INTRODUCTION

Each decade of its life, the biotechnology industry attracted over $100 billion of venture capital (Pisano, 2006). This was largely due to promising scientific research experiments involving the manipulation and customization of deoxyribonucleic acid (DNA) molecules, which is a process known as recombinant DNA. The Harvard case study *Kleiner-Perkins and Genentech: When Venture Capital Met Science* by Hardymon and Nicholas (2012) reveals that venture capital met science when venture capitalist Robert Swanson and biochemist Herbert Boyer sought to undertake recombinant DNA research through the financial utilization of the private sector in the mid 1970's. In a sense, venture capital was Swanson's and Boyer's way of escaping from issues regarding governmental guidelines and regulations, as well as ethical concerns. These issues ignited many controversies despite efforts to control recombinant DNA research in laboratories, and they continue to flare up present-day debates. Although environmental concerns may eventually be settled, ethical concerns may continue to be an issue despite the funding source of recombinant DNA experiments (i.e., governmental or private).

Background

Shortly after the formulation of recombinant DNA by biochemist Herbert Boyer and geneticist Stanley Cohen in the early 1970's, Swanson and Boyer founded Genentech in efforts to commercialize new gene-engineered medicines (Genentech, 2014). Humulin (i.e., human insulin) was one of the first products that Genentech was able to produce in its own laboratories in 1978 that proved a working methodology of recombinant DNA (Hardymon & Nicholas, 2012). As "the first recombinant DNA drug product in the world" (Gebel, 2013), Humulin improved the lives of many people with diabetes. However, cloning human insulin by extracting human DNA, synthesizing a specific gene, and inserting a gene into a bacterium to replicate (Hardymon & Nicholas, 2012) did not extinguish the blazing controversies against recombinant DNA research. Questions remained about the potential threats of replicating genes that were not intended to do so in nature. According to Singer (2016), many thought that the manipulation of DNA and its bases may unintentionally and unknowingly produce harmful material that could destruct human health. However, understanding the human genes and developing products to benefit the human species could not be possible without recombinant DNA research, which seemed to gain a significant political attention at that time.

Recombinant DNA (i.e., recombining the DNA) research controversies began to emerge over two decades after the discovery of the chemical structure of the humans' hereditary material (i.e., DNA) by James Watson and Francis Crick as early as 1953 (Pray, 2008). These controversies were later evident in the congressional hearings of the Recombinant DNA Research Act of 1977. For example, Dr. Tim Carter of the Subcommittee on the Health and the Environment expressed in his statements that recombinant DNA research must continue, whereas Richard Ottinger of the Committee on the Interstate and Foreign Commerce insisted that researchers not move rapidly towards "this new horizon" (U.S. Congress, 1977). The governmental regulations and guidelines that emerged restricted experimentation with gene technology, especially those funded by the government due to not only environmental

concerns, but also ethical issues and the unsettling concept of "playing God". According to Watson and Berry (2009), many people felt that recombinant DNA provided researchers with the tools to "play God" as they [researchers] intervened and manipulated the nature of human DNA. Furthermore, efforts to commercialize gene-engineered products merely added fuel to the fire, and rigorous recombinant DNA research guidelines were yet to emerge.

Alternatives

The congressional hearings of the Recombinant DNA Research Act of 1977 revealed that although the National Institute of Health (NIH) had already established guidelines and regulations for recombinant DNA research, they were not mandatory unless they were funded by the government (U.S. Congress, 1977). The idea was to restrict recombinant DNA experiments not only to those that were federally funded, but also those of the private sector. However, due to the number of unknowns in genetic engineering, it would be almost impossible to setup specific guidelines to apply to recombinant DNA research. For example, the product of engineering a pair of genetic bases is simply unknown until tested in a laboratory. Therefore, guidelines and regulations would have to be inclusive of all genetic testing, which would limit a large number of harmless experiments. Such regulations do not seem ideal because researchers would no longer have the opportunity to dive into a better understanding of the human DNA, and they [regulations] would limit their abilities to suggest ways to prevent certain diseases from occurring, especially hereditary ones such as diabetes.

Proposed Solution

Although genetic engineering raises some significant concerns regarding biohazards, it may be possible to conduct experiments under controlled environments so that biotechnological advancements can continue to evolve. The highly controversial subject matter must be considered from both the ethical side and the scientific side. It is important that medical science evolves to advance treatments in medicine while maintaining the integrity of the ethical developments. This proposes the solution that laboratories may continue to genetically engineer in a way that it wouldn't harm the environment. This is particularly evident in the scientific breakthrough of The Scripps Research Institute (TSRI) scientists who successfully engineered the first ever organism to include a pair of bases not found in nature (McCurry-Schmidt, 2014).

TSRI Associate Professor Floyd E. Romesberg and his research team members discovered the unnatural base pair (UBP) d5SICS and dNaM and the way it may be able to self-replicate (Malyshev, et al., 2014). The importance of these molecules seem to lie in the nature of their application to the bacterium E. coli (Escherichia coli). The *Nature* journal published an article in 2014 comprehensively detailing the steps taken by the TSRI team, which revealed that d5SICS and dNaM can only be introduced to the E. coli bacterium by a special unnatural triphosphate – known as the transporter – after being added to an outer fluid solution (Malyshev, et al., 2014). More importantly, the scientists found that if this transporter is not provided, d5SICS and dNaM would simply disappear and only natural base pairs (i.e., Adenine-Thymine and Cytosine-Guanine) would maintain in the DNA (Malyshev, et al., 2014). This suggests strong control over the system,

which ultimately provides the assurance to those with concerns about the presence of biohazards in the environment. For example, if a lab is applying the aforementioned method to replicate DNA with the new UBPs d5SICS and dNaM and recognizes an unexpected production of biohazard material, it can simply stop the transporter, and the DNA would begin to only replicate its natural pairs, and hence not harm the environment. However, this would only be true if the lab has no intention of purposefully replicating harmful material, which suggests unresolved ethical issues and the need of firm regulations.

Recommendation

Controlling the laboratory environment is not a new technique in preventing the spread of biohazards. In fact, it was suggested by Dr. Lee in the aforementioned 1977 congressional hearings where he stated, "I do think that such research should be carefully controlled since it is potentially dangerous. We might produce a super strain of bacteria, though I think that that is rather unlikely" (U.S. Congress, 1977). Recombinant DNA research has yet to show the world how it could be disastrous. However, due to ethical and environmental concerns, and the probable threat of destroying human species, recombinant DNA research should be approached and conducted with caution. Governmental regulations seem to be extremely vital in this case because recombinant DNA is not merely a small or simple lab experiment as it involves the human nature. Moreover, breakthroughs in this science could potentially save the lives of many people with serious illnesses.

Therefore, aside from controlling the environment within which these experiments are taking place, new regulations must emerge to monitor the ethical intentions of laboratories. One specific recommendation would be to oblige laboratories to report to the NIH what they intend to produce or research through their use of recombinant DNA as well as how they plan to do it. This inevitably calls for the government to be involved in setting such regulations so that laboratories conducting recombinant DNA experiments do in fact report to the NIH whether or not their research is federally funded.

Conclusion

In conclusion, obtaining a comprehensive understanding of human genes and the potential to develop products that might aid in the treatment of serious illnesses (e.g., cancer) would not be possible without research involving recombinant DNA. Environmental issues may be resolved with system control; however, ethical concerns may continue to surface until some regulations are put in place to penalize those who use recombinant DNA to intentionally produce harmful material. Many may seek ventral capital to conduct their recombinant DNA research because governmental funding may limit the magnitude of such research. Therefore, new regulations should immediately arise to prevent the unethical conduction of such experiments regardless of their source of funding.

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