nemesis, multiple sclerosis (MS). One of them stood me up—and then ran into trouble with the law. None of them were tough enough to defeat multiple sclerosis.” - MSPatient (“A Valentine’s Day Meditation,” 2011)

**Detrimental Impact of Shareholder Primacy**

Biogen Idec’s business model built upon shareholder primacy thus shaped not only their decision making process, but also illustrates how they defined value. As argued by Stout (2012), the shareholder model places profits above all else, pushing the company toward short-term solutions in an effort to generate immediate market value for shareholders. The emphasis on immediate return is evident in Biogen Idec’s decision to expedite the FDA application process, as their primary focus was the earning potential of Antegren. Before Biogen Idec even announced the intention to submit Antegren’s application for approval, analysts had already estimated Antegren would lead to between $35 million and $90 million in sales (Margolis et al., 2007). Investors, many still reeling from Biogen’s merger with Idec and the resulting suppressed stock value, were thus enthusiastic and supportive of the expedited process. Instead of
considering the long-term implications of a rushed approval process, Biogen Idec’s decision ultimately signified they placed profit over people, disregarding the future implications on patient safety. Their short-term financial strategy proved to be unsustainable, as immediate market gains only lead to a steep decline following the withdrawal of Tysabri (See Exhibit 1). Following the suspension, the stock price fell 43%, wiping out over $9 billion in market capitalization and further jeopardizing Biogen Idec’s relationship with stakeholders.

**A shared value approach.** Furthermore, Biogen Idec’s business model incorporates Porter and Kramer’s (2006) concept of shared value. The organization attempted to point out the shared value that would be generated for patients, suggesting an expedited approval process would help patients struggling with MS obtain relief faster. However, their strategy for expediting Antegren’s approval was generated in an effort to advance their own self-interests rather than for the benefit of the MS community (Aakhus & Bzdak, 2012). In following the shared value model, Biogen Idec proposed Antegren as the solution to a significant health problem they identified and defined (Aakhus & Bzdak, 2012). However, this problem was defined and shaped by Biogen Idec based upon the forecasted financial benefit of their solution drug Antegren (Aakhus & Bzdak, 2012). Furthermore, while the company did work with the FDA during the application process, it was also based on an effort to advance their financial interests in Antegren rather than a collaborative effort to improve regulation across the pharmaceutical industry. Throughout their decision making process Biogen Idec lost sight of what should have been their primary focus: patient safety. By embracing the shared value model the company essentially neglected their stakeholders, instead implementing strategies that would increase their bottom line.

**Reactionary, one-directional communications.** Finally, as Biogen Idec measured and
defined value around short-term initiatives and immediate profit generation, their communication strategies and tactics were aligned in the same fashion (Handy, 2003). Instead of engaging in communication with key stakeholders including employees, patients, and the MS community, the CSR instruments for communication were one-directional as well as reactionary (Aakhus). The most frequent communications were delivered either directly from Mullen or issued through press releases, traditional CSR instruments for communication (Aakhus). However, according to the Edelman trust barometer utilizing Mullen to direct the communications was detrimental as CEO’s are identified as one of the least credible and trusted sources of information for the public (Edelman, 2012). Furthermore, each announcement from Biogen Idec generated significant buzz (see Exhibit 2), leading to short-term increases in stock price after nearly all of the releases. This lead to a false sense of hope for current MS patients, hindering their well-being once Tysabri was recalled. While Mullen held a conference for the media and investment community following the withdrawal, this was a reactionary initiative based on the impending stakeholder backlash. The lack of strategically integrated CSR was thus evident in the reactionary and one-directional communication from Biogen Idec, resulting in severely diminished relationships with key stakeholder groups.

**Questioning Biogen Idec’s Core Values: A gaping hole in value alignment?**

“We are dedicated to serving all our constituents, because Biogen Idec is in business to make a difference for all those we serve.” -Biogen Idec’s About Us Corporate Overview 2013

As mentioned previously, Biogen Idec’s inconsistency with communicating its core values and utilizing reactive communication strategies calls into question the establishment and consistency of these core values in the first place. Clearly, Biogen Idec’s network of stakeholders ranging from patients to collaborative partners is one that is complex and is commonly seen in the pharmaceutical industry. As noted in the literature by Fieseler, Meckel and Hoffmann (2010)
regarding stakeholder engagement in pharmaceutical organizations, “Systematically addressing societal challenges and effectively managing stakeholder relations therefore necessitates significant alignments of business practices and the implementation of according structures and processes” (pg.3). In an effort to further challenge the business model of Biogen Idec, one may look at how the organization communicates its mission and core values through its public communication channels and how these messages change overtime.

In 2004, Biogen Idec’s mission was “We create new standards of care in oncology and immunology through our pioneering research, and our global development, manufacturing and commercial capabilities” (see Exhibit 4). Furthermore as noted on the same webpage as well as in the case study, the organization lists its core values including courageous innovation, quality, integrity, and honesty. However, the current corporate webpage makes no mention of these core values and instead has replaced them with how the company holds unique relationships with its key stakeholders as the only evidence of information regarding a mission is found on their corporate overview page (see Exhibit 5). This raises concerns that there is a lack of a clear statement that articulates Biogen Idec’s core values and communicates them in a way that it radiates throughout all of their key stakeholders. It seems as though the focus has been lost and the messages are blurred in vague statements such as their dedication toward “making a difference.”

On the current webpage dedicated to company’s view on “Improving Lives” (see Exhibit 6), patients are highlighted as the organization’s main focus and that patients are in fact “the reason” why the organization is in business. However, as previously mentioned, the actions of the company do not align with this view supported by evidence such as the corporate overview highlighting the profitable achievements of the organization thanks to its collaborative alliances.
Clearly the values of the organization are not communicated consistently throughout its channels of communication and there is a lack of focus on what are, if there are currently any, core values that are upheld in the organization.

As illustrated in the case study, a lack of core values and a clear mission statement can be detrimental to an organization in communicating with its stakeholders. The widespread lack of focus has also affected the company’s reactive communication strategies rather than being more proactive in establishing consistency in the first place. In the case study, a clear example of the tensions that arise within different stakeholders is the discovery of PML in cases of patients using Tysabri and the decision to withdraw the drug in 2005. The same core values on their website from 2004 remained the same on their website in 2005, yet the reactive nature of the organization and lack of clear communication of its core values primarily in honesty and integrity led to constant finger-pointing from all sides of their stakeholders wondering why they withdrew the drug and even led to reports of insider trading. Clearly, the organization was plagued with a heavy amount of disjointed criticism from all different directions which again calls into question the lack of effectively communicating the core values that were established at the time and anchoring them in the relationships among all stakeholders.

Looking back and breaking down the situation that the company was in during the withdrawal of Tysabri, it is clear that the relationship the organization had with its stakeholders was fragmented and primarily reactive rather than a collaborative effort. The proposed stakeholder model by Kuhn and Deetz (2008) hints at how an organization can come about identifying core values while maintaining the importance of stakeholder communication through “focusing on outcomes and interests in the interaction” (pg. 190) rather than “focusing on problems or wants and bargaining over preferred solutions” (pg. 190). In the case of Biogen Idec
at the time, they acted on short term goals and had a problem-oriented mindset rather than one
that is focused on long term, positive outcomes. Before jumping into creating a new stakeholder
model, it is suggested that Biogen Idec re-evaluate its relationship with each stakeholder.

**Solutions: A Proposed CSR Intervention**

“This idea is reminiscent of the concept of sustainability, i.e., business does not pursue
only short-term profits, but rather a multitude of goals which all combine to guarantee
business’s survival and prosperity in a changing environment” (Kakabadse et al., 2005, p. 283).

**The Normative Stakeholder Prioritization**

The re-evaluation of Biogen Idec's stakeholders from that of shareholders/investors,
management/executives, partners/collaborators, patients/MS community and lastly, employees is
crucial in the transition to incorporate corporate social responsibility into their business model.
According to Bhattacharya et al. (2011), stakeholders are the central component of a strategic
approach to corporate responsibility. In order for CSR to create the greatest potential value for
Biogen Idec, the organization first needs to fulfill some of the most basic needs of its key
stakeholder groups (Bhattacharya et al., 2011). The stakeholders ranked on an ideal priority scale
should begin with the patients/MS Community, the employees, the partners/collaborators,
shareholders/investors, and at the end is where the management and executives should remain. In
the healthcare world, “patients rely on their doctors to do what is best for them, there is no place
for greed” (Hirsch, 2008, pg. 607). Biogen Idec's executive management team should not have
taken part in insider trading and should have withdrawn Tysabri from the market as soon as the
serious adverse event was apparent. It is crucial to recognize the “corporate governance in
pharmaceutical companies that focus on the shareholder's bottom line is completely inconsistent
with healthcare, medicine [and] access to pharmaceuticals, where the patient should come first”
(Hirsch, 2008, pg. 607). Biogen needs to reconstruct their business “where patient health is the
highest value” by realigning their interests to that of all of the customers (Hirsch, 2008, pg. 608).

Patients are the most important stakeholder in this pharmaceutical due to the company making products that directly affect those who are in need of medical attention. The safety and well-being of these patients is what truly matters. Employees follow in second as they make the business function. Biogen was too carefree in their mass hiring and mass firing. They wasted time, effort, money, and resources in these on and off-again layoffs and closure of facilities. Employees seemed to have been disregarded when in reality they are the ones who are creating the product, writing the protocols, and who have a direct influence on the well-being and safety of the patients through their daily tasks at work. Partners and collaborators are next in importance as they directly make an instant difference in the life of the business as a corporate citizen. Not only does it increase its overall profit and workforce but it brings about “two distinct phases: strategy development and strategy implementation” which includes “values which drive the strategy and alternatives which encompass the various range of options available to decision-makers” (O'Riordan & Fairbrass, 2008, pg. 21). Collaborations and partnerships not only establish new innovation amongst businesses it projects sustainable strategies to aid in making the patients the most important stakeholder since the decisions that they make directly influence them on all levels in the future of medicine and in the quality of life.

Shareholders and investors as well as management and executives are placed at the end of the ideal priority scale due to the ongoing debate on ownership. This debates leads back to the 1930's between Adolf Berle and Merrick Dodd in which the argument about “whether a corporation owes a duty to society as whole or just to its shareholders” (Hirsch, 2008, pg. 620). Berle felt that it was the managers duty to the “shareholders because the shareholders own the corporation” whereas Dodd believed that the corporation “should focus not only on the interests
of its shareholders, but on the interests of its employees, consumers, and the general public” since it was that of public opinion that created change whether it was in relation to profit or that of social service (Hirsch, 2008, pg. 630). Biogen's decision of withdrawing Tysabri and the restructure of their business to reflect their core values, intended collaborations, and CSR strategies are the elements that align their philosophies to side with Dodd's ideas. It isn't just about profit or about patient, it is about all of these entities working together and participating to ensure a better quality of life for the business and vice versa. The “negative image associated with [pharmaceuticals] is the repeated occurrence of certain high profile events, labelled by many as ‘scandals’ (O'Riordan & Fairbrass, 2008, pg. 3). This type of perception not only breaks trust and reputation of the company, but if these 'scandals' as in Biogen are occurring on an executive team level, what does that say about the level of power and the ability to take advantage of something that was supposed to benefit the 400,000 people in the United States suffering from multiple sclerosis.

In the implementation of corporate social responsibility, it begins to transition from that of a “shareholder approach to that of a stakeholder approach” where it would allow the focus of the “pharmaceutical companies to protect the health of their customers” and in essence “recognize the specific rights to medicine and health, as well as human rights in general” (Hirsch, 2008, pg. 621). This biotechnology company in utilizing this realignment of stakeholders realizes that the “corporation owes a duty to individuals or entities who affect or are affected by corporate operations” and in that said, corporate social responsibility presents the opportunity to “protect human rights of these groups specifically recognizing that health is a human right” (Hirsch, 2008, pg. 623-632). This reorganization of stakeholders allows for the reinvention of the Stakeholder Model that includes values and those necessary stakeholders, in
level of importance to that of Biogen Idec.

The enhanced stakeholder approach therefore places the organization’s values in the center surrounded by each key stakeholder group, representing Biogen Idec’s accountability to each of the primary stakeholders (see Exhibit 3). As the foundation of the organization, the core values shape not only their business strategy but also illustrate how Biogen Idec’s socially responsible decision-making impacts each key stakeholder group. Based on the suggested re-prioritization of stakeholders, patients and the MS community are at the top of the cycle. This represents Biogen Idec’s commitment to the MS community and the need to place people over profit by considering patient safety throughout the organization’s everyday activities. Management and executives, meanwhile, have been placed in between the core values and each remaining stakeholder group, representing how the decisions they implement impact the MS community, employees, partners and collaborations, and shareholders and investors. As argued by Kakabadse, Rozuel, and Lee-Davies (2005), “It is the role of management to balance all the moral rights and interests involves, while at the same time safeguarding the objectives of the firm” (p. 295). This enhanced model will ultimately provide Biogen Idec with the groundwork needed to co-create CSR with key stakeholder groups through open communication and collaboration.

Alignment: Co-creating social value

In order for Biogen Idec to effectively integrate CSR into their business strategy they need to not only expand their organization’s core values, but also strategically align them with their business strategy (Boyton, 2012). An organization’s core values serve as the foundation of their business model and can also generate alignment between the company’s business strategy and key stakeholders (Euler, 2010). According to Euler (2010), corporate social responsibility is
only effective when aligned with the organization’s business goals in the form of long-term investments. Biogen Idec thus has opportunity to harness their organizational purpose to create value and generate long-term sustainability through goals incorporated into their business model (Bhattacharya et al., 2011). Once value creation can be achieved in the organization’s strategies, Biogen Idec generates the opportunity to develop a strategic purpose for CSR that results in proactive business strategies and stakeholder engagement initiatives (Bhattacharya et al., 2011).

Value alignment can generate new opportunity for Biogen Idec through partnerships, employee relations, and customer interactions. According to Euler (2010) value alignment is a critical component of sustainable collaborations as partners are strategically selected based on shared goals, interests, and strategies. Additionally, value alignment allows for the co-creation of CSR with two of Biogen Idec’s key stakeholders groups: employees and customers (Bhattacharya et al., 2011; Boynton, 2012). As argued by Bhattacharya et al., (2011) value alignment with stakeholders can be achieved through the three U’s: understanding, usefulness, and unity. If Biogen Idec understood the values held by employees and customers and provided meaningful opportunities to enhance their lives, these key stakeholders are more likely to feel unified with the organization (Bhattacharya et al., 2011). Furthermore, according to Word Business Council on Sustainable Development, value alignment can also benefit the MS community as they state, “the integration of social values within a company’s core business operations and engagement with stakeholders improve the well-being of society” (O’Riordan and Fairbrass, 2008, p. 747).

**Strategic Integration of CSR**

A second opportunity for Biogen Idec is the strategic integration of CSR into their business model. This would allow the company to shift their focus away from short-term profit
generation, instead incorporating business strategies that support long-term sustainability through the creation of value (Bhattacharya et al., 2011). According to Nishinaga and Lane (2013), Biogen Idec has a unique business opportunity to generate a competitive advantage in the pharmaceutical industry by harnessing CSR in their approach to health and wellness. In other words, Biogen Idec can strategically integrate CSR into their organizational model in an effort to generate new solutions to society’s largest healthcare problems, such as MS (Nishinaga and Lane, 2013). Nishinaga and Lane (2013) suggest this strategic integration of CSR in an effort to solve social problems demonstrates the evolution of CSR, having moved away from the defensive and reactive business model Biogen Idec was accustomed to.

As Bhattacharya, et al. (2011) suggest, a business model incorporating the strategic integration of CSR allows organizations to view stakeholders “as individuals who can create value for the company through their individual behaviors” (p. 26). The emphasis on the co-creation of value by Biogen Idec in turn would allow the organization to develop a strategic purpose for CSR, resulting in a proactive business strategy and proactive stakeholder engagement initiatives (Bhattacharya et al., 2011). Biogen Idec would then be able to develop communication strategies that engage stakeholders and solicit their input for collaborative solutions. According to O’Riordan and Fairbrass (2008), Biogen Idec can create value with stakeholders by participating in an open communication process that allows all parties to express their views and engage in a positive debate regarding the shape and scope of corporate social responsibility generated by the organization (p. 755). The co-creation of CSR initiatives is thus more likely to generate buy-in among key stakeholders, as they will have a greater understanding of Biogen Idec’s business activities and the resulting impact it has on them (O’Riordan and Fairbrass, 2008).
Finally, while collaboration with all relevant stakeholder groups potentially could have generated improved outcomes for Biogen Idec, open collaboration with the FDA has the potential to create value not just for Biogen Idec and the FDA, but also for the entire pharmaceutical community. Collaboration between the two organizations had the potential to serve as a powerful strategy in achieving new standards for the pharmaceutical application approval process (Gajda, 2004). As both Biogen Idec and the FDA communicate a strong commitment to patient safety, a strategic collaborative effort would be particularly effective based on the alignment of this shared goal between the two organizations (Euler, 2010). The collaboration would not focus on the shared value generated by each organization’s self-interests, but would rather create value as it has the potential to benefit all pharmaceutical companies and MS patients (Aakhus and Bzdak, 2012).

**Implications for the Future of Biogen Idec**

The lack of establishing core values and aligning CSR goals throughout the organizational networks clearly has cost Biogen Idec not just financially, but also in the trust that they have tried to establish with the medical community as well in terms of business ethics and regulation. Had Biogen Idec established and communicated their core values consistently across all their stakeholders, they would have avoided some of the tension that arose during times of crisis. Furthermore, it is clear that having these core values embedded in the first place within the organization's business model could have resulted in less backlash toward Biogen Idec for losing their focus on what is truly important for their business.

In order for Biogen Idec to encompass CSR practices, it is clear that there needs to be an initial set of core values that are consistent within its business model. Only then will this
organization be able to effectively communicate with its cast, complex network of stakeholders and in turn execute proper business practices that will lead them toward a sustainable future.
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Biogen share price and trades by volume. Retrieved from finance.yahoo.com/q?s=BIIB
Appendix

Exhibit 1: Biogen share price and trades by volume

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Share Price (Closing)</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>June 2003</td>
<td>$33.96*</td>
</tr>
<tr>
<td>A</td>
<td>June 2003</td>
<td>$33.96*</td>
</tr>
<tr>
<td>B</td>
<td>February 18, 2004</td>
<td>$53.23</td>
</tr>
<tr>
<td>C</td>
<td>May 25, 2004</td>
<td>$63.54</td>
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<tr>
<td>D</td>
<td>November 23, 2004</td>
<td>$57.43</td>
</tr>
<tr>
<td>E</td>
<td>February 25, 2005</td>
<td>$38.65*</td>
</tr>
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*Reflects end of month closing price
Exhibit 2: Antegren interest and Biogen stock price

Exhibit 3: Stakeholder model
Exhibit 4: Biogen Idec Corporate Overview Webpage 2004

Company

Vision and Values

Vision

At Biogen Idec we are passionate about our work and have a profound commitment to advancing the health of people worldwide. Our vision is to discover, develop and deliver innovative treatments that address the unmet needs of patients. Our breakthrough science and our understanding of the biology of disease will ensure that we are in a position to provide new and meaningful therapeutic options.

Mission

We are a leader in translating the discoveries we make in the laboratory into patient benefits. We are committed to developing new products and expanding the range of options available to patients and their families. Our mission is to discover, develop and deliver innovative treatments that address the unmet needs of patients.

Core Values

Courageous Innovation

We apply our knowledge, talent and resources to help redefine existing standards and create new ones. We are equally committed to meeting our shareholders’ expectations and the expectations of our patients, employees, partners and the rest of the world.

Quality, Integrity, Honesty

We are committed to the highest standards of quality. Our work is governed by a high code of ethics and commitment to the highest standards of quality. We are committed to cultivating excellence in all aspects of our business.

Team as a Source of Strength

Our company is strong because our employees are diverse, effective and collaborative. We pursue our fullest potential as individuals contributed to our team members and our leaders.

Committed to Those We Serve

We are committed to serving those who need our help and we are committed to being good corporate citizens. Our employees are dedicated to being good corporate citizens.

Growth, Transformation and Renewal

Consistent with our core values, we are committed to being a diversified and leading company with a focus on continuous improvement and innovation.

Exhibit 5: Biogen Idec Corporate Overview Webpage 2013

CORPORATE OVERVIEW

BIogen IDec TODAY

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, we are the world's oldest independent biotechnology company and a Fortune 500 company with more than $5 billion in annual revenues. Patients worldwide benefit from our leading multiple sclerosis therapies.

That's one perspective on Biogen Idec, though it's not the only one. To your patients, we are the trusted source of vital therapies for multiple sclerosis, such as AvONEX® and TYSABRI®. We also discovered Rituxan®, the world's most prescribed treatment for non-Hodgkin's lymphoma and an effective treatment for rheumatoid arthritis. Our patients count on us not only for medications, but also for a variety of support programs that help them deal with the rigors of living with serious illness.

To our employees, we are an exciting and invigorating place to work, an ambitious and nimble company where courageous innovation is encouraged and expected...
Exhibit 6: Biogen Idec Improving Lives 2013

Biogen Idec’s commitment to improve lives starts with patients. They are the reason we’re in business. And we strive to make a meaningful difference in their lives through our therapies, by offering financial assistance and advocacy services and by walking alongside them to raise awareness and funds.

We also seek to improve the lives of people in the communities in which we operate and for the Biogen Idec employees who make it all possible. At the intersection of these two priorities is our annual Care Deeply Volunteer Day, which provides employees around the world with the opportunity to make a difference in their local communities. In addition, through the Biogen Idec Foundation and other company resources, we support medical and science, technology, engineering and math (STEM) education, provide humanitarian assistance and fund important community projects.