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Regulations on Biotechnological Research and Biologically Modified Products

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Abstract:

The developments in biotechnology have brought not only benefits but also harms to society. On the one hand, the biotechnologically modified products has rapidly changed our lifestyle, but on the other hand, they could also endanger the ecosystem due to their reproduction and novel characteristics, and raise sharp debate over social values, including moral and religious values, and ethical standards. These rapid developments and problems of biotechnology posed a significant challenge to policymakers. E.g., are current regulations enough? Or do we need more regulations for biotechnological experiments and the development of genetically modified products because of their potential negative impacts? After comparing the advantages (such as the avoidance of the negative and special influences of biotechnology, and the solution of market failure and social injustice) and disadvantages (such as economic loss, government failure, and violation of social justice and freedom of scientific experiments), this research addressed that more and specified regulations are necessary. However, the scope of regulations – or how much control the government should have in scientific development – should be reasonably limited to give consideration to the independence of scientific fields, and economic developments. First, the regulations of biotechnological experiments should be looser than those of genetically modified products because of the different substantial impacts on consumers, and the respect of the freedom of speech (or research). Second, more participation of the general public will help to avoid the professionals' and governments' arbitrary decisions. Third, the regulations of “Physical Risks” and “Social Risks and Ethical Considerations” should be different because their influences are varified.

Key Words: Biotechnology, Biotechnological Research, Biotechnologically (genetically) Modified Product, Regulation.

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1. Issue

The 21 century's developments in biotechnology have brought not only benefits but also harms to society. On the one hand, biotechnology has rapidly changed agricultural and medical practices, promising new drug, cloned animals, and biological products, that have altered ou lifestyle. For example, about 30 to 35 percent of soybeans and 25 percent of corn grown in United States in 1998 came from genetically modified seeds¹. Approximately 60 percent of packaged foods in supermarkets contain genetically modified organisms².

Despite its benefits, all the changes have not been beneficial. First, genetically modified products could endanger the ecosystem due to their reproduction and novel characteristics. Though there is no significant evidence, scientists are exploring the possibility that genetically modified products could change some functions of biological system as a result of genetic modification and inserted foreign genes. Second, genetically modified products and biotechnological experiments have raised sharp debate over social values, including moral and religious values, and ethical standards. Society is divided on the issue because biotechnology is strongly related to human's basic relief and value system.

The rapid developments of biotechnology in the last 20 years posed a significant challenge to policymakers. In order to assess and control the new developments of biotechnology and the accompanying ethical questions, environmental concerns, and potential physical damages, regulations are necessary. The regulations can be divided into two main categories. One is "biotechnological experiments" that are related to research and development (R&D) processes in manufacturing. The other is category genetically modified products (GM products) that may be directly used or ingested by consumers.

However, the scope of regulations – or how much control the government should have in scientific development – is a hotly debated issue. Are current regulations (see discussion infra part 3) enough? Or do we need more regulations for biotechnological experiments and the development of genetically modified products because of their potential negative impacts on biological and ecological system, or simply because of their different and special characteristics. These concerns arose in the 1980s and have been debated in political, scientific, and ethical areas. For example, the debate on how much the government should regulate biological experiments has focused on moral values and economic development and the debate continues raging (see discussion infra part 4.1, 4.2 and 5.2). Governments, the public, and scientists also have argued about whether the risks of genetically modified products include social risks and physical risks (see discussion infra part 6.3). These conflicts are mainly between scientists, governments, manufacturers, and the public. Scientists and manufacturers generally argue that existing laws that regulate traditional technology and its derivative products are satisfactory for biotechnological experiments and genetically modified products. They believe that (1) too much regulation would cause biotechnology industry's dilemma and stymie its development³, and (2) the government should not intervene too much in business and scientific affairs and the market. However, the government and some conservatives have argued that new and more extensive regulations are necessary⁴ because (1) the influences of genetically modified products are new and unknown in some cases, and totally different from those of traditional technological products, and (2) existing laws do not address biotechnological issues. For example, the Federal Food, Drug, and Cosmetic Act and related

¹Julie Teel, *Regulating Genetically Modified Products and Process: An Overview of Approaches*, 8 N.Y.U. Env'tl. L. J. 649,649 (2000).

²Id.

³*U.K. to Overhaul Biotechnology Regulations*, 5 No. 12 J. Proprietary Rts. 40, 40 (1993).

⁴Teresa Pechulis Buono, *Biotechnology-Derived Pharmaceuticals : Harmonizing Regional Regulations*, 18 Suffolk Transnat'l L. Rev. 133, 138 (1995).

evaluation system are designed to regulate technological end products. Few existing standards and acts regulate scientific research⁵.

Therefore, this article will first discuss the characteristics and special influences of biotechnological experiments and genetically modified products (see discussion *infra* part 2.3). And then it will address the cons and pros of more regulations in biotechnology (see discussion *infra* parts 4 and 5). Last, this article will discuss the substantial content of the regulations, such as who will regulate and what biotechnological issues should be regulated (see discussion *infra* part 6), and conclude that more regulations is necessary because of the protection of consumers and moral values, but the scope of regulations should be limited to give consideration to the independence of scientific fields, economic developments.

2. Introduction to Biotechnology

2.1. The development of Biotechnology

The term biotechnology describes a laboratory technique that uses biological organisms to create new modified organic products⁶. In fact, biotechnology is not a totally new and developing sciences as some biotechnological applications such as plant hybridization have existed for centuries. Thousands years ago, people had started to use breeding methods to improve the quality and quantity of crops and farm animals by hybridizing different breeds. For example, the mule is the hybrid from a donkey and a horse. Our ancestors also used microorganisms to make bread, to convert milk into cheese, and to brew alcoholic beverages⁷. Centuries ago, these traditional biotechnological applications were limited to a small number of fields because people had no knowledge about molecular biology and biological mechanisms of the body, in part due to technology – they had no access to microscopes and other tools to examine the molecular structure of cells.

The biotechnology field rapidly advanced in 1953 when basic double-helix structure of heredity substance, deoxyribonucleic acid (DNA) was discovered and described by James Watson and Francis Crick⁸. This discovery helped scientists understanding the inherent heredity mechanism, deciphering the genetic code, which led to the biotechnological techniques revolution. Through the understanding of genes, scientists could manipulate genetic material and change the structure on the smallest known scale – individual genes – by applying the techniques of genetic engineering. The use of genetic modification allows scientists to bypass traditional sex-crossing and natural selection in breeding processes, and makes it possible to eliminate undesired traits or add desired traits to a plant or animal⁹. Therefore, the “improvement” of the genetically modified animals and plants is no more random and natural but controlled by human hands. Today, scientists are no longer ‘passive observers’ of life, but ‘active creators’ of life¹⁰. For example, if scientists want to create a new and sweeter species of tomato, and they know that the sweetness is controlled by DNA-X, they can

⁵Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 183 (1987).

⁶Teresa Pechulis Buono, *Biotechnology-Derived Pharmaceuticals : Harmonizing Regional Regulations*, 18 *Suffolk Transnat'l L. Rev.* 133, 136 (1995).

⁷Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 967 (2d ed. 1991).

⁸*Id.*, 964.

⁹Julie Teel, *Regulating Genetically Modified Products and Process: An Overview of Approaches*, 8 *N.Y.U. Env'tl. L. J.* 649,652 (2000).

¹⁰Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Env'tl. L.* 183, 184 (1987).

use a restriction enzyme to cut out the DNA molecule in the host's (origin tomato's) microorganism and replace or insert foreign "sweet" DNA to produce an "improvement" or "genetic modified" tomato (novel tomato or genetically modified tomato) which has never existed before in nature. Another example of genetic modification is that the gene producing insulin in a human cell can be isolated and inserted into a bacterium that can produce or clone many identical copies of the gene. If the gene can be coaxed to manufacture the same insulin in bacteria that it does in a human, large amounts of low-cost insulin can be produced to aid diabetics¹¹.

With advanced techniques, the application of biotechnology has become varied and widespread in many industries such as agriculture, medicine, pharmaceuticals and the environment. It also has improved human life in many areas particularly with new biotechnology-derived pharmaceuticals for treating diseases, and with genetically modified agricultural products that increase the production quantity of crops. In medicine, genetic research has produced many medical benefits because genes play a key role in the disease process and treatments¹². Scientists have also developed numerous genetically modified crops that are more resistant extreme weather, salty soil, insects and animals than the original species, and produce more efficiently. However, like many other powerful new technologies, biotechnology carries risks as well as benefits¹³. These influences include not only the visible effects such as physical harm to people and animals and environmental pollutions, but also the invisible effects such as emotional reactions, destruction of established social values and ethical concerns.

2.2. The Definition of Biotechnology

Biotechnology, defined as technology that transform biological processes, includes a board range applications including traditional applications that can create genetically modified products. The influences of traditional biotechnology is not absolutely immediate and danger. For example, it is hard to imagine the fermented bread would cause physical injuries. In narrowest definition, biotechnology employs recently established biological technologies using living organisms¹⁴ (or parts of organisms) and techniques such as cell fusion, recombinant DNA, and bioprocessing¹⁵ to make or modify products, or to alter plants or animals biologically for beneficial use. Comparatively, those newly developed biotechnologies strongly involve product development in fields such as agriculture, environmental monitoring, and health care¹⁶, and have great possibilities to cause physical harms and environmental pollutions.

There are two reasons for using the narrow definition in this article. First, the regulatory approach was developed to deal with the problems following with the development of modern biotechnology. Therefore, the traditional biotechnology which spans hundreds years and has no significant harm does not need more regulating. Second, the narrow definition that excludes the application of traditional biotechnology would help to simplify this issue.

2.3. The Characteristics of Biotechnology

¹¹Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 967 (2d ed. 1991).

¹²Henry T. Greely, *Speech : The Revolution in Human Genetics: Implications for Human Societies*, 52 S.C.L. Rev. 377, 377 (2001).

¹³Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 964 (2d ed. 1991).

¹⁴Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 185 (1987).

¹⁵Teresa Pechulis Buono, *Biotechnology-Derived Pharmaceuticals: Harmonizing Regional Regulations*, 18 *Suffolk Transnat'l L. Rev.* 133, 136 (1995).

¹⁶*Id.*, 136-37.

Because biotechnology is a technique designed to biotechnologically modify products by using living biological organisms and aimed at improving the functions of plants or animals, the relationship between biotechnology and life is close. In addition, because biotechnology deals with the issues related to life, there are some special characteristics that set biotechnology apart from other technologies.

(1) Biotechnology as it relates to humanity

There is an unavoidable contradiction between nature and artificiality existing in the development of technology. Namely, because biotechnologically modified products are artificial products manufactured by scientists' hands but not by Mother Nature, there are numerous arguments about how much should scientists intervene the naturally biological processes. On the one hand, some experts argued technology should obey the natural laws because it existed and developed under the natural environment. On the other hand, because technology is a tool used to change natural phenomena to meet human needs, it is unavoidable to step in the naturally biological processes. Thus, the contradictions raised by biotechnology are that scientists want to change natural phenomena via biotechnology, including humans, animals and plants. The natural development, growth, existence, and reproduction of human or other living organisms are strongly intervened and molecularly modified by biotechnology and as results, become unnatural and artificial. Because biotechnology involves manipulation of nature, it implies high relevance with of humanity and nature.

(2) Biotechnology is related not only to lifestyle but also to life itself

Unlike other traditional technologies that aim to control, manipulate, and improve the physical environment, such as chemical or civil engineering, biotechnology aims to change human, animal and plant's biological structures. Biotechnology is not focused on external and temporal change by inventing new equipments, but is interested in changing vital life processes by internal and long-term intervention.

(3) Biotechnology is related to society values

No other technology more directly related to family, social and religious values than biotechnology. Because biotechnology deals directly with and tries to change life processes and life itself, biotechnology and threatens basic beliefs, and social and religious values. And because biotechnology has a close relationship, like the issue of abortion, there are highly conflicting and entirely different attitudes and opinions toward biotechnology. Achieving a common consensus is difficult because the conflicts involves with the most basic ideas of human's values, and raises ethical questions such as should human manipulate natural biological processes? Should we clone animals, or people?

3. Regulatory Approach to Biotechnology in U.S. and Its Shortfalls

Based on its various purposes, characteristics and operations, the regulatory approach of biotechnology can be divided into two main fields in U.S. One is regulating "biotechnology research and development" which focuses on the pure scientific research and biotechnological experiments in science society and manufacturers before manufacturing. The other is regulating "genetically modified products" which focuses on influences of the final products on consumers, ecology system, and environment.

3.1. Biotechnology Research and Development

The regulatory history of biotechnology experiments in the United States began in 1970s when a small group of scientists promoted the needs of regulation¹⁷. In 1976, the U.S. National Institutes of Health (NIH) established restrictive guidelines for the use of recombinant DNA technology¹⁸. The guidelines offered recommendations for protecting the public and the environment from risks associated with federally funded recombinant DNA research¹⁹.

The guidelines though were limited as they applied only to public funded research. Private funded research was not regulated. President Ronald Reagan in 1984 formed a comprehensive regulatory program, the “Coordinated Framework for Regulation of Biotechnology” (“Coordinated Framework”), to regulate both private and public funded research; it was revised in 1986²⁰. The Coordinated Framework involves four federal administrative agencies: the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Department of Agriculture (DOA), and the Food and Drug Administration (FDA). Under existing law, each agency is responsible for establishing and updating a biotechnology regulatory structure pertaining to its regulatory activities²¹.

Besides the division of responsibilities and powers, the range of regulations also became broader than the initial one. The early controls were exercised only over recombinant deoxyribonucleic acid (rDNA), but current controls cover other methods of biotechnology such as recombinant ribonucleic acid (rRNA) technology and cell fusion²².

However, some experts have argued that the existing laws are not adequate to regulate biological experiments. First, the Coordinated Framework is only a framework or a division of labor. It can help to clarify different agencies’ responsibilities and powers regarding new developments in biotechnology. But because the framework based in existing laws, which were designed for regulating the post-evaluation and derived products but not designed for regulating research and development before production, this framework does not resolve the debate on how and how much the government should interfere with scientific affairs. For example, biotechnological experiments are not clearly in the Federal Food, Drug, and Cosmetic Act. Because of the absence, the government has no adequate means to regulate manufacturers’ development or research on genetically modified products, and manufacturers have no trustworthy standards to follow.

Second, even though there are some clauses related to regulations of scientific researches, the existing laws were designed to regulate traditional technology. The federal legislature in making regulations did not consider the special characteristics of biotechnology, such as reproduction process and long-term effects. Those regulatory strategies obviously cannot handle the potentially new and significant problems caused by biotechnology. Therefore, it is also improper to apply or extend existing laws to regulate biotechnology.

3.2. Genetically Modified Products

¹⁷Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 189 (1987).

¹⁸Teresa Pechulis Buono, *Biotechnology-Derived Pharmaceuticals : Harmonizing Regional Regulations*, 18 *Suffolk Transnat’l L. Rev.* 133, 139 (1995).

¹⁹*Id.*, 140.

²⁰*Id.*

Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 183 (1987).

²¹Peter Mostow, *Reassessing the Scope of Federal Biotechnology Oversight*, 10 *Pace Env’tl. L. Rev.* 227, 233 (1992).

²²Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 185 (1987).

Like biotechnology experiments, U.S. federal government has similar policies toward genetically modified products. Until now, no statutory provisions or regulations address biotechnology specifically²³. Federal policies, such as the Federal Food, Drug, and Cosmetic Act, backed by the biological research community and manufacturers states that genetically modified products are to be treated similarly to other potentially hazardous and harmful products, such as new drugs and food, with the exception that genetic modified products and genetic engineering techniques are also subject to risk assessment and evaluation under the FDA's prior review requirement²⁴. For example, except for marking products with "genetically modified products" or similar statements on the labels, the regulations of genetically modified products are basically the same as other food, drugs, medical devices, cosmetics, and animal food and drugs under the Federal Food, Drug, and Cosmetic Act.

According to Professor Peter Barton Hutt, two existing types of general federal regulatory statutes protect the public's health and safety: those that regulate particular products, and those that regulate industrial processes²⁵.

(1) Particular Products: According to the Toxic Substances Control Act (TSCA) of 1976, the EPA can set "requirements or limitations upon manufacturer or use that may be justified to prevent an unreasonable risk to health or environment"²⁶, and the range covers both old and new chemicals, including biotechnology products. The Organic Act of 1944, the Federal Plant Pest Act, Noxious Weed Act, and Federal Seed Act also authorized the USDA plenary authority to regulate the development and introduction of new plants and plant pests. The Endangered Species Act of 1973 authorized Department of the Interior (DOI) to regulate "the importation and introduction of exotic species of plants or animals into natural ecosystems in United States."²⁷ Food, drugs, medical devices, and cosmetics are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938. Human biological drugs are regulated under the Biologics Act of 1902, and animal biological drugs are regulated under the Virus Serum Toxin Act of 1913.

(2) Industrial Processes: The Occupational Safety and Health Act required employers to maintain working conditions to protect employees from harm, and authorizes OSHA to issue related standards. In addition, several environmental statutes, such as the Clean Air Act, Water Pollution Control Act, Safe Water Drinking Act, Resource Conservation and Recovery Act, Comprehensive Environmental Response, Compensation, and Liability Act, and the Marine Protection, Research, and Sanctuaries Act are available to "regulate the byproducts of industrial processes in order to assure a healthy and unpolluted environment."²⁸ Besides, obtaining pre-market approvals, bioengineered products' manufacturers need to apply for a new drug application (NDA), a biological product license, new animal drug application (NADA), and a new medical devices application to protect the public's health²⁹. For food products, the preclearance or approval of food additives including those prepared using biotechnology techniques is required³⁰, and some standards have been put into place over the past decade. For example, manufacturers of new drugs and biologics must operate in conformance or compliance with current good manufacturing practice (CGMP) regulations.³¹

²³Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 976 (2d ed. 1991).

²⁴Amal Kwar, Richard Sherlock, *Theoretical Issues in the Regulation of Genetically Engineered Organisms: The Case of Deliberate Release*, 7 (2) *Politics and The Life Science* 129, 129 (1989).

²⁵Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 973 (2d ed. 1991).

Although no specific statute regulates genetically modified products, some experts argue that the existing statutory system is adequate for the regulation of genetically modified products because the agencies can “extend their experience with these regulatory mechanisms and apply them to the products of biotechnological process.”³² The FDA also proposes no new procedures and requirements for individuals or industries to regulate the genetically modified products.³³ Currently, all regulations governing biotechnologically modified products are controlled by various federal agencies, including the FDA, OSHA, DOA, and EPA. This diversified and unorganized system can cause inefficiency, especially when the influences of genetically modified products are multidimensional and can negatively affect the health and safety of living beings and the environment. In addition, if we still apply the existing old regulatory strategies to regulate the new genetically modified product, we might ignore the special effects of genetically modified products on public health, environmental protection, the ecosystem’s balance, and social orders, such as moral and religious values. Even though the U.S. Congress gave the FDA authority to regulate products regardless of how they are manufactured, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Services Act, it is doubtful whether the FDA can effectively regulate genetically modified products if there is no universal and detailed regulation to address the complex dimensions and problems of the products.

While some politicians, business groups, scholars, scientists and policymakers believe that the current statutory provisions can be extended to fit the regulations of genetically modified products, I question this premise:

(1)

Biotechnology is a virtually new and rapidly developing technology with very little evidence on the effects of genetic modifications of plant and animal organisms for experts to evaluate. Furthermore, some believe that the effects of some biogenetic processes (i.e., those that affect the environment or reproductive processes) will not be evident for years or decades to come.

(2) Current statutory provisions are not designed for genetically modified products. The current statutes might not “fit” genetically modified products, and might neglect some important outcomes or problems. For example, there is no particular statutory provision that deals with food produced by new biotechnology.³⁴ Most issues concerning the safety of food will involve the application of either section 342(a)(1) or section 349 of Federal Food, Drug, and Cosmetic Act. According section 342(a)(1),³⁵ “if a food produced by new biotechnology contains a higher level of a substance than it might ordinarily have”, the food may be “injurious to health” under section 342(a)(1). But should the inserted genes be counted as a level of a substance”? If the effects of genetically modified products occur over a long period of time, say 100 years, or four generations, through complex mechanisms, could the current regulations effectively address the possibly negative outcomes? We will discuss these questions in *infra* parts 4.1.2 and 4.1.3.

Since 1978, FDA has tried to propose regulations requiring that all recombinant research on, and production of, any product for which a submission was to be made to FDA must be conducted in compliance with significant guidelines³⁶, such as NIH Guidelines³⁷, “points to consider³⁸” and general requirements for manufacturing

³⁶Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 976 (2d ed. 1991).

³⁷43 Fed. Reg. 60134 (December 22, 1978).

³⁸49 Fed. Reg. 1138 (January 9, 1984), 49 Fed. Reg. 23456 (June 6, 1984), 53 Fed. Reg. 5468 (February 24, 1984), and 54 Fed. Reg. 46305 (November 2, 1989).

biotechnological products³⁹. Government also tried to coordinate all federal regulatory agencies to contemplate and manage overall regulations of biotechnology. For example, in 1984, Interagency Working Group on Biotechnology, chaired by the Office of Science and Technology Policy (OSTP), concluded that “a closely managed regulation of biotechnology by all federal regulatory agencies under OSTP oversight⁴⁰.” But this suggestion was abandoned by White House because of fearing “adding another layer regulation and hinder commercialization of biotechnology⁴¹.” But these endeavors still cannot resolve all of the problems which are caused by biotechnology because of political interference, interest conflicts and lack of a macrocosm design.

4. The Benefits of Increasing Regulations on Biotechnology

4.1. The Impacts of Biotechnology

The need for more regulations on biotechnology stems mainly from the differences between biotechnology and traditional technology. In this section, I discuss three key characteristics of biotechnology and genetically modified products, and explain why these characteristics necessitate more regulations.

4.1.1. Biotechnology and Social Values

Because biotechnology has a close relationship with social values, the impacts of biotechnology developments result not only in physical risks such as health problems, environmental pollution and ecosystem violations, but they also pose a social risk as they call into question social values and challenge society’s moral and religious values. However, regulatory agencies generally are concerned with physical risks, but neglect the social impact on society. For example, the federal agencies have complete assess systems to evaluate human physical harms, and environmental pollutions, but do not have proper assess systems to evaluate the influences on moral and religious values, and people’s spiritual functions.

In many cases, conservatives and religious groups are the main proponents of to greater regulations, along with the biotechnology industry which is focused on protecting its interests. These social and moral issues are deeply based in cultural and religious beliefs and values and consequently, it may take decades, or centuries for societies to form a consensus on these issues. And the support reflects the burden of the freedom of biotechnological research is mainly from traditional social morality and religious values. For instance, the issue of cloning and using fetus tissue to generate new organs are two controversial issues. The opponents argued the biotechnology option should force society as a whole to reexamine moral values regarding who should control life and what is life? Should we use one human’s genetic material to form the organs of another’s? Should the donors be compensated? Can fetuses be bought and sold?

The most controversial issue is embryo experiments and related products because they directly call into question human dignity, moral frameworks, and religious faith. We can use this example to describe the relationship between biotechnology and values. First, since there is no consensus about whether the embryo is a human being or not, the utilization of embryos in basic research and in medical applications have prompted religious, political and other interested groups to advocate the protection of human dignity, which in most cases means, a call to ban the use of embryos in research and in medical applications. Second, many religious groups deeply believe that humans should not play the “Creator’s role.” However, advocates of the use of embryos argue that they are not playing “God” but are trying to improve the quality of human’s life, cure diseases and prolong life.. Thus, as we can see, biotechnology creates many conflicts. Some may argue

³⁹43 Fed. Reg. 27622 (December 6, 1984), and 51 Fed. Reg. 44451 (December 10, 1986).

⁴⁰Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 976 (2d ed. 1991).

⁴¹*Id.*

that these conflicts are good for a society to debate and engage in and others may argue that these conflicts are inevitable and must be addressed sooner or later because biotechnology and science can not be readily controlled.

Even though some biotechnological techniques and genetically modified products do not directly affect core moral and religious values, such as genetically modified plants and microorganisms because they are not related to human dignity. Many skeptics still argue that these products go against natural order and could irreparably damage the environment, and in this way, would violate human dignity, and moral and religious values.

These social and moral debates might be very slight in other traditional technologies. But because of the close relationship between biotechnology and moral values, biotechnology could escalate into huge conflicts and possibly economic losses or illegal operations if the government ignores these issues. Therefore, even though biotechnology is one branch of technology, and biotechnology scientists and manufacturers have professional standards, and even though religious and moral groups have valid points, it seems that society will need to set forth regulations for biotechnology and in so doing, must consider social, cultural, religious and moral values along with the economic, scientific and medical benefits that biotechnology offers. Because the traditional technologies do not produce life-altering results and thus such strong conflicts, current regulations need to be updated and reinforced to address biotechnology issues. Therefore, biotechnological science and manufacturers of genetically modified products need specific regulations that address these moral issues. It seems that we need not only regulations specific to biotechnology research and the manufacture of genetically modified products but we need regulations that take into consideration the impacts on entire society including values shifts. Only then , can biotechnology set clear goals, function freely and achieve its goals.

4.1.2. The Uncertain Influences of Biotechnology

The techniques of biotechnology are “extremely powerful because they allow a large number of controls over biological systems.”⁴² The enormous power of biotechnology over biological and ecological systems can result in strong and unexpected influences that are far more powerful than the effects of traditional technologies. This also supports the need for new or updated regulations of biotechnological experiments and genetically modified products. The fact that negative results of genetically modified products could surface decades, even centuries later strengthens the argument in favor of a cautious approach to managing biotechnology. Three factors cause this uncertainty:

- (a) Modern biotechnology is a relatively new and developing science, less than 50 years old if we consider Watson and Crick’s “discovery” of the basic double-helix structure of DNA in 1953. Because of this limited time and experience, scientists, manufacturers and other interested parties have not been able to accumulate enough information to accurately evaluate the outcomes.

⁴²Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* 964 (2d ed. 1991).

Due to the rapid development of biotechnology and the potential enormity of its effects on biological and ecological systems, not enough time has passed to properly assess the results, and to envision and measure the possible consequences accompanying these developments. And the insufficient time in order to collect information on biotechnology developments could cause not only unpredictable outcomes but also difficulties in building causation relationship. It becomes difficult to identify the long term harm, if any, connected to biotechnology techniques.⁴³ For example, the scientists can use genetically modified microorganisms to produce more and purer proteins to supply the market. But scientists cannot adequately assess whether these modified microorganisms could, over time, develop new characteristics or if the newly developed characteristics could cause unknown epidemiological diseases in humans, animals or plants; if this happens, it could cause an ecological crisis. The uncertainty factor prevents scientists from controlling outcomes and fully evaluating the potential damages.

(b) Because biotechnology can change organisms' molecular structures, and can alter the basic hereditary substance, DNA, to improve organisms' traits, intervention via biotechnology could alter hereditary traits and wreck havoc on an individual's genetic makeup as well as his or her descendents because the influences of biotechnology might not show up for several generations. Since the impact of biotechnological experiments or products could take generations to surface, the uncertainty factor becomes higher and it is difficult for scientists or manufacturers to decrease this uncertainty. Scientists can only base their analyses on statistical findings, and since so many unknowns exist, these statistical cost-benefit, or risk-benefit analyses may be ineffectual.

Similar problems have arisen from traditional technological products. For example, the environmental problems revolving around DDT (one popular pesticides 20 years ago) have been attributed to a myopic view of its benefits without adequate consideration of risks⁴⁴. DDT was not forbidden until scientists found the poisonous elements in DDT are absorbed and accumulated in organisms. Similar results occurred earlier in time with Thalidomide which caused many birth defects and cancer cases a generation later, yet it was supposed to help women at risk of miscarriage carry their babies to term and to reduce pain. Because the manufacturers and the government did not see that the negative effects might surface in the long-term, thousands pregnant women took Thalidomide in many countries, such as Japan, in 1960s. However, the Thalidomide caused gene mutation and deformed babies, which the manufacturers and government regulators did not foresee. In order to prevent similar situations from happening, and since biotechnological products need more time, possibly several generations, to properly assess the results more than is needed by traditional technological products, unique regulations are necessary.

(c) Because modern biotechnology techniques allow the scientists to apply extremely subtle procedure to control the production of biological molecules than ever before, and the effects on the organism or ecosystem can be very slight and hard to identify. For example, the result might be a change in a recessive trait that can cause hemophilia. The change is slight and recessive, and may not appear until the two recessive genes are matched. These kinds of influences are more difficult to discover and evaluate. Existing risk assessment procedures and regulations that are designed to address obvious and detectable influences might not be able to prevent or assess results of these operations that have very subtle influences.

According to present regulations, products are assumed to be harmless if there is no positive evidence to suggest or prove that they are dangerous or can cause ill effects. This further points to the fact that, there are so many uncertainties in biotechnological experiments and genetically modified products that they must

be closely regulated and assessed. “Care must be taken to distinguish between evidence for the lack of risk” when there is little concrete or abstract evidence of negative effects.⁴⁵ Biotechnology should thus be held to stricter standards than simply limiting false negatives or false positives. In pure science, a false positive is “an indication that a stated hypothesis is true when it is not⁴⁶,” and a false negative is “a finding that there is insufficient evidence for a hypothesis which is correctly correct⁴⁷.” False positives and false negatives, suggest that scientists, including biotechnologists can make wrong assumptions about the risks and probability of the risks of genetically modified products. Generally, scientists do not consider tests of negative effects as sufficient to substantiate the hypothesis that a particular substance causes a particular effect unless the results are statistically significant, which means that there is only a 5 percent chance of a false positive or a false negative⁴⁸ (Fig.1). Therefore, if the probability of a potential risk is less than 5 percent, then the risk is not statistically significant, and the scientist would assume that the negative result would not happen. However, given the immense repercussions of biotechnology this standard might be too broad, as even a 5 percent risk is a large risk if the results could impact an ecosystem or cause a deformity or death, etc. In order to minimize the risks in biotechnology, stricter critical standards and the acceptance of close to zero risk should be adopted.

2.5%

2.5%

critical value

2.5%

2.5%

critical value

Fig. 1 Critical Values

4.1.3. The Increasing Complexity of Biotechnology Development

Most scientists, scholars, and even politicians agree that biotechnology involves much more complex techniques, has greater potential alter to biological and ecosystems, and more unknowns or risks than traditional technologies. Besides, the uncertain influences also increase the degree of the complexity. The complexity makes it difficult to make proper risk assessments and evaluations. First, the influences of biotechnology can cause global effects due to countless and unexpected variables. Therefore, the risk assessment is impossible, or at least difficult, because it is often difficult to simulate a similar environment and assess the long-term multi-generation effects. Second, many genetically modified products have a special characteristic – the abil-

⁴⁵Judith Miller, *Environment Protection and Uncertainty: The Case of Deliberate Release of Genetically Engineered Organisms*, 7(2) *Politics and the Life Sciences* 142, 145 (1989).

⁴⁶*Id.*, 145.

⁴⁷*Id.*

⁴⁸*Id.*

ity to reproduce – which can affect the world’s gene pool and unbalance the delicate ecosystem worldwide⁴⁹. For example, opponents of genetically modified products are fearful that genetic material will cross over into wild strains and reduce biodiversity by crowding out other organisms.⁵⁰ Many external factors also can influence bioengineering experiments, such as weather conditions, wind currents, humidity, temperature, and food supplies could affect the growth and reproduction of genetically modified organisms or the people who utilize those products. Those external factors thus add to the complexity and unpredictability of biotechnology. In some conditions, the influences may not appear because the environment may not support the growth and reproduction of genetically modified organisms. But if the scientists apply the traditional regulations and framework to evaluate the genetically modified products and ignore the complex external factors, they might have totally wrong conclusions. Third, the mobility and microscopic size of modified microorganisms also increases difficulties in managing and controlling them.

In comparison, generally, the influences of traditional technological experiments and products are limited to a small area and limited population. But genetically modified products might affect the whole world, and the factory emissions might cause global warming even if they comes from some developed countries. Therefore, the risk assessment and regulations are simpler, more predictable and easier than those of biotechnological experiments and genetically modified products. Therefore, existing regulations and guidelines appear to satisfy no one, and will likely increase in complexity.⁵¹

4.2. Market Failure

4.2.1. Information Asymmetry

Asymmetric information, meaning consumers have relatively weakened power than manufacturers and scientists in gaining information about influences of biotechnological research and genetically modified products, is a serious issue in the assessment strategy and market operations of genetically modified products. The complexity of the science behind bioengineering, specifically for genetically modified products makes it difficult for government regulators, consumers and others to assess the safety of the products and effects compared to other technological products. According to Federal Food, Drug, and Cosmetic Act, the main consumer resources for product information are product labels⁵². In this assumption, consumers can make rational and efficient decisions by considering the information on the label. But this system is not workable for genetically modified products market.

Since the potential harmful effects of genetically modified products are often uncertain, indirect and complicated, simply labeling them at “genetically modified products” fails to inform the consumer of all of the potential risks. The complexity involved in genetically modified products creates a “bounded rationality” – the limitation of an individual (in particular, a consumer) to make informed decisions. Some experts question whether labels can provide consumers “useful” information to help them make rational decisions, particularly with bioengineered products.⁵³ Or the information would just only confuse the consumers, and

⁴⁹Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 193 (1987).

⁵⁰Julie Teel, *Regulating Genetically Modified Products and Process: An Overview of Approaches*, 8 *N.Y.U. Env'tl. L. J.* 649, 649 (2000).

⁵¹*Id.*, 183 (1987).

⁵²Some experts argued the advertisements are another resources for genetically modified products. But the advertisements are totally controlled by the manufacturers, and any consumer who believes an advertisement lack intelligence; no one in their right mind believes ads nor should they. Thus, this article do not regard advertisement as a proper resources of information.

⁵³Julie Teel, *Regulating Genetically Modified Products and Process: An Overview of Approaches*, 8 *N.Y.U. Env'tl. L. J.* 649, 654 (2000).

give them an elementary understanding of the genetically modified product and its influences. The evaluation of the effects of genetically modified products requires specialized information and knowledge. Besides, because of the rapid development and novelty of this technology, even scientists have difficulty accurately evaluating or predicting actual influences. Therefore, we can not expect that the current labeling system will communicate adequate, useful and thorough enough information to consumers. Even if there is enough information, it is also difficult to expect that consumers can exactly know the meaning of the information. This could cause consumers of bioengineered food and pharmaceuticals to suffer the consequences of their uninformed decisions.

Another problem with the current situation is that scientists and manufacturers have more power and access to information on biotechnological experiments and genetically modified products than government officials, consumer watchdogs and consumers have. Furthermore manufacturers have been known to reveal limited and generally only positive information to the public and ignore the negative effects of their products. Take, for instance, the cigarette industry. Some researchers and company insiders found that cigarette manufacturers had been aware that the contents of cigarette such as nicotine and tar could be harmful to human's health. But manufacturers and some scientists decided to conceal the fact that cigarettes might cause lung cancer and other diseases because it would decrease their profits. Years later, independent scientists arrived at the same conclusion and then the public had chance to test the risks. Comparatively, because genetically modified products' influences may be more dangerous and widespread than cigarettes' effect, the need to balance the information asymmetry and fully inform the public of the possible effects and consequences becomes even more imperative.

However, here is a trade-off situation. On the one hand, the current labeling system cannot supply sufficient information to consumers as discussed before. But on the other hand, more information does not guarantee that consumers will enjoy more protection or make correct decisions with biotechnology products because they do not have enough of a background in biotechnology or science in general to understand this complex field. For example, according to EPA's policy, evaluation and risk assessment of biotechnology processes and products are different from the its practice of classifying the hazards of general non-biotechnology products by product type, agent, and context, but by the technique by which it is produced.⁵⁴ Besides, the information of inserted/deleted genes characteristics is also required.⁵⁵ But even though the information would be helpful to prevent manufacturers from abusing their power, to improve the quality and depth of information provided to the consumer, and to further eliminate information asymmetry, putting this information on labels along with techniques applied is of little use for most consumers because it is too specialized. Some experts also suggest that the detailed information, such as applied techniques and characteristics of inserted/deleted genes, is not necessary to reveal to the public because the information is difficult to understand and sometimes useless to evaluate.

Therefore, an independent and professional committee that can evaluate the information and reveal some simple and understandable data to consumers might be necessary, and a workable option for manufacturers of biotechnology and pure scientists, along with government regulators and consumer watchdog groups. At the very least, the government should set a standard and regulations making manufacturers of biogenetically engineered products include the most important evaluation items and matters needing attention, and then consumers can make more reasonable and efficient decisions in accordance to the standard rather than blindly guessing. And the information on labels should not only be limited to the products' risks as current

⁵⁴Amal Kavar, Richard Sherlock, *Theoretical Issues in the Regulation of Genetically Engineered Organisms: The Case of Deliberate Release*, 7 (2) *Politics and The Life Science* 129, 129 (1989).

⁵⁵Id.

regulations dictate, but also include the processing risks.⁵⁶

4.2.2. Externality

The issue of externality comes into play when examining legal and ethical issues surrounding this new field of biotechnology. Externality means that consumers and the general public do not reap profit accompanying with cost when engaging in economic behaviors. But that often the community indirectly bears the cost when environmental pollution occurs, or unsafe products are sold, or when unsafe manufacturing processes cause environmental or other damage. For example, when manufacturer X produces a product to make a profit, and in manufacturing the product, this manufacturer discharges contaminated water into a river, X manufacturer generally does not pay the cost of pollution, unless sued by the consumers or residents living in the polluted area. Comparatively, the residents living near the factory, who cannot reap any profits from the manufacturer's economic behavior, should not have to bear the effects of the pollution or spend money to remove the pollution, but they often do bear the costs in terms of health risks and public clean up costs paid for by their taxes. Therefore, this product has "external costs" because people who are engaged in economic behaviors are often forced to pay for the manufacturer's unsafe processing costs. Similarly, when company Y plants many flowers to make a profit, the surrounding residents can enjoy pleasant fragrances and beautiful scenes at no cost. This then is an external benefit in Y's economic behavior because the residents can realize a free profit from Y's production.

Unlike other traditional products, because of the complexity of bioengineered products, and the uncertainty involved in outcomes and the long-term effects on reproduction, genetically modified products have stronger externality factors. For example, genetically modified products might require fewer pesticides, and consequently cause less environment pollution. These benefits would not be reflected most likely in a lower price to the public due to the high costs of manufacturing. Comparatively, the residents around the farms who have nothing to do with the production would enjoy a cleaner and safer environment. Then genetically modified products also have external benefits. On the other hand, these same genetically modified products might violate the ecological balance, not only in the farm's immediate region but the negative effects could affect the ecosystem and biological organisms well beyond the region, across the country and the world. These costs also would not reflect the product's price either. Hence, there are external costs in the production process because the residents who might never have a chance to use the genetically modified products are forced to pay the cost.

The external cost might cause common and frequent market failure of biotechnology. And the failure could not only cause inefficiency but could also seriously affect the world's ecology and delicately balanced environment. Therefore, we will discuss more about the influence of external cost on genetically modified products market below.

In the free market, "social marginal benefit (SMB)" should be equal to "social marginal cost (SMC)" and achieve the most efficient resource allocation/distribution. But when there is external cost in the reproduction of genetically modified products, the SMC will be greater than "private marginal cost (PMC)" (see Fig. 2). Manufacturers can underestimate production costs and set lower prices because the cost does not reflect on their production costs. For example, manufacturers of both genetically modified products that can cause environmental damage or harm to humans and animals can ignore the potential cost of risks such as toxicity and environmental pollution when producing genetically modified products. Especially when the influence does not appear until several decades later, or the causation between harm and products is not clear. Thus

⁵⁶Julie Teel, *Regulating Genetically Modified Products and Process: An Overview of Approaches*, 8 N.Y.U. Envtl. L. J. 649, 659 (2000).

it is unlikely manufacturers would add these costs to their production. Therefore, if governments do not intervene with market operations, and let the free market dictate the price and quantity, the maximum quantity decided by the free market (Q_2) would be greater than the maximum quantity decided by social welfare (Q_1). And there will be a deadweight loss resulting from the difference between the Q_1 and Q_2 (area abc in Fig 2).

P_1

P_2

Q_1

Q_2

S' (=PMC)

S (=SMC)

D (= PMB= SMB)

c

b

a

price

P_1

P_2

Q_1

Q_2

S' (=PMC)

S (=SMC)

D
(= PMB= SMB)

c

b

a

price

Fig 2. External Costs

The loss includes not only inefficient economic behavior but also damage to the ecosystem, including potentially loss of human and animal life. In this scenario, consumers can underestimate the real price and the potential cost of a product due to the free market price (P_2), which does not include external costs, and is lower than the real price (P_1). Since consumers, no matter how purposely or not, do not see the whole picture, that is, the potential costs, they generally use cheaper products, failing to see the long-term effects that their decision entails.

Therefore, even if the genetically modified products pose risks to the environment and the ecosystem, the market does not reflect these cost and thereby adjust the demand and supply curve to achieve an equilibrium point that is the most efficient condition of social welfare (point b). Because the price does not reflect external costs, consumers would underestimate the real cost in using genetically modified products. They can be, in effect, changed when buying cheaper products without regarding the actual harm that they can cause. Therefore, the utilization becomes more than the maximum quantity decided by the social welfare, and cause more pollution on the environment and more violation on ecological balance. On the manufacturers' side, because the cost is shared by the consumer, the apparent cost is less than the real cost. And because manufacturers can underestimate the cost, they can produce more products and cause the actual production quantity (Q_2) to be more than the maximum quantity decided by the social welfare (Q_1). Both consumers' and manufacturers' economic behavior errors (lack of foresight and concern) can cause inefficiency and damage to the ecosystem.

Therefore, in attempting to resolve the potential market failure, the genetically modified products market might not be as free as the market of other traditional products, and thus, adds another reason to why the government should initiate regulations and license fees and taxes to internalize the external costs.

4.2.3. Social Justice

Some scholars also argued that the broad application of biotechnology might create a "genetic underclass." For example, some people such as mid-class laborers and the poor may not be able to afford the more expensive products, and buy the cheaper ones, that may have more chemicals or have undergone genetically modified processes that could harm them or their children or children's children. They have no choice but buy cheaper genetically modified products and neglect the potential risks. Therefore, if the government does

not address the potential risks and lets genetically modified products enjoy the same trustworthy safety as non-genetically altered products, theoretically, the government would be allowing unfair treatment of mid-class laborers and the poor.

These unfair situations can also occur in international relationship. For example, countries that have strong biotechnological industries can export their genetically modified products, and other “unsafe” products to poor countries that comparatively have weak biotechnological industries, and disregarding the potential threats of these products to humans and/or the ecosystem crisis. For example, in the 1960s, when thalidomide was in the evaluation process in U.S., it was sold by American pharmaceutical company to Japan and other developing countries because the latter did not have strong pharmaceutical industries and nor a strict evaluation system. Therefore, the drug claimed hundreds victims in Japan including the pregnant women who took thalidomide, and the babies who were born with deformities. This unequal treatment, or at best, thoughtless economic transactions can cause harm to people and environments of developing and third world countries, in part, because the developing countries do not have sophisticated evaluation systems and are desperate for certain products or industries. Over time, the damages caused by biological experiments and the export of genetically modified products can spread from one country to another and affect the delicate global ecosystem.

I assert that in order to resolve these problems, more regulations are necessary for bioengineered products and biotechnology practices because (1) the current regulatory system cannot ensure the safety of genetically modified products, and (2) there are only few international standards for adequate evaluation of products and processes that can cross national borders, but it is obviously not enough. Especially, most U.S. domestic statutes care about the effects of genetically modified products and biotechnological research within U.S., but do not seriously regard the influences on other countries. Although statutes such as the Noxious Weed Act, the Federal Seed Act and Endangered Species Act authorize the USDA and Department of the Interior (DOI) to monitor and control the import of plant material and animals, these regulations are limited to the domestic arena and are trying to prevent potential dangerous products from being imported from other countries to U.S. There is no regulation aimed to prohibit U.S. corporations from exporting potentially dangerous products to other countries. Some experts argued that those regulation of export should base upon the statutes of the importing countries. U.S. government does not have obligations to monitor the potential risks for the people in other countries. However, since the biotechnology has unbounded influences on environmental and ecosystem as discussed before, should the western countries still adopt the conservative attitude toward the regulations of biotechnological research and genetically modified products.

4.2.4. The Proud of Science Challenge

Science is not neutral and independent as some people assert. Like a two-sided blade, science can improve human life and welfare on the one hand, but its misuse might also cause negative outcomes. Throughout history, many tragedies have resulted from the over confidence of scientists especially following the industrial revolution. Many scientists have believed they could improve human life simply by employing “omnipotent” scientific technology, which they believed would be beneficial for society, and individuals’ sacrifice is worth and necessary. Then in the intentional operation by a person with illegal or selfish objectives, the logics and statistics are the basic and only values without regarding the importance of human life, dignity and social values, and science became the highest values which violated basic human rights. Some governments and manufacturers even violated human rights and seized interests that operated in guise of science. For example, early genetic researcher in the beginning of the twentieth century developed and promoted the myth of eugenics – a theory that “superior species” and “inferior species” exist. Furthermore, some governments such as Germany Nazi used scientific techniques to screen the “inferior species” and as a rationale to execute

people. In essence, the Nazis used science to justify inhumane policies and practices such as the slaughter of 6 million Jews as along with discrimination, compulsory ligation, and compulsory abortion to “improve” the species. Genetic engineering techniques can also be used by autocrats and terrorists to “improve” the biological and chemical weapons to achieve destructive consequences. For example, Japanese trop used Chinese victims in biological weapons test in World War II.

The current U.S. regulatory system has many regulations to reduce the misuse of scientific techniques. But some experts argue that these might not be adequate to prevent the misuse of biotechnology. First, current regulations do not specify who should have the power to handle and control these new and potentially harmful technologies. This issue becomes key when the technology can affect human life, and the world’s ecosystem. Some Hollywood movies such as *Jurassic Park* have described possible disasters that could result if the wrong people use and abused these newest techniques. Second, in order to efficiently regulate the abuse of biotechnology, government’s power should be expanded. But the problem lies in the balance between the expansion of the government’s power and individual and free market freedom. This issues needs further examination (see discussion infra part 5.1). Third, the current system has placed much emphasis on the protection of human’s life and health values. But some scientists are used to applying quantifiable and measurable standards to see the issues of human’s life and health values, such as morbidity and mortality, without regarding the core of human dignity as being strongly related to non-physical evidence, such as social psychology, and moral and religious beliefs. Besides, the government also ignores the balance between the development of science and the protection of different life forms such as animals and plants and the potential risks and influences on these from human interventions.

5. The Disadvantages of More Biotechnology Regulations

5.1. Constitutional Issue – Freedom of Biotechnology Researchers and Market Enterprises

The constitutional issues related to increasing the U.S. government’s regulations on biotechnology focus primarily on biotechnological experiments. There is not much debate about whether the government should regulate genetically modified products because these products will enter the market or already exist in the market, so it is reasonable to expect the government to protect people’s safety and health.

But the regulations on the biotechnological experiments before the production of genetically modified products raise concerns because some may fear that the regulations might violate the independence and freedom of academic research. Regulatory issues were initially framed by the process versus product debate, where, in general, biotechnology critics argued that all genetically modified products should be regulated via new legislation because they result from genetic modification, and thus regulations of biotechnological experiments are necessary. Biotechnology proponents argued that genetically modified products should be regulated only on the basis of specific product characteristics⁵⁷, and those characteristics would not show in the period of R&D until the manufacturers start producing them.

Most discussions of academic freedom center on the teacher as source or purveyor of the knowledge, ideas, and viewpoints that are to be explored, developed, and disseminated through the academy.⁵⁸ Comparatively, scientific expressions, experiments and theories, often put forth in universities and commercial laboratories in the U.S. have no constitutional protection under the First Amendment of the U.S. Constitution, no matter

⁵⁷Les Levidow, Susan Carr, *Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA*, 11 Risk: Health Safety & Env’t 9, 13-14(2000).

⁵⁸E. Edmund Reutter, *Academic Freedom Rights of Students: Some Recent Cases*, 108 Ed. Law Rep. 1, 1 (1996).

if the expression is communicated via spoken or written words, or via experimentation.⁵⁹ Some experts have argued that neither of the two components of scientific expression – (1) formulation and communication of ideas via spoken and written words, and (2) formulation of ideas via experimentation – has express constitutional protection under the First Amendment. Although a persuasive argument can be made that the pursuit of knowledge is implied in the first amendment protection of free speech, such protection would encompass only the communicative aspects of scientific speech.⁶⁰ However, some scholars have made a persuasive argument that scientific experiments are hardly distinguished from scientific speech which is covered under First Amendment protection.⁶¹ In addition, there is no way to develop scientific inquiry without scientific experiments. If “research freedom” is not included in the protection of the first amendment, and the government can forbid some types of research and essentially violate “research freedom”, it is hard to see whether scientific speech is actually protected by the U.S. Constitution. According to some countries’ constitutions, such as Germany’s⁶², Japan’s⁶³, and Taiwan’s⁶⁴, research freedom is viewed as the core of academic freedom, and protected as a basic right. In these countries, scientists and scholars have total freedom to choose any topics, procedures, objects, time and place to do the research. And there is strict standard to follow if the government wants to regulate the academic speech and behavior. Based on this, at least one commentator argues that experiments are expressions⁶⁵, and that scientific expression constitutes academic freedom and thus should be protected under the first amendment guaranteeing free speech. When a government tries to “abridge” or curtail freedom of scientific research, its reasons for doing so can be placed into two broad classes. The first is restricts freedom because of its due to content; that is, because of the ideas or information contained in it, or because of its general subject matter. The second reason for curtailing freedom of expression rights is when the government seeks to avoid negative repercussions not connected with the content, but the government’s regulation has the incidental by-product of interfering with particular communications. For example, in Gitlow v. People of the State of New York⁶⁶, the Court described that right of free speech is not absolute right to speech without responsibility, and under police power state may punish utterances inimical to public welfare⁶⁷. In Rice v. Paladin Enterprises, Inc.⁶⁸, the Court also argued that if a publication could be found to have no other use than to facilitate unlawful conduct⁶⁹, the speech creating a significant societal harm is enough to give rise to a compelling governmental

⁵⁹Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 185 (1987).

⁶⁰*Id.*, 185-86.

⁶¹*Id.*, 186.

⁶²Article 5 Section 3 of German Constitution.

⁶³Article 23 of Japan Constitution.

⁶⁴Article 11 of Republic of China Constitution.

⁶⁵Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 186 (1987).

⁶⁶*Gitlow v. People of the State of New York*, 268 U.S. 652, 45 S.Ct. 625 (1925).

⁶⁷*Id.* at 630.

⁶⁸*Debs v. United States*, 249 U.S. 211, 39 S.Ct. 252 (1919).

⁶⁹*Rice v. Paladin Enterprises, Inc.*, 128 F.3d 233, 255 (1997).

The fact of Rice is that James Perry murdered Mildred Horn and Janice Saunders by shooting them through the eyes and strangled Ms. Horn’s eight-year-old quadriplegic son, Trevor. It appears that James Perry was not acting without assistance—a copy of *Hit Man* was found in his apartment after the murders. Published by Paladin Press, *Hit Man* teaches the reader how to solicit business, choose a weapon, make a silencer, perform the kill, dispose of the weapon, and much more—all in explicit detail. Relatives of murder victims brought a suit against publisher instruction book that assisted murderer in soliciting, preparing for, and committing murders.

interest in proscribing such speech⁷⁰. But the limitations must be reasonable⁷¹, and Holmes argued that the intent could be inferred from the natural tendency and probable consequences of the speech, as well as suggesting that the encouragement need not be direct⁷²,” and “the jury . . . could not find the defendant guilty for advocacy of any of his opinions unless the words used had as their natural tendency and reasonably probable effect to obstruct the recruiting service, and unless the defendant had the specific intent to do so in his mind⁷³.”

In the case of biotechnology, we have to consider whether the state’s interest in protecting the public health and the environment is “sufficiently important” to justify regulating the “nonspeech element of experimentation.”⁷⁴ Some experts claim that biotechnological experiments meet the requirements of scientific expression as set out in the First Amendment. First, because of the uncertainty, complexity and long-term influences of biotechnology, the content of scientific experiments is a sufficient reason for the government to regulate. Second, because biotechnology has a potentially strong effect on social values, then it is also reasonable for the government to regulate biological experiments to prevent the negative effects of the “by-product.” Therefore, the regulations that control biotechnological experiments are not against the Constitution. Therefore, regulations aimed to control or limit biological experiments might potentially violate the independence and freedom of academic inquiry and scholarship. However, because the state has a legitimate interest in protecting the environment, and the public’s health and safety, the state interest should be “sufficiently important” to justify regulating the nonspeech element of biological experimentation.⁷⁵ But the state has obligations to carefully address the limitations because they might easily violate people’s right of free speech and academic freedom. Valerie M. Fogleman suggested that if regulations were narrowly drafted to address only safety measures, a rational basis for the regulations would probably be sufficient. But if regulations actually served to suppress knowledge, however, the state would probably be required to show a compelling interest for the regulations.⁷⁶

5.2. Economic Loss

Many biotechnology manufacturers also argue that more regulations are not necessary due to competing interests and competition in the market. In other words, the free market and different interest groups will find a balance and efficient point rather than the government’s regulation strategies. Manufacturers can bear their products being tested by the routine procedure to assure their safety to humans line because via the assessment system, they can in advance test the safety of the genetically modified products and avoid more compensation requirements if the product harms people or the environment. However, if the experiments or research of the products also need to be regulated in advance, manufacturers suffer not only freedom of developing the products but also the loss of the competition with other manufacturers, especially foreign manufacturers with looser regulations. For example, President George W. Bush declared that the publicly funded research will not be allowed to carry out any embryo experiments. The limitation no doubt will substantially restrict the development of biotechnology in the embryo area. However, in some countries such as China, embryo experiments are allowed because the government does not regard an embryo as a life

⁷⁰Isaac Molnar, *Resurrecting The Bad Tendency Test To Combat Instructional Speech: Militias Beware*, 59 Ohio St. L.J. 1333, 1355 (1998).

⁷¹*Debs v. United States*, 249 U.S. 211, 216, 39 S.Ct. 252, 254 (1919).

⁷²Isaac Molnar, *Resurrecting The Bad Tendency Test To Combat Instructional Speech: Militias Beware*, 59 Ohio St. L.J. 1333, 1357 (1998).

⁷³*Debs v. United States*, 249 U.S. 211, 216, 39 S.Ct. 252, 254 (1919).

⁷⁴*Id.*, 187.

⁷⁵*Id.*, 187.

⁷⁶*Id.*, 187-88.

form, and there is no conflict between biotechnology and moral/religious values. Therefore, the regulations in China become more loose than in U.S. And the different national regulations consequently may decrease competition in the biotechnology market in U.S.

Besides, if the public requires detailed information about biotechnology products and procedures, and if the government enforces regulations requiring full disclosure of dangerous ingredients and processes, or the state tries to regulate biotechnological experiments before the production of genetically modified products, then some manufacturers will suffer by having to reveal their business secrets, and confidential and proprietary information to competitors which could decrease or deprive them of potential profits. And this requirement could discourage manufacturers from investing more resources in the research and development of genetically modified products. This could then cause not only the loss of economic profits but could also stall the development of biotechnology.

Therefore, many biotechnology manufacturers believe that regulation should take place after research is completed but before commercial production and marketing begins. They believe that the regulations should focus on the safety and reaction procedures, but not on the contents of the experiments. In other words, they believe that the government should only ask the manufacturers to set safety standards to prevent potentially dangerous experimental materials from entering the environment and a cleanup procedure to decrease the harm if the harmful materials touch the environment. Some advocates of biotechnology freedom argue that the government should not enact more regulations in terms of which biotechnological experiments are allowed and which are not, where the biological experiments should take place, and under what circumstances they should be allowed.. Many people believe that the current regulations such as the assessment of environmental influences and risk assessment of drugs and food are enough to protect the public's safety and health.

5.3. Government Failure

According to regulatory theory, more regulations, including the banning of some types of biotechnological experiments and products, would not necessarily ensure that genetically modified products would not enter the market, but rather would create a black market for the products. As a result, the government would face more problems in monitoring the risks and safety of genetically modified products in the black market, and furthermore, the free market would be violated.

Besides, the price of genetically modified products might increase because the supply are limited and decreased. There are two situations might happen. First, the increased price of genetically modified products would become higher than the price of the non-genetically modified products, and everyone will use the later products. There is no much debate in this situation. But if the increased genetically modified products (see point A' in Fig. 3) is still lower than the price of the non-genetically modified products (see point B in Fig. 3), the mid-class and low-income laborers would still buy the genetically modified products because they would be less expensive than the normal products.

Pg'

Pg

Qg

Sg' – supply of genetically modified products

after regulating

D

A – price of genetically modified products *before* regulating
price

A' – price of genetically modified products *after* regulating

S_n – supply of non-genetically modified products

Q_g'

Q_n

P_n

B – price of non-genetically modified products

P_g'

P_g

Q_g

S_g' – supply of genetically modified products

after regulating

D

A – price of genetically modified products *before* regulating
price

A' – price of genetically modified products *after* regulating

S_n – supply of non-genetically modified products

Q_g'

Q_n

P_n

B – price of non-genetically modified products
Fig. 3 Price Changing by Regulatory

S_g – supply of genetically modified products

before regulating

5.4. Social Justice – Relativism

Genetic modification processes and genetically modified products can offer consumers “lower-cost products that taste good, are easy to transport, and have increased shelf life and nutritional value.”⁷⁷ This is appealing to all classes of people, including the middle-class and low-income laborers with fixed and scarce resources for their multiple needs such as food, health care services, work training, and housing. Therefore, buying cheaper and larger quantities of genetically modified products would alleviate the financial pressures facing mid-class and low-income families.

Here is a trade-off situation. Even though the price of genetically modified products is low, but the safety and influences are uncertain under current regulations. But more regulations on genetically modified products also means that the manufacturers have to spend more to meet the regulatory requirements, which they will pass on to consumers. Thus, if stricter regulations would be enforced, they would have to spend more money than before the new regulations and they would suffer more risks consequently creating a social injustice.

If the goal of legal reform in the biotechnology field is to protect the public’s health and safety, then more regulations of genetically modified products and biotechnological experiments are necessary. But if the regulations are based upon some interest groups’ political or religious preferences or values, then the regulations would deprive the public, including mid-class and low-income laborers’ right to access cheaper and better products. And if society and the government has to spend more money on normal products, consequently they would have few resources in medicine, housing and other basic life requirements.

In addition, according to existing evidence, there is no clearly demonstrated health or safety problems related to genetically modified products. Thus far, the effects are slight or based on moral objections. For middle-class and low-income laborers, the weight of the uncertainty and slight effects is much less than the problem of starvation and sickness. Even though biotechnology has uncertain, complex, and possibly long-term influences on health, the middle-class and the poor might not care because the influences might happen long after, and they would not survive at all if they cannot get sufficient food. It is impossible to persuade the middle-class and lower-income family to buy the expensive natural food instead of cheap genetically modified products just because they “might” cause an “uncertain” disease at age “75”. For them, the immediate need is gaining cheap and nutritious food. Many experts also have predicted that the world’s food supply will be threatened in future decades because of the global warming effect and increasing population. And the increasing price of food might cause unfair distribution to poor nations. Many proponents of bioengineered food believe it is a solution for meeting the food needs of a growing global population while minimizing the amount of arable land needed for agriculture, and reducing food costs.

Even though some opponents of bioengineering have argued that more regulations of biotechnology are needed, some experts claim these reasons are improper and due to subjective moral and religious values. They claim that the regulations should not involve issues of morality. These proponents of biotechnology argue that when the government considers the safety of biotechnological experiments and genetic modified products, it should not base its regulations on “middle-class morality” or “religious values.” The government should consider only the impact of biotechnology on human health, safety, and environmental protection and laws should be decided by Congress, which represents the people and not by the executive branch or the courts.

Therefore, more regulations can protect the poor and the general public from unsafe genetically modified products, but on the other hand strict regulations could also limit the poor people’s access to sufficient

⁷⁷Julie Teel, *Regulating Genetically Modified Products and Process: An Overview of Approaches*, 8 N.Y.U. Env’tl. L. J. 649,653 (2000).

and nutrient food. When the government tries to set more regulations on biotechnological experiments and genetically modified products, it cannot neglect the needs of all of society including the working class and the poor. If the government forbids biotechnology experiments and genetically modified products without regarding the needs of the poor it could “attend to the superficial and neglect the essentials.” For the U.S. government, its duty to protect people’s right to life is important. In essence, the biotechnology issue is complex and unpredictable. On the one hand, its development could cause an ecological crisis and on the other hand, it could possibly save many poor nations from starvation. Yet adding more regulations could cause social injustice and violation of human rights, but not adding them could cause social injustice and a violation of human rights if the poor end up using products that are not adequately tested. Added to this, without strict regulations, bioengineered products and processes could cause a worldwide ecological crisis. Thus, the government – politicians, policymakers, lawmakers and scientists and public interest advocates – must carefully consider the potential benefits and risks.

5.5. Feedback and Diversified Regulatory Methods

According to opponents of biotechnology, more regulations would prevent genetically modified organisms from destroying the ecosystem, and protect varieties of organisms in the ecosystem. But according to the other viewpoints, more regulations might result in the deterioration of the world’s delicate ecological balance because we could over-farm the land and use too many pesticides to produce enough food for the world’s growing population. For example, banning or discouraging the use of genetically modified products would cause more exploitation in suburban and rural areas and contribute to the destruction of forests to grow enough crops to supply the world. And the agricultural expansion could cause the extermination of desired organisms varieties.⁷⁸ Because regulations that aim to protect organism varieties, inversely could destroy some organisms’ environment.

The conflicts for policy and lawmakers exist everywhere, especially in developing countries, where a stable food supply is more important than the protection of the ecological balance. However, the interests of more efficient farming and development clearly do not always assist developing countries as we have seen with the situation destruction of the rain forests in South America, where the government has allowed businesses to cut down trees in exchange for economic growth. Clearly careful analysis of the costs-benefits and benefits-risks must be carried out before any laws are established.

More regulations could preserve the ecosystem, but they also might indirectly cause a loss of biodiversity. Genetically modified products could also help to feed millions of people and help preserve and enhance life on earth. But how to resolve the potential risks is a question policymakers and lawmakers must ask. Manufacturers argue that the resolution should not be more regulations on biotechnology experiments and genetically modified products. They think that the adequate reservation methods would be more efficient to protect the environment and human health, and would also support the development of the economy. For example, the government can “create buffer zones or refuges for non-resistant insects that will dilute the resistance built up by insects in the genetically modified organisms,” or build “germplasm banks” to prevent an organism from being eradicated by a disease or a genetically modified organism.⁷⁹

These measures would not only delay the implementation of biotechnology techniques, but also reduce the threat to the ecological system from the new biotechnology. And they also believe that biotechnology could help to preserve the biodiversity. Therefore, they argue, more regulations on biotechnology are unnecessary and incapable of resolving the current threats caused from biotechnology.

⁷⁸Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 187 (1987).

⁷⁹*Id.*

6. The Contents of Regulations of Biotechnology

Based on the above discussion, I believe that biotechnology must be regulated but to an appropriate degree. However, two questions need to be decided: (1) who will regulate, and (2) what issues should be regulated.

6.1. Who Will Regulate – Is Self-Regulation Enough?

6.1.1. Some Scientists' Viewpoints

Some scientists believe that biotechnology should be regulated, but they also wish to maintain their freedom to experiment and explore the array of fields open to biotechnology, from stem cell research to agricultural applications of genetically modified plants. Many scientists would agree to be regulated by society or the government.

Many scientists argue that the decision-makers on biotechnology regulations require specialized scientific knowledge; they believe that to be rationally discussed all “participants should understand the subject matter.”⁸⁰ Generally, scientists do not want the public to intervene in their jobs. It is generally believe that the fears of those opposed to biotechnology are based on emotional and political forces and that they lack scientific evidence. They believe that the public overreacts without complete and detailed statistics and proof, or at least unproved reports. For example, an author of the “Berg letter” which recommended the regulations of biotechnology admitted the letter “was based on emotional instead of scientific data.”⁸¹ However, the public was influenced by the report and as a result, following the letter, there was an upsurge of public support for the regulations, including the NIH’s guidelines on biotechnological experiments. Throughout the past decade, scientists have spent much effort in countering the public’s fears that biotechnology is not dangerous as what the public thought, and in proving the public has had established stereotype about biotechnology and hardly been changed even when most scientists believed that the biotechnology or biotechnological modified products are harmless. In addition, scientists advocate for independence and freedom to research and believe their work should not be controlled by politics, irrational fears and social and religious values.

⁸⁰Id.

⁸¹Id, 189.

6.1.2. The Public's Viewpoint

Portions of the U.S. public wants to have more control over biotechnology based on founded and unfounded facts and fears of biotechnology's danger that the scientists did not reveal.⁸² The public's suspicion is due to past scientific miscalculations about the safety of processes that have resulted in accidents such as Chernobyl and the tight relationship between the scientists, manufacturers, and politicians. Large segments of the public believes that the scientists will not voluntarily reveal the danger of biotechnology processes or biologically modified products because of self-interest. The belief is not entirely groundless. No doubt, the information about the biotechnology's ill effects, and the call for stricter regulations threaten scientists' and manufacturers' self-interest. Scientists are not independent and neutral especially when they work for the manufacturers, or they can benefit from selling genetically modified products. Therefore, scientists and manufacturers' credibility is weakened when they argue for self-regulation and relaxation of regulations. The public's participation in assessing the risks and benefits of biotech products and processes would help to increase the credibility of scientists' evaluation, reduce the public's mistrust and prevent manufacturers' abuse of information power. It would also prevent the scientific community's and the public's perception of risks becoming polarized⁸³.

Second, the public has the right to participate the regulations. Public participations in scientific discussions should not be prevented or discouraged just because of the complex and difficult to understand scientific nature of the topic. Even though the decisions are related to technological and scientific issues, the public is still "not satisfied by what appears to be elitism and arrogance on the part of scientists⁸⁴." The scientific nature of biotechnological experiments and genetically modified products should not grant the scientists the complete authority to make decisions, and forbid the public's participation on the basis that the public can not understand such complex issues. In fact, the public can educate itself if need be and can take into consideration the opinion of many "experts" whose opinions might differ. The public might need to respect the scientists' opinions, but need not to entirely accept their decisions without any preconditions. Besides, scientific knowledge belongs to everyone, not merely the scientific community or the manufacturers. The public also needs to express their ideas, and "only then can a meaningful exchange of ideas take place⁸⁵."

Third, the public has right to require a safe environment and standards that match its varied values but not entirely follow the scientists and manufacturers' descriptions. The development of research and modified products is indirectly based upon the desires and needs of the public which often wants a more convenient and comfort life. When the public has a vivid imagination of mad scientists creating Frankensteinian monsters, or of using live human beings in ghastly experiments, they "demand input into research decisions."⁸⁶ I believe that these the demands should be respected. Scientists and manufacturers should not ignore the public's fears, even if it is unreasonable, by advocating for independence of scientific expression from the public's control.

6.1.3. Conclusion

⁸²Id, 191.

⁸³Id, 194.

⁸⁴Id, 192.

⁸⁵Id, 192.

⁸⁶Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 184 (1987).

The public needs accountability from the biotechnology industry and is making more vocal demands for it to meet health and safety requirements. Accountability cannot be achieved without the public's participation, especially since biotechnology could potentially destroy the global ecosystem and harm human and animal life. In addition, it is tightly related to the social morality and religious values. The public has the right to regulate potential risks to its own safety, rather than trust in self-regulation by the scientific community.⁸⁷ Besides, because the influences of biotechnology can be so widespread and uncertain, that any major errors could create massive ill effects. Thus, the public has the right to set its own criteria to regulate its affairs.

Many advocates believe that scientists' self-regulation in the biotechnology realm, whether in experimental processes or in genetically modified products, does not provide enough safeguards and checks and balances to the public. However, decision-making without scientists' participation is not adequate either because their expertise and insights can add value to the debate and to regulations.

6.2. What Issues Should Be Regulated?

Because of biotechnology's close relationship to social values, legal analysis must extend beyond physical risk. The government and legislators must consider biotechnology's impacts on both physical risks and social impact and ethical considerations⁸⁸.

6.2.1. Social Risks and Ethical Considerations

Some experts argue in the context of "social risk" that "knowledge of biotechnology is viewed as dangerous or against the public interest," and "biotechnology research is viewed as morally wrong" because of the fears about future abuse of biotechnology.⁸⁹ Based on this thinking, many limitations have been adopted not due to scientific risks but due to what is viewed as "moral incorrectness" of biotechnological processes and products. For example, President Bush has banned federal subsidies to support promising research into stem cells that have been extracted from embryos on the moral premise that it is improper to use human embryos for research because they once were living creatures; fears also exist they embryos that could survive could also be used for research.

However, many scientists have complained that the tighter policy will cause the U.S. to fall behind other countries in the development of biotechnology, especially because some countries allow it because they do not value morality arguments, nor they do not care about the tensions between social values and scientific endeavors. It appears though that the difference between countries pursuing biotechnology development will be obvious in 10 years. For example, because of different cultures and religion, China does not believe that the embryo is a form of life and thus allows research using embryos (see discussion supra part 5.2).

Besides, because the fear of "social risks" not only apply to biotechnology experiments but also genetically modified products, the extreme and broadest view of "social risks" could also cause the collapse of biotechnology and related industries. Because U.S. society's hostile attitudes toward biotechnology could cause the government to implement stricter regulations for biotechnology this could further impede the expansion of the industry. Then the industries would move to other countries to produce more and cheaper genetically modified products.

Therefore, the impacts of biotechnology on social risks are unavoidable, but it is also counterproductive to

⁸⁷Id.

⁸⁸Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 *Envtl. L.* 183, 195 (1987).

⁸⁹Id.

excessively expand the definition of “social risks” because the abuse of social values may become obstacles for economic and biological development, and the subjective nature of social values will cause the scientists and enterprises do not know exactly what course to take. It is hard to deny that a policy could be a mistake and cause the tragic environmental or biological disaster that would upset the social order if it is mainly based upon pure scientific evidence and without considering social and moral values. But the extreme emphasis on social values can also cause paranoia block the development of science and economics, and impede the free flow of scientific thoughts and creativeness, just like the Middle or Dark Ages. I believe that the weight of scientific evidence and social values should be placed in careful balance. Sociological and ethical judgments are important but they are value judgments in the evaluation or decision-making process of biotechnology regulatory system⁹⁰, and not scientifically based at all times. These hose judgments should somehow align with the public’s interest and scientific proofs. The absence of value of science per se does not mean that ethical judgment should become the only value that influences decisions on regulations. The unknown knowledge and unknown influences of products need to be rationally evaluated by quantifiable methods and qualified sources in different domains including the scientific, social, moral, legal, environmental safety perspectives, and economic development. And only under such a complete and diversified consideration, can the cost/benefit analysis be acceptable.

In my opinion, there are two ways to address the “social risks” issue. First, “social risks” should be limited in the most basic and destructive conflicts, and have different weight in different areas. Namely, the ideas of social values should not endlessly expand, but be limited in the most important beliefs that the society believed. For example, the Catholic regards it is extremely immoral to not treat embryo as a life. Because different groups have different values and emphasize different issues, the weights of different social values are not all the same. For example, environmental risks should not become the main concern when biotechnology applied is to plants. Discussions and safety evaluations of genetically modified plants and medical procedures should be based solely on scientific statistics, nor should they be based solely on ethical codes. Neither should moral issues become the most important characteristics in assessing whether embryo experiments should be approved. Second, in order to lighten the negative effect of “social risks” on the development of biotechnology, “social risks” should not be the only standard in setting regulations. Introducing scientific data about the benefits and damages could efficiently decrease the influences of “social and environmental risks.”

Third, in order to avoid the ‘social risk’ become an ideal thought without thinking the difficulties in practicing which the general public might face, the weight should not be decided by scientific elites, interest groups, or legislators, but by the general public. For example, the leading opponents of biotechnology might argue that genetically modified crops could change the biological world to a “designed” world and that biotechnology knowledge should be put in “a different path . . . whose goal is to foresee how better to participate with rather than to dominate nature⁹¹.” But the hungry people in Africa and their governments might be strongly against this viewpoint because their main concern regarding biotechnology is that it can produce more and cheaper crops to resolve their starvation problems. If there is no significant and clear danger to the environment or to human and animal safety, they would not want to give up those technologies just because of “social risks.” In this kind of decision-making model, the viewpoints of opponents, manufacturers, scientists, and the general public should be considered together.

Therefore, when governments try to establish regulations, they should consider different interest groups’

⁹⁰Id, 197.

⁹¹Id, 196.

opinions and set different weights got social risks such as its potential influence on the global environment, family relationships, moral values, and religious beliefs. For example, opponents can argue that biotechnology could “lead to a ‘designed’ world rather than a natural one”, while scientists can argue that the risks are very small, and the general public can argue that they want cheap products more than so-called “politically correct” morality. In this way, the government can make proper decisions on regulating biotechnological experiments and genetically modified products taking into consideration significant environmental and social risks.

6.2.2. Physical Risks

According to Valerie M. Fogleman, the physical risk in biotechnology experiments has at least three potential outcomes: (1) construction of a unique organism not existing in nature, (2) the organism’s establishment in the environment, and (3) harm caused by the novel organism to the environment and/or people.⁹² If any one of these three components was shown to be totally false, the biohazards of biotechnology would be proven unfounded.

However, these three outcomes are just general descriptions. Clear standards to judge by which evaluate the contribution of biotechnological components are not yet clearly established. The undefined and indefinite standards also cause the regulations to be relatively loose. For example, the regulators consider “a absence of evidence is not evidence of absence” because “it is virtually impossible to prove that risks do not exist in scientific experimentation”, and “risks inherent in direct release experiments cannot become apparent until after an experiment is conducted.”⁹³ But the loose regulations might not fit biotechnology experiments and genetically modified products, and may need to be changed. There are three reasons why “physical risks”, unlike “social risks”, should be stricter and with no gray areas:

(1) The characteristics of physical risk are not like those of social risks. Physical risks are specific, objective and quantifiable. Social risks are more subjective, indistinct and might be controlled by religious or interest groups. Since physical risks can be objectively evaluated by quantifiable data, then it is not necessary to fear that the stricter standards would obstruct the normal development of biotechnology, or excessively interfere with the freedom of research and the operation of the market by means of moral or religious values.

(2) The influences of physical risks are directly related to the well-being of humans and the environment. And because of biotechnology’s close relationship with human beings and life, it is necessary to set stricter standards to regulate the physical risks.

(3) The risks of biotechnology might not show up until the next generation because of the uncertainty and complexity involved in altering molecular processes. I agree that “risks in direct release experiments cannot become apparent until after an experiment is conducted,” but the problem is that the risks might not become apparent even when the biotechnology experiments are finished or genetically modified products are in the market. As was discussed before, the effects of biotechnology are uncertain because the impacts might not be appear until the next generation. Besides, the interactions between genetically modified and unaltered organisms and the environment, are not clear. It is also hard to set a clear and definite mechanism to test the causation, or to identify whether the influences were caused by biotechnological techniques. Because of the uncertainty and complexity, the loose standards ??

⁹²Id, 199.

⁹³Id, 199.

Therefore, the standard of physical risks should be stricter, meaning that if, after excessive evaluation, if biotechnological experiments or genetically modified products “might” be related to the physical risks, then the experiments and products should be regulated or prohibited without regard to the causation. There are several methods to prevent potential physical risks. One method which was discussed in this article before is limiting “false negatives” or “false positives.” Normally, scientists would not consider the tests of negative effects as sufficient to substantiate a hypothesis that a particular substance causes a particular effect unless the results are statistically significant. And statistical significance is decided by the corresponding critical point, the probability of physical risks. But here I suggest that the critical value should be stricter, or less, than the normal value; meaning that the probability of physical risks of a genetically modified product should be less than the normal corresponding value. Only then can the product can be considered safe. The other value is in regard to the “absence of evidence” as the “evidence of absence.” Using this logic, scientists and manufacturers would be more motivated to prove the causation between the influences and novel products.

7. Conclusion

Regulating biotechnology research and genetically modified products is difficult because sound scientific evidence regarding its safety and environmental risk factors are scarce and nondefinitive.⁹⁴ In addition, there are questions about whether the regulations should be enforced after research is completed but before commercial production begins or before the research and development processes,⁹⁵ whether the government or the public should intervene in scientific research or whether the independence and freedom of science should be protected, and whether self-regulation is adequate. According to the complexity of the science of biotechnology and genetically modified products, there is a great possibility of the abuse of professional power, and potential widespread and long-term harm to the environment and the well being of plant and animal life. Due to this, I think that more regulations are necessary. But I believe we should be careful to avoid over-control by the government, and the overestimated and abuse of social values, and the possible counter effects of regulations such as violations of social justice and damage to economic and scientific development.

⁹⁴Id, 200.

⁹⁵Id, 192.