

The pharmaceutical industry maintains a large portion of the private sector in the United States. In fact as one of the most profitable industry in the American economy, *Fortune* magazine named it as the most profitable industry in 1999 due to the net profit margin of 18.6% (median of 5.0).¹ Thus, it can be said that the pharmaceutical industry greatly influences the medical field. The advent of new technologies in genomics after the sequencing of the human genome in 2003 has brought new possibilities to the industry and the public. More informed research can be done to advance the science associated with treating diseases, both viral and bacterial. Furthermore, patents and the idea of patenting genes has become of great importance. Policies, as well as moral views have come under scrutiny as the industry and the government attempt to adapt to the new technology. The impacts of the decisions made in these areas affect not only the researchers and the physicians who are in daily contact with the new technologies, but also the general public as the treatment of diseases becomes transformed by the industry. Thus, to understand the growing field of genomics and the development of new technologies one must first understand the interactions between the pharmaceutical industries, patents, and the burgeoning technology associated with genomics itself.

Pharmaceutical Industry: Past and Present

It is commonly said that everything is determined by the market. This is especially true here in the United States. For this reason it is not surprising that the leading industry in the United States, the pharmaceutical industry, should have such a large influence on patients' lives and on the development of new treatments. The

approach of pharmaceutical companies, like for any big business is looking toward profit margins and expansion. Their main strategies toward getting the funds to cover the tremendous expenses include different sources such as lobbying lawmakers, fighting to prolong patent protection, targeting drugs which help larger markets, creating demand from patients, and approaching doctors.² Developing new drugs and treatments is a time-consuming and expensive venture. To pharmaceutical companies the less needed to produce the drugs the better because the more net profit will be gained. The multi-step process in drug development and proliferation into the market can be broken down into four general steps, including: drug discovery, animal studies, clinical trials, and commercialization, each with unique difficulties and aspects which affect the overall process.³ This process and its drawn out nature has become the impetus for many pharmaceutical companies to raise costs to the consumers. In particular, the amount of money spent on Research and Development (R&D) is used as a valid excuse by the pharmaceutical industries for increasing prices to the consumers.

Having to put their products under several rounds of costly clinical trials, there are few drugs that actually become released. In addition, this sector contains a large portion of the costs incurred in the development of drugs. For instance, in 2001 it was projected that more than \$30.5 billion (18.5% of sales revenue) was spent on the development of drugs.² Some of these discoveries never even fully make it to the medicinal stage, since only 2% become commercial drugs.² Thus, the time and energy spent on developing a drug does not correlate to the yields. Furthermore, getting approval from the F.D.A. takes an average of 13 years.² Despite the fact that R&D has little to do with the actual cost to

the consumer, it is used by the pharmaceutical companies as justification for the costs and many risks associated with their industry.

Another important part of the drug industry appears to be that in the past few decades the pharmaceutical industry has shifted its focus. With the high costs and large amount of time spent on clinical trials many focus on developing drugs for chronic diseases rather than antibiotics. Logic presents the situation clearly, as producing a drug such as Lipitor™, used daily for many years will allow greater profits while other treatments are still being developed⁴. Furthermore, since the pharmaceutical industry is molded by ten big name companies which hold more than 50% of the sales⁴, smaller companies must also focus on such drugs in order to compete. The concepts behind producing drugs for the masses also come into play with the advent of genomics, since the new technology produces drugs targeting fewer individuals. Only the individuals containing a specific gene can use the drug, helping in the transition away from mass drug production. Nevertheless, the profit margin would still be greater as less time will be spend finding target genes and the drugs produced will be more likely to work. Specifically, before genomics, \$1 million was spent on creating one drug, but after genomics the costs went down 60%.³ Also, the percentage of drugs that have gone through the whole innovation process and are released into the market has skyrocketed. Before the advent of genomics only 5% of drugs 20 years ago made it through the entire development process and into the hands of patients, while today that number has reached 20%.³ This is a direct result of genomics' ability to decrease the cost of screening the validity of a drug, thus bringing drugs with a better potential for success to the costly clinical trial phase.³ Furthermore, by targeting a specific protein which is known to cause