Nicole Floro

Process Review: Example 1

I chose to include the peer commentary (and my responses) because along with the initial description it helps provide a context for my development through the semester. I reflected on and revised all installments before including them in the final project. Therefore before it was passed along to the peer reviewer, it underwent a critical review from me. However there were still several useful comments Laura was able to provide as well as suggestions for further clarification. This again shows how critical thinking is a journey and never really finished. I believe that anyone that reads my report will be able to find something else to add or revise because they are looking at it from a whole different perspective. I can't possibly think of everything or look at it completely without bias (although I certainly tried). I have been intimately involved with these installments for 13 weeks so I am no longer able to read it from an unbiased/ outside perspective. This is why peer commentary is so invaluable to the improvement of one's work. I spent a week away from the report, awaiting Laura's comment, and when I came back I had a fresh perspective and was able to consider her comments and revise my paper accordingly.

Additionally in comparison to the initial description and other installments provided, this example shows my progression through the semester. I was able to synthesize my installments (which were sometimes unfocused) into a cohesive report. Over the course of the semester, I was asked to consider alternative perspectives in my revisions. In my final report, I incorporated alternative perspectives in the theme of the report. This shows my ability to receive constructive criticism and use it to improve upon future assignments. It also shows my improvement in thinking critically over the semester. As we discussed in class, it is a journey and the journey isn't over once the semester ends. I will continue to strive to critically think and engage in the learning process past fall semester.

Introduction

At the inception of this project, I set out to study pharmaceutical industry practices to determine if they were ethical. This proved to be a much more complicated question than originally proposed and was an impractical task to take on in a 13 week class. As the semester progressed I tended to look at how consumers viewed the pharmaceutical industry and how these views were shaped by different influences. Taking a step back and reviewing the installments in totality, showed many of my writings discussed an issue in which the consumer and industry had different views and how this affected their relationship. Their relationship is currently an unstable one as feelings of unease and distrust have developed among consumers in regards to the pharmaceutical industry. It may be hard to imagine an industry which has saved countless lives through the development of effective medicines can be held in such poor esteem by the general public. Nevertheless, a divide has grown between the two groups based in part because of the differing perspectives and opinions. In order to bridge the gap between the two groups, their relationship has to be renewed with a focus on trust. As a consumer of pharmaceuticals and also a member of the industry through my work as a Patient Safety Specialist I have a unique perspective which has allowed me to evaluate both sides of the argument. Therefore my project evolved into looking into the different approaches the consumer and industry take on these issues as a way to understand their individual perspectives and work towards narrowing the gap that exists between the two groups. At the completion, I will have proposed some suggestions to be used by both consumers and the industry as a means to improve their relationship so both parties can benefit equally.

Really great intro- explains your thought process switching gears from your original topic to the consumer/pharmaceutical industry relationship, as well as capturing the reader's attention (since we are all consumers of pharmaceuticals)

Orphan Disease Act: Guaranteed profit

Prior to the passing of the Orphan Disease Act in 1983, diseases that affected small populations of people were generally neglected. These diseases were so named "orphan" because they had been largely ignored by the healthcare industry and affected only a small number of individuals (health orphans)[Aronson, J. Rare diseases and orphan drugs]. The pharmaceutical industry did not pursue research or development to treat these diseases in part because it wasn't lucrative. To bring a drug to market requires considerable costs both in research efforts and money. On average it costs over a billion dollars and requires approximately 10 years. Therefore if profits weren't expected by the end of the process, companies wouldn't be eager to take it on. The Orphan Drug Act was passed in 1983 and provided tax credits, extended patent protection, and simplification of marketing authorization procedures. These incentives essentially guaranteed pharmaceutical companies would make a profit if they pursued the development of orphan drugs. The guaranteed profit helped entice the industry to focus on the development of orphan drugs. By focusing research efforts on orphan diseases, did the industry genuinely intend to improve society, or were they thinking ahead of the opportunity to profit? Although understanding the true motive is difficult the perceived motive was profit and this contributed to the distrust by the consumers.

Consumers and patient advocacy groups tirelessly worked for the passing of the Orphan Disease Act because they recognized the lack of research and support for patients with Orphan Diseases. They correctly believed the Orphan Disease Act would spur industry to research and develop drugs for these diseases. They also correctly assumed the industry was at least partly motivated by profit. By increasing the opportunity to profit, the government in turn influenced the scientist's research. Instead of focusing on many disease areas, they were driven to concentrate their efforts on orphan diseases. The regulations inherently prevented competition, which in turn raised the prices of many of these drugs. The allowance of corporations to have a monopoly on orphan drugs resulted in high costs to the patients. For some drugs, such as Cerezyme, the average cost per year was $250,000 and this treatment was required for a lifetime resulting in considerable costs to the consumer. The goal of the Orphan Disease Act may not have been to assist corporations in making substantial profit but ended up being one outcome.

With profit comes certain responsibly and ethical practices to uphold. Social responsibility is the company's obligation to improve society. Corporations are required to works towards benefiting the greater good, through such things as environmental initiatives, or philanthropic efforts. The theory of social contract asserts there is a "contract" in place between the corporation and society. The corporations agree to act in such a way to be socially responsible while society "allows" them to be profitable (Makandi, P. 2010). Innate to the pharmaceutical industry is the ability to improve society through the development of life saving medication. The new attention on orphan diseases improved corporation's social responsibility because they now benefited more groups of people. However benefiting society isn't the only outcome of the social contract. Corporations recognized how important social consciousness was to consumers and used their efforts to enrich society as a marketing tool. Advertising their philanthropic efforts improved their reputation and in turn increased their ability to profit. Consumers can't help but consider how the social contract has become a business strategy as industry purports their "goodness" as a way to gain more profits.

On a superficial level, it seemed the Orphan Disease Act was enacted to benefit individuals with orphan diseases. The intention may have been pure but as time went on and there become more advantages to the industry, the consumers began to feel as though they "fell victim" to the Industry. Consumers were the ones who advocated for the passing of the Orphan Disease Act but in the end felt taken advantage of as the industry garnered profits. However do consumers need to feel taken advantage of? Can both parties benefit in different ways, consumers with life saving drugs and industry with profit? Why does it have to be one or the other? Why is profiting seen negatively by the consumer? Unfortunately further examination is required to answer these questions and thus they won't be answered in this paper but understanding each others' perspectives would be helpful in bettering the relationship between consumer and industry. Recognizing the advantages to each group and respecting the other's right to benefit would prove helpful as well.

Interesting topic! Was your research on the Orphan Disease Act related to a specific theme we discussed in class or an installment you wrote? Maybe make the tie-in to class a bit clearer in this section.

NF Comment: *This installment was from the Pellagra class, showing how the passing of this legislature influenced the direction of scientific research in the pharmaceutical industry for years to come with the shift to orphan diseases. We saw in the case of pellagra, causal explanation can be related to the political and social climate of the time. Government intervention could affect what was researched and how it was presented to society.*

Metaphors: Be More Careful

Metaphors are often used to make the complex more easily understood by the audience. Medicine, inherently, is a complex subject but also affects everyone so it is important that analogies and metaphors are used as a way to give a reference to the audience, to make the concepts relatable. This sentence is a little bit confusing…maybe consider re-wording it? NF Comment: *Thanks, fixed to make it more readable.* However metaphors also can create a bias and further the divide between industry and consumers.

One of the most widely used metaphors is the idea of medicine or pharmaceutical industries, "playing God." There is the idea that industry is assuming God's role by letting men live or die. It becomes an ethical debate whether or not man should have the ability to allow someone to die for example through assisted suicide or the ability to provide life through in vitro fertilization or human genetic engineering. The metaphor of "playing God" in this instance has negative connotations for health care industry. The industry is being viewed as over extending their authority. This popular metaphor is damaging to the industry's reputation and perpetuates the negative feelings towards the industry by the consumer.

"Medicine is war" is a metaphor that relegates the patient to a lower position where the enemy is the disease and the doctors take on the disease using technologies which are seen as weapons. The patients are seen as "clinical material" and not as a major player in this "war." In clinical trials subjects or patients are organized into cohorts within the phases of study. The word cohort, in Roman times, meant a set of identical and expendable soldiers used to win the battle. Interesting! To compare patients to an expendable participant rather than a major player demotes the importance of the patient in this war. Often the disease is viewed as an object rather than a process. Viewing disease as an "it" implies that it is something you can get rid of. A cure is seen as a physical removal of the disease and the patient is seen as a vessel for the disease. The patient is merely a container for the disease and thus is again seen as less important (Hodgkin, P., 1985). These metaphors put consumers in a negative light as they are passive players in their own disease. When diagnosed with any disease, the last thing a consumer wants is to feel is helpless. However when metaphors place patients as the central character it can also be misguided. The metaphor of "disease is an enemy" puts the disease in the patient's control and they become responsible for "battling" the disease and ultimately being "victorious." In this metaphor, patients who pass away are seen as weak because they aren't able to "defeat" the disease. "Losing the battle" implies it was a something that could be won or lost, but diseases are not contests. This can be demoralizing to the patient whose health is deteriorating as they mistakenly believe it is their fault.

These examples show how metaphors can influence one's views, and why then it is important to be careful when using them. Industry needs to make an effort to stop the media blitz of using the metaphor of the disease being an enemy because it puts too much pressure on the patient. They don't have as much control over their health as the sentiments often imply. At the same time, consumers need to work on discontinuing the "playing God" metaphor because it furthers the idea of an arrogant industry that believes they are above everyone else. Metaphors can really permeate a culture and change people's perspective which is why it is important to be responsible when using them and not further the divide between consumers and industry.

I can see the connection between metaphors and your topic- great job!

Supply Shortage: Media Coverage

When there was a Fabrazyme shortage (what is Fabrazyme used for? **NF Comment:** *I have added a sentence describing disease so there is more of a context to this section. Good suggestion*) beginning in 2009 due to a virus in the bioreactors of Genzyme's manufacturing facility, patients publicly denounced the company-the same company they had previously lauded for saving their lives. Public denouement through the media can be especially damaging to corporations because news reports are one of the biggest sources of information for society on current affairs. If these stories have an underlying tone, one that is not neutral, it can sway the reader's opinion. Journalists must therefore strive towards unbiased reporting. It is especially critical in reports covering the pharmaceutical industry because bias can perpetuate the distrust and further the divide between consumers and industry. The following articles written in response to the supply shortage have differing tones and exemplify how this can affect the reader's beliefs.

The patient accounts, those whose health was put in jeopardy, were highly critical of Genzyme and discuss their suffering publically. One patient interviewed by ABC news, refused to give his last name, in fear that Genzyme would single him out as a "trouble maker" and not provide him drug (James, S. 2011). Patients seemed to believe Genzyme was allocating drugs to certain groups of people and were not looking out for the entire patient population. Another patient echoed that sentiment as he stated, "…we are not confident they are doing everything they can for the Fabry community (explain what "Fabry community" is- **NF Comment:** *Fabry community is simply the community of patients with Fabry disease but I will make sure that is clear in my final report*) (James, S. 2011)." Patients began to doubt Genzyme's commitment to the patient community. Patients, such as Olshewski who used to do speaking engagements for Genzyme and believed it was a wonder drug, now said, "I think they should be held on criminal charges for what they're doing to people…our tax dollars paid for the research and development of this drug, and they turn around and ship it to another country…it's nothing but greed (Silverman, E. 2011)". When companies fail to deliver what is promised, the consumer usually has a strong and immediate reaction against the company. A popular stereotype of the "money hungry" corporation against the "innocent" patient is often employed. The general public, many who are not involved in the shortage, will read these stories and continue to distrust the industry due to the harshly negative tone.

The drug shortage can also be viewed from a former employee's perspective, which is an interesting perspective because it is an insider account of the situation but is not the company's public statement. Mr. Boisvert, a lead maintenance technician, claimed he began looking into the conditions of the manufacturing facility in 2008 and noticed there were dead bugs, dust, rust, and mold growing within the rooms that were designated "clean rooms". The use of quotations within the story implies the room wasn't actually clean and triggers the reader to start to question the legitimacy of Genzyme's manufacturing practices. Mr. Boisvert went on to further explain that he took his concerns on the sanitation of the facility up his chain of command, eventually reaching the CEO but was told the problems wouldn't hurt anyone. Not happy with that response, he contacted the FDA directly with his issues and ultimately was fired by Genzyme (Lord, R., 2012). The story is structured with Mr. Boisvert as the main character, and the reader follows him as he makes his discoveries on Genzyme's flawed practices. The emphasis on Mr. Boisvert's efforts makes him appear as a hero for exposing Genzyme to the public. However we never see the other sides of the story, how the managers reacted to his claims, what new processes were implemented, what evidence they used to decide it wouldn't harm humans etc. Only Mr. Boisvert's opinion is important in this story and all other's opinions are dismissed. The use of a central character, one seen as a hero, is written with a bias against everyone who opposed Mr. Boisvert.

Genzyme's commitment to the patient did not waver as much as these stories (thanks for typo correction!)indicate. When the shortage was announced, Genzyme sent a letter to health care professionals which contrasts the patient accounts. These letters outlined an emergency access program that provided drug in safe, effective doses based on a dose maintenance study. All patients were considered and prioritized accordingly. If any patient deteriorated, resuming full dose was to be considered by the health care professional. The structure of these letters are objective and without emotion. They acknowledge the problem at the beginning and further outline the necessary processes that would be undertaken. In the closing, Genzyme recognizes that it is a temporary problem and welcomes requests for further information (Genzyme, 2009). This article is meant to be informative and subsequently is stoic and direct which sharply contrasts the expressive language used in the other stories. However, consumers can mistake the lack of emotion in the article for lack of concern.

Although it is understood that bias is inherent in writing, if a journalist minimized their bias and wrote with a neutral tone, it may improve the relationship between consumers and industry rather feeding into the distrust. Consumers rely heavily on the media for their news, and with that come a certain amount of trust between the media and consumers. Therefore when the media publishes stories about the industry, consumers will believe the story and follow the tone of the report. If the media published more positive stories about the industry there would be a balance of information for the public to read which would help to improve the relationship between consumer and industry.

I'm guessing this installment related to the story telling theme? Again, maybe for the context of our course, be really explicit about the connections between our class discussion and your topic? **NF comment:** *I tried to not be too explicit in making the connection between the class discussion and each section. My audience is not the class so I didn't want to focus the paper on connecting each section to individual week's topics. I think for the most part the class discussions are easily observed within the sections of this paper without having to add the connection directly.*

Reye's Syndrome: Social Actions without Established Causation

Part of the divide between industry and consumers can be attributed to the belief that scientists don't have a complete understanding of the disease before they promote or reject treatments. Consumers want to be able to trust the "experts" with providing them safe and efficient therapies. However, sometimes without a complete understanding of the cause, social action may be initiated in response to a scientist's *favored* causality rather than the true cause. Although the distrust is often directed at industry for not putting patient safety first, it is often the government that dictates regulations and initiatives and industry is required to follow the directive. Reye syndrome, an orphan disease, (give a little bit more detail about the syndrome- to an outside reader who doesn't know what Reye Syndrome is, it is a bit hard to connect to this section of the paper without having more details on the symptoms, people it effects, etc. **NF Comment:** *I have added a few sentences on Reye Syndrome so the reader can understand this section*) exemplifies this practice as social actions were put in place in reaction to the perceived association between aspirin and the syndrome, without an established causation.

Epidemiologic studies showed an association between aspirin use and Reye Syndrome (Weiner, D., 2012). Reye syndrome often develops following a viral infection and it was believed that the use of aspirin during the infection lead to the syndrome. More than 80% of individuals diagnosed with Reye Syndrome had taken aspirin within three weeks of their diagnosis, however less than 0.1% of children who took aspirin developed the condition (Weiner, D. 2012). Although a causal relationship (got the theme for this section!) wasn't established, government health authorities, nevertheless, sprang into

action based on scientist's favored association between aspirin and Reye syndrome. Beginning after 1980, governing bodies including the Centers for Disease Control and Prevention, U.S Surgeon General, American Academy of Pediatrics, and the FDA all provided counsel. It was recommend that aspirin, or compounds containing salicylic acid, were not given to individuals under the age of 19 during illness induced by fever and companies were required to add warning labels to their drugs (Aspirin and Reye's Syndrome, 2012).

However these actions didn't satiate the consumer because they accused industry of not acting quickly enough and believed corporations pressured the government to delay the public warnings (Tanner, L., 1987). People criticized the pharmaceutical industry for thinking about their own interests ahead of patient safety. Consumers seemed to believe the industry delayed adding warnings to their product because they didn't want sales to decrease. The industry argued that any perceived delay in warning labels was due to the lack of causation. Few cases linked aspirin use to Reye's syndrome and further research and discussions were required. Industry did not want to purport what was not scientifically sound without further research (Tanner, L. 1987). Despite concerns with the association, industry did comply with government imposed regulations and included a warning on their label. Even recently scientists have claimed that Reye's syndrome may have been a viral mutation or was caused by metabolic disorders that were not been recognized (again, I am interested to know more about what Reye Syndrome is to understand this section better **NF Comment:** *I have added sentences above about Reye Syndrome*). Studies show the syndrome disappeared from countries where aspirin was not used in children and in countries where aspirin continued to be prescribed despite warnings (Orlowski, J. et al., 2002). There have been no animal models which show causation or demonstrations that salicylates are in the blood or urine of Reye's syndrome patients (Orlowski, J. et al., 2002). These results support the actions of the industry in being cautious with promoting the association.

A relationship with mutual respect and trust will never develop between industry and consumers if there is an idea that companies would jeopardize patient safety for profits. It is important that industry makes it known that they value and protect patient safety. As an employee within the safety department of pharmaceuticals, it is easy for me to see how safety is supported and appreciated by the industry; however consumers don't have the ability to see this firsthand. Once there is doubt that industry is not protecting consumer, there is an immediate divide. Therefore industry must make an effort to show their commitment to patients and consumers must be willing to forgo their preconceived beliefs.

Crohn's Disease: Unknown Cause but Many Treatments

It is critical to determine the cause of diseases because understanding the cause not only leads to treatment but also provides insight on prevention. However sometimes there isn't just one cause, often there are multiple causes and a multitude of solutions and preventions. The complexity of the causes can be confusing and can lead to misunderstandings on how to approach a treatment or prevention. Treatment for diseases is of significance because finding and utilizing the right treatment can be tremendously beneficial to affected patients while a lack of appropriate treatment can be debilitating and in severe cases fatal. However good patient care, also means understanding why a disease happens and how it could be prevented (Rose, G. 1985). Understanding risk factors and recognizing individuals who are susceptible to certain diseases would be beneficial to society by reducing incidence rates.

One of the more visible orphan diseases, Crohn's disease, exemplifies why it is so critical to look at all the factors that lead to a disease when developing treatment. (Add a little bit about what Crohn's

disease is.**NF Comment:** *I have added information on the disease and symptoms to provide context for this paragraph)*There are many theories as to what causes the disease but none have been proven. Research shows that the disease can be caused by a combination of immune system problems, genetics, and environmental factors. It is believed that genetics plays a role because scientists identified a gene associated with the disease where if the gene is mutated the body will react to microbes differently than a normal reaction and overtime can develop into Crohn's disease (WebMD). Environmental factors also have an influence on the development of the disease. Some factors may trigger the disease but not necessarily cause Crohn's disease while other factors may directly damage the lining of the intestines (WebMD). Since there are a multitude of causes, it is difficult for physicians to treat the disease. Often patients change their diet, avoiding foods that cause flare ups and take medications to reduce inflammation (WebMD). There is also a new therapy that uses stem cells to replace cells of damaged tissues which has its basis in the genetic/cellular causes of the disease (ScienceDaily). Without a cause, there can be no prevention. Despite the lack of prevention measures, certain actions can be taken to minimize the severity of symptoms which include regular exercise, healthy diet, abstinence from smoking, and use of non-NSAID for pain.

Crohn's disease represents only one orphan disease in which the cause is unknown but many factors leading to its development are known. Treatment options can be unique to the cause and if some causes are not recognized and explored, some valuable therapies could be neglected. If research was only focused on one cause of the disease, the patient might not receive adequate treatment. Researching the cause not only helps in treating Crohn's disease but also may lead to the development of preventive measures. If the disease can be successfully prevented, treatments won't need to be pursued. However, there may be an idea among consumers that industry isn't working towards preventing the disease because it means they will lose sales. If the disease can effectively be prevented, treatments won't be necessary and companies who manufacture these therapies will lose profits. This idea, although especially jaded, exemplifies the sometimes strong distrust by the consumer. We see consumers again re questioning industry's' motives. Whether or not they are right in their distrust, companies need to reinforce their commitment to patients. This may be done through better communication to the patients regarding their research efforts both in prevention and treatment as a way to emphasize their dedication to patient's health.

Green Pharmaceuticals: Helping the environment or a company's profit margin?

The potential eco-toxicity of pharmaceutical drugs is becoming a popular issue as society's focus on protecting the environment grows. Drug residues can end up in the environment through human excretion as well as through improper disposal of excess medication. The growing awareness of the negative impacts on the environment has forced the pharmaceutical industry to create "green pharmaceuticals." Calling these new drugs, "green" implies that the currently produced drugs are not "green." It can therefore be deduced that general perception does not believe pharmaceuticals are safe for the environment. However no significant research has been published to date that indicates pharmaceutical waste is harmful to human health. Studies have detected low levels in the environment which are unlikely to affect humans although there is a recognized potential for impacting aquatic life (glaxosmithkline, 2011). Despite the lack of strong evidence, consumers might be hesitant to consume drugs that are not "green."

In response to consumer's desire for environmentally safe pharmaceuticals, industry has begun to develop drugs that are "green." These are drugs that are harmless to the environment at their

inception. However creating these drugs is a challenge to the industry as many drugs are stable and effective *because* of their resistance to degradation. Are "green" drugs, manufactured in a "green" way? Does "green" only refer to the product or the process? (You don't necessarily have to add this to your paper, but I'm just wondering! **NF Comment:** *It refers to both the product and process, however, this is not clear in the current draft but will clarify for final paper*) Additionally, bringing drugs to market is a long expensive process. To add another criterion for market approval is not something companies would be eager to take on unless it was beneficial to them in terms of profit. Therefore there must be incentives for creating "greener pharmaceuticals" much like the incentives to create drugs for orphan diseases. During an EEA (what's EEA? **NF Comment:** *European Environment Agency*) workshop held in 2010, a patent system that would encourage companies to measure the environmental impact of the drug along with its safety and efficacy was suggested. The patent would be extended for drugs that are "benign by design." The profits garnered while under the extended patent would offset the costs to research the environmental impact (EEA Workshop, 2010).

The focus on creating drugs safe for the environment may be viewed as a business strategy rather than a true concern for the environment. Products become more marketable and subsequently profitable when it fits society's needs, which in this case is an environmentally friendly drug. This business strategy taken together with the proposed incentives for creating green pharmaceuticals would directly increase a company's profits. The initial response by corporations was to accommodate patient desires; however it became a way for them to increase their profit margin. Similar to the aforementioned Orphan Disease Act, there is a benefit to both parties involved albeit in different ways. However consumers may feel taken advantage of, initially believing their concerns were supported by the industry but instead were used in business strategy. Again the question is raised, why does one party have to become the "bad guy" when both groups are benefiting? The group who takes on this "bad guy" role is dependent on perspective; therefore a possible solution would be to minimize the bias and respect one another's position.

Forums: Improving Patient Outlook

Gaucher disease is a lysosomal storage disease which means it affects the lysosomal activity of cells. The lysosomes are missing an essential enzyme that breaks down fatty substances; therefore lipids accumulate in cells and certain organs. (Good description of the disease- simple and easy to understand) Prior to the development of Cerezyme, patients with Gaucher disease were provided palliative care to treat their symptoms because there was no therapy focused on treating the disease itself. Cerezyme is a form of enzyme replacement therapy in which the missing enzyme, beta-glucocerebrosidase, is manufactured in the lab and infused into the patient. With this enzyme, the deficient activity of the enzyme is normalized and the lipids can be broken down and removed from the body rather than accumulated. If the patient is started on treatment early, they will experience very minimal symptoms and can live an active, normal lifestyle.

However, the medication is required for life and costs approximately $250,000 a year. The drug is taken intravenously and depending on the patient can take 2-4 hours every two weeks to infuse. Taken the high costs and the long administration, patient compliance can be difficult. Patients may feel healthy and take it upon themselves to go on "drug holiday" or they may be tired of going to the infusion center every two weeks and decide to skip some infusions. The symptoms of the disease will come back and some of them are irreversible (what are some of the specific effects? **NF Comment**: *I added some examples of irreversible symptoms so the reader would better understand the disease and the importance of adhering to treatment)* . To combat the angst associated with the disease, there are several patient support groups for the Gaucher community such as the National Gaucher Foundation

and National Organization for Rare Disorders. These groups provide resources and advice for patients experiencing the disease and adjusting to the treatment regimen. Genzyme recognized the need for patient support and has a patient advocacy department within the company which provides live webinars, information on legislations as well as health insurance assistance. Due to the criticality of patient adhering to therapy, these resources can be incredibly beneficial.

Providing patient support through forums or support groups will certainly narrow the divide between industry and consumers. When corporations provide support, it humanizes the patients and makes them believe they are more than just a number to the corporations. It means the corporations genuinely care for them and their health. Further interactions between patients and industry will only continue to improve the relationship. Current research in Gaucher disease is developing an oral therapy that provides the same results without requiring the biweekly infusions. The idea that research is directed at making consumer's lives easier furthers the notion that patients are a priority to corporations.

Looking Forward: Evolution and Extinction

The pharmaceutical industry, as we know it today, is a nascent industry and increasingly susceptible to change. These changes can be viewed in the frame of evolution. Evolution as taught in the classroom is the concept of descent with modification where inherited characteristics change over generations. One mechanism of evolution is natural selection. Natural selection is not directed at a defined goal, it is an outcome of differences among organisms as they respond to their current environment. Companies who are able to adapt to the changing environment will succeed while those that cannot, will eventually go bankrupt or be bought out by a larger company. This is comparable to the concept of survival of the fittest where those organisms with favorable traits will flourish while those without will die off. As society and technology change, the environment in which the pharmaceutical industry operates will change and thus companies need to change in parallel to stay in business. These changes may, for example, be in demographics, regulations, globalization, or attitudes of the patients and investors. Companies compete for resources similar to how Darwin described organisms competing for resources in his "On Origin of Species." Unlike organisms that compete for food, space, and mates among other things, companies compete for investments, patients, and knowledge. As companies struggle to survive, they need to adapt their structure and capabilities.

Changing in response to the environment is not the only means by which a corporation can "evolve." For example, during scientific research mistakes can be made which end up being successful discoveries. When these mistakes happen in industry, it can completely change the direction of the company. For example if a company was focused on developing treatment for renal cell carcinoma but in the process, discover a mechanism to treat hypertension the company may redirect its resources to now focus on developing treatment for hypertension. This chance discovery can be compared to a random mutation in the DNA of an organism. Both happen by chance and both may lead to an "evolution" of sorts.

There are many ways a corporation can change and many reasons for the change. However, if corporations do not evolve as the market landscape changes, there may be extinction of some business strategies or in some cases extinction of the entire company through bankruptcy or acquisitions. The pharmaceutical industry, more so than many other industries, has a high rate of "extinction". It takes on average 10 years to bring a drug to market and over a billion dollars. It is difficult for companies to obtain the resources of capital and knowledge and at the same time adapt to the changing environment. Those that don't go "extinct" have the ability to change by some means and by some degree. It is critical

that industry appreciates the criticality of evolving as a means to avoid extinction. The divide that currently exists between the pharmaceutical industry and consumers could lead to extinction of some companies because the healthcare market recently had put more emphasis on the patient and is becoming consumer driven. Therefore to follow the theory of evolution as it applies to the pharmaceutical industry, companies should consider changing their business strategy in response to this changing landscape. The pharmaceutical industry should work towards fostering a better relationship with consumers as outlined in this report. Going forward concentrate solutions would prove more successful in bridging the gap between the groups but the most critical improvements are in fostering trust and opening the lines of communication-the key to any successful relationship.

Great job Nicole- it's obvious how much time and effort you put into your project over the semester! My only comments would be to try to make a clearer connection between the themes we discussed in class with your topic. Also, is your intended audience the general public/consumers, the pharmaceutical companies, or our Bio in Society class? **NF Comment:** *Although it seems very broad; my audience is consumers of pharmaceuticals and the pharmaceutical industry. I had to keep it this large because I am looking at both of their perspectives and trying to improve the relationship between both groups. I therefore had to include both groups as my audience, despite wanting to narrow it down.)* I think as your installments progressed, you were able to adapt the themes more easily (the same was for me too – I found the metaphors and causal explanation themes much easier to relate to my topic) and took each side of the argument for those themes as either the consumer or the industry perspective. I'm not sure if that was your intention, but maybe add in a little bit more to define your audience more clearly. Besides that, awesome job!

-Laura

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Nicole Floro

Process Review: Example 2

I chose the draft and subsequent revision to my second installment on stories for several reasons. It was an earlier installment so it shows where I started in this semester as a critical thinker and how I progressed from there. Also, I feel it shows for the first time I understood the comments you provided and started to also understand what it meant to think critically. When I submitted the initial installment, I thought I did a good job so when I saw the request to revise and re-submit I was confused. After more consideration I realized it wasn't that I did a "bad job" per-se on the original submission, rather your intention was to expand my thinking and push my paper further with the analysis of more stories and their structure and contrasts. Before submitting all subsequent installments I tried to think ahead and look for weak areas that I could strengthen. I also used the idea of looking at the same issue from different perspectives in my final report because of this installment.

When I read the initial submission again, I could very clearly see the lack of depth. I was merely responding to what I thought was the theme of the week (storytelling) and putting it in the context of orphan diseases. There wasn't much discussion on the structures of the stories or interpretations of these structures. My revision provided these discussions and interpretations with additional examples of stories as provided by you. Before I revised my installment, I sat back and thought about how these stories were structured and why they were written in that style. I was able to see, for example, that the story concerning the "whistleblower" was written with the individual presented as a hero and described how this presentation could affect the reader's interpretation. Now reading the installment, I am proud of how I was able to respond to your comments and write a strong, well thought out report. I have annotated the final version to highlight these changes.

Installment #2

When there was a Fabrazyme shortage beginning in 2009 due to a virus in the bioreactors of Genzyme's manufacturing facility, patients publicly denounced the company. The same company they had previously lauded for saving their lives. This turn of events and turn of the public opinion show how the tone of stories can be influenced by external forces and bias. Is Genzyme a terrible company that doesn't care about the patient or is it a company who cares deeply for the patient and did everything they could in light of the shortage? It is probably somewhere in the middle but as a consumer it is important for you to recognize the different structures of the same story.

The patient accounts, those whose health was put in jeopardy, were highly critical of Genzyme and discuss their suffering due to the lack of medication. One patient interviewed by abc news, refused to give his last name, in fear that Genzyme would single him out as a "trouble maker" and not provide him drug (James, S. 2011). This comment, exemplifies the sentiment of many patients. They believed Genzyme was allocating drugs to certain groups of people and were not looking out for the entire patient population. Another patient echoed that sentiment as he stated, "…we are not confident they are doing everything they can for the Fabry community (James, S. 2011)." Patients began to doubt Genzyme's commitment to the patient community. Patients, such as Olshewski who used to do speaking engagements for Genzyme and believed it was a wonder drug, now said, "I think they should be held on criminal charges for what they're doing to people…our tax dollars paid for the research and development of this drug, and they turn around and ship it to another country…it's nothing but greed (Silverman, E. 2011)". When companies fail to deliver what is promised, the consumer usually has a strong and immediate reaction against the company. They often say the consumer is not being protected and the company's focus is only on profit. There is the stereotype of the "money hungry" corporation against the "innocent" patient. These stereotypes bias patient accounts against the Corporation, sometimes unfairly.

Genzyme's commitment to the patient did not waver as much as these stories' indicate. When the shortage was announced, Genzyme sent a letter to health care professionals which contrasts the patient accounts. These letters outlined an emergency access program that provided drug in safe, effective doses based on a dose maintenance study. All patients were considered and prioritized accordingly. If any patient deteriorated, resuming full dose was to be considered by the health care professional. The structure of these letters are objective and without emotion. They acknowledge the problem at the

beginning and further outline the necessary processes that would be undertaken. In the closing, Genzyme recognizes that it is a temporary problem and welcomes requests for further information.

The drug shortage can also be viewed from a former employee's perspective, which is an interesting perspective because it is an insider account of the situation but is not the company's public statement. The individual, Mr. Boisvert, a lead maintenance technician, claimed he began looking into the conditions of the manufacturing facility in 2008 after refusing to sign off on inspections that weren't performed. He noticed there were dead bugs, dust, rust, and mold growing within the rooms that were designated "clean rooms". This was an interesting use of quotations within the story because it implies the room wasn't actually very clean and triggers the reader to start to question the legitimacy of Genzyme's manufacturing practices. Mr. Boisvert went on to further explain that he took his concerns on the sanitation of the facility up his chain of command, eventually reaching the CEO but he was told the problems wouldn't hurt anyone. Not happy with that response, he contacted the FDA directly with his issues and ultimately was fired by Genzyme. Analyzing this story shows how its structure can be used as a way to influence the reader. The story is structured with Mr. Boisvert as the main character, and the reader follows him as he makes his discoveries on Genzyme's flawed practices. The emphasis on Mr. Boisvert's efforts makes him appear almost as a hero for exposing Genzyme to the public. The use of whistle blower in the title furthers this idea as a whistle blower is often viewed positively, as someone who is a martyr and risked their job for the greater good. However we never see the other side of the story, how the managers reacted to his claims, what new processes were implemented, what evidence they used to decide it wouldn't harm humans etc. Only Mr. Boisvert's opinion is important in this story and all other's opinions are dismissed. The use of a central character, one seen as a hero, is written with a bias against everyone who opposed Mr. Boisvert.

Comments: *The above paragraph was added following the articles you provided me along with your comments. It allowed me to view the shortage from another perspective and also gave me the opportunity to look at the structure of the story. After analyzing the structure, I was able to interpret the use of the "hero" storyline which provided a certain bias against anyone who went against Mr. Boisvert (i.e Genzyme). This furthered the negative portrayal of the pharmaceutical industry.*

An additional perspective one of a former consultant for Genzyme is presented. Dr. Barranger worked at the NIH in the 1970s and developed the technology that was used to produce Fabrazyme. He explained his team studied lysosomes and along with a competing team determined how to synthesis the

enzymes that break down waste products. People who have Fabry or Gaucher disease do not have these enzymes and the waste accumulates in their cells. While consulting for Genzyme he said he loved the company and everything they were able to achieve. He said went on to say he was promised a percentage of the gross from his invention. He has never been compensated but took no action until Genzyme was bought by Sanofi Aventis leaving its executives with 8 figure paydays. When he saw other people benefiting from his work, he decided he wanted his compensation. He publically denounced the company and said, "they took far too many profits out of the cures of these diseases." Dr. Barranger's respect for the company quickly turned to disdain. The way Dr. Barranger's story is structured is similar to Mr. Boisvert in that he is again the central character who is fighting against the "evil" corporation. Dr. Barranger is portrayed as the hero for making this discovery that went on to improve people's lives and Genzyme is taking advantage of it to garner more profits. Even though Dr. Barranger himself is fighting for some of that profit, the overall tone of the story is the "good vs. evil" concept where Dr. Barranger is the "good" scientist helping people while the corporation takes advantage of their diseases.

Comments: *The above paragraph was also added to the installment following your comments. This story added yet another perspective of the shortage and again gave me the chance to interpret structure which I didn't really do in the initial installment. After reading and thinking about this story I realized it had a similar structure to the one discussed above with the use of a central character and how the author used a "good vs evil" theme. I didn't make these types of connections with my initial submission.*

The story of the drug shortage written by the corporation contrasts the stories written by the patients and former employees. Genzyme's letters are much more stoic and direct, while the other accounts use more expressive language. It is important to recognize the difference in structure and tone while reading the different stories as it provides insight into the possible bias and external influences.

Overall comments: *The addition of these paragraphs strengthened my installment because it provided more in-depth thinking that was lacking in my initial submission. I very literally presented storytelling and how it related to the supply shortage in my initial submission, without spending much time on the structure and subsequent interpretations of these structures. I think my revisions clearly show my thinking progressed and I was able to include interpretation in my second attempt.*

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Nicole Floro

Process Review: Example 3

I chose my revision on installment six because this piece was far enough along in the semester for me to be familiar with the process of critical thinking and the process of installment writing. However when reading my initial installment and the comments that followed, I realized I still had room for improvement. I allowed my opinions on the industry to enter my writing which is exactly what I warned against in my second installment on storytelling. I wrote with a bias against the pharmaceutical industry emphasizing their need to profit and didn't realize I let my bias into my writing until I read your comments. Because the idea that profitability is of utmost important to industries has permeated society, I didn't realize it was my opinion and not fact. As you said, I took it as a given or something that was natural to the industry. However, I didn't think how in some societies healthcare is a right and is a nonprofit. You mentioned the alternative was the idea of social contract. Writing about the alternative in whatever issue you are discussing is crucial to critical thinking. In this installment, without the alternative discussed, the paper is weak because it discusses only my opinion. Therefore following your suggestion and adding the social contract strengthened this installment. I also continued to employ this technique in my final project with my presentation of an issue and the differing perspectives.

As mentioned this installment was fairly far along in the semester, however my reports still needed to be strengthened and revised. This helps to illustrate the idea that critical thinking is a journey. I am of course not going to produce perfect installments by installment 6, it is a practice. I believe I am getting better at critical thinking but sometimes I need a push or a different perspective to improve my thinking. It is something I will continually work on and did work on through this 13 week journey.

Prior to the passing of the Orphan Disease Act in 1983, diseases that affected small populations of people were generally neglected. These diseases were so named "orphan" because they had been largely ignored by the healthcare industry and affected only a small number of individuals (health orphans)[Aronson, J. Rare diseases and orphan drugs]. The pharmaceutical industry did not pursue research or development to treat these diseases in part because it wasn't lucrative. To bring a drug to market requires considerable costs both in research efforts and money. On average it costs over a billion dollars and requires approximately 10 years. Therefore if profits weren't expected by the end of the process, the company wouldn't be eager to take it on. Although the pharmaceutical industry makes life saving drugs for people, it is important to remember it is a business and profitability is of [**comment**: removed "utmost" because after further consideration and your comments, I realized profit isn't always the most important to the industry] importance. The government, with patient advocacy group backing, intervened to encourage the industry to focus on orphan diseases. The Orphan Drug Act was passed in 1983 and provided tax credits, extended patent protection, and simplification of marketing authorization procedures. These incentives essentially guaranteed pharmaceutical companies would make a profit if they pursued the development of orphan drugs. The guaranteed profit helped entice the industry to focus on the development of orphan drugs. The passing of this legislature clearly influenced the direction of scientific research in the pharmaceutical industry for years to come with the shift to orphan diseases.

The government enacted the Orphan Disease Act in part based of the assumption that the lack of research in this disease area was due to the lack of profitability. By increasing the opportunity to profit, the government in turn influenced the scientist's research. Instead of focusing on many disease areas, they were driven to concentrate their efforts on orphan diseases. To you, the consumer, this Act seemed to be positive because research was conducted in favor of previously ignored diseases and treatments were now being provided. However that wasn't the only outcome, the regulations inherently prevented competition, which in turn raised the prices of many of these drugs which in most cases was the only treatment option. The allowance of corporations to have a monopoly on orphan drugs resulted in high costs to the patients. For some drugs, such as Cerezyme, the average cost per year was $250,000 and this treatment was required for a lifetime, resulting in considerable costs to the consumer. The goal of the Orphan Disease Act may not have been to assist corporations in making substantial profit but ended up being the outcome.

As illustrated, profitability is important to corporation's sustainability, however with that profit comes certain responsibly and ethical practices to uphold. Social responsibility is the company's obligation to improve the status of society. Corporations have been required to strive to benefit the greater good, through such things as environmental initiatives, or philanthropic efforts. The theory of social contract asserts there is a "contract" in place between the corporation and society. The corporations agree to act in such a way to be socially responsible while society "allows" them to be profitable (Makandi, P. 2010). Innate to the pharmaceutical industry is the ability to improve society through the development of life saving medication. However, it is interesting to note that not all sectors of society benefited equally, especially prior to the Orphan Disease Act, because individuals with orphan

diseases were largely ignored. The new attention on orphan diseases improved corporation's social responsibility because they now benefited more groups of people. The idea of a social contract between society and corporation was probably intended to protect society which it has done but it also has become a business strategy. Consumers are more willing to "consume" goods from corporations that are socially responsible. Companies can market themselves as enriching society whether it is through the development of orphan drugs or philanthropic efforts, thereby improving their reputation and in turn increasing their ability to profit.

Comment: *Added this entire paragraph following your recommendation to research social contract. Although it initially was added as an alternative: industry also improves society through social responsibility. This showed that there is a balance and profit isn't the only goal. However in my thinking, I realized social contracts can also used as a marketing strategy by the industry because as I mention consumers are more likely to consumer goods from corporations that are socially responsible. So not only was this an alternative to profitability it became its own issue with different perspectives: industry seeing it as a way to give back to society and consumers seeing it as another marketing ploy. This added another dynamic to my installment and eventual final paper.*

The influence society has on the healthcare industry is far reaching but not always visible to the consumer. On a superficial level, it seemed the Orphan Disease Act was enacted to benefit individuals with orphan diseases. However the monopoly on the product and the increased drug prices harmed consumers. The benefits to the corporations, though profits and improved reputation, seemed to outweigh the benefits to the consumers. By focusing research efforts on orphan diseases, did the industry genuinely intend to improve society, or were they thinking ahead of the opportunity to profit? **[Comment:** I added this question after thinking about the social contract, did the industry see the use of social consciousness as a marketing strategy from inception or did it evolve? Was social responsibility motivated by pure intentions or was it motivated by profit? I am not sure I will ever get an answer but it is an interesting question.] It is difficult to understand the true motive but it is important to appreciate the interplay of social policy and science. It has been the motive for many initiatives and advancements but has also been the reason for the neglect of certain diseases and social policies throughout history. In this example, government's authority had the ability to influence the focus of clinical research and the eventual discovery of many treatment options that may not have been pursued.

Nicole Floro

Process Review: Example 4

I chose to include my initial description in my process review because it most clearly shows where I started in this course. It was the first writing assignment and I was still not completely sure how to approach this project. I think that is evident in how broadly I described my topic and audience. I wasn't sure what we were "supposed" to write about and didn't know how I was going to apply my project to different class topics. I chose a very broad topic of ethics in the pharmaceutical industry which was certainly ambitious for a 13 week semester. I didn't end up discussing the ethics of the industry in much of my installments. Without having a focus in my installments, my final paper was difficult to write. I didn't have this initial description to give me perspective while writing which meant my installments catered to the theme of the week instead. The only constant was orphan diseases. Therefore I ended up spending considerable time trying to find a theme that permeated all installments to write my final paper. I wish I appreciated the importance of the initial description and spent the time looking at it during the course of the semester. It may be useful to have students revisit their initial description mid way through the semester to see if they following their original thoughts or if they should work on revising the description. The installment that week might be submitting a revision or commentary on your description that could be used in the final project. Personally, it would have been helpful to revisit my initial description after having a better idea of how my installments/paper were developing.

Initial Description:

The recent focus of pharmaceutical companies developing and marketing drugs to treat orphan diseases has led to economic, ethical, and social implications. Orphan diseases, in a broad sense, are diseases which affect a small percentage of the population. These diseases were designated as "orphans" because they had often been neglected by the healthcare industry and affected only a small number of individuals (health orphans). [Aronson, J. Rare diseases and orphan drugs]. In the last 25 years, however, new regulations have encouraged pharmaceutical companies to focus their research on orphan diseases. The Orphan Drug Act was passed in the United States in 1983. This was followed by similar legislation in Japan (1985), Australia (1997), and the European Union (2000). These regulations include tax credits, extended patent protection, and simplification of marketing authorization procedures. Taken together these incentives have allowed many orphan drugs to become blockbusters which in turn give companies billions of dollars of profit. The regulations, initially advocated by patient groups, were intended to protect the patient's right. However as the industry has evolved the regulations now protect the corporation's right to profit. [**Comment**: *Initially I believed the Orphan Disease Act would be the cornerstone of my project. I ended up using it in one of my installments and in the final paper but it wasn't as important to my report as I thought it would be.]*

During the semester I intend to research how the popularity of orphan diseases in the pharmaceutical industry has affected society from an ethical and economical standpoint. As the semester progresses I will attempt to determine if this affect is positive or negative, although I am not sure if it can be defined so easily [**Comment**: *I seemed to recognize my topic was vague and might be hard to use it in my final project, however I didn't offer any other topics or a way to solve this. I don't think I did it on purpose, I think it was just a consequence of not really understanding the project or the class*] An additional foreseeable challenge will be incorporating the weekly class discussions into my project. To aid my research I will use information on the regulations as well as learn more about the patient advocacy groups. Additionally, my first hand experience working at Genzyme, a biotechnology company focused on orphan diseases, will be of assistance in my research. Some topics that I will further investigate include the industry practice of inflating recommended dosages to be more profitable, recent drug shortages, common marketing practices, NORD, and patient stories. I hope to engage consumers of orphan drugs, industry and healthcare professionals, as well as society as a whole [**Comment:** *Although I didn't follow my initial topic in the installments or final paper, I did use some of the resources mentioned as well as the sub-topics presented which is interesting. My audience initially was also very broad (I included society as a whole!). Although you suggested I narrow my audience to be more effective, it ended up staying fairly large including the pharmaceutical industry and consumers of pharmaceuticals. My paper ended up requiring I keep the audience large because I was trying to reach both groups as a way to improve their relationship. I recognize the paper would be easier and more effective with a smaller audience; it wasn't feasible with the topic I ended up focusing on.]*