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BIOETHICS: A REVIEW

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ABSTRACT

Development and application of biotechnology raises ethical questions, some of which are serious enough to generate significant opposition from the consuming public to certain technologies and their applications. The purpose of this section is merely to bring light on certain issues related to GMOs (successful or unsuccessful), ongoing debate on ethics and social concerns. Nonetheless, this study indicates that researchers who need to understand risk perception of agricultural biotechnology in the developing world should exercise caution when using morality as a theoretical ‘‘prism.’’ Dictionary based definitions will now be presented to help the reader put the subject anti proper perspective. Ethics is the science of morals in human conduct (i.e. the study of moral principles). Morals are concerned with the accepted rules and standards of human behavior in a society. It involves the concept of right or wrong, the goodness or badness of human character or behavior. Value is basically the worth attach to something. In other words ethics is evaluative of the decisions people make and the actions they take as they are presented with dilemmas. Morality depends on values in order to determine the goodness or badness of an action. In a pluralistic society there are differences in the sense of values (i.e. relativism). Consequently, there is a variety of moral theories that do not necessarily constitute truth. Furthermore, law, religion and customs should be distinguished from morality in law; lawmakers define what is right or wrong. Those who break law are subject to punishment prescribed by legislature, in religion right or wrong are based on revelation or scriptural authority.

KEYWORDS: Bioethics, Biotechnology, Morals, Issues.

1. INTRODUCTION

"Bioethics" emerged in America as a field of scholarly reflection in the 1960s.[1] The field concerns itself with fundamental questions, including what it means to be human, the nature and value of human life (and death), the ends of medicine and the purpose of science. It began with a series of conferences convened to discuss the tensions between the humanistic and scientific dimensions of medical practice wrought by extraordinary advances in biomedical science and biotechnology. This constellation of governmental activity marked the birth of a new branch of bioethics—*public bioethics*—concerned with the *governance* of medicine, science and biotechnology in the name of ethical goods.[2] Biotechnology provides a wealth of products which improve the lives of many individuals. Some improve the quality of life of the person while the others extend their lives. Another biology oriented research area is synthetic biology, which is a sub-category of biotechnology. Products from synthetic muscle tissue and medications to biofuels are the subjects of research today.[3] Each product developed has to be evaluated as to whether it can be produced sustainably and economically while taking into consideration the effect on the environment and protection of human rights. With the introduction of new products and technologies, bioethics is evolving, which means the educational community has to be up to date with the current bioethical issues and accepted practice in order to prepare the engineering students to be involved in research as a student and in industry. The development of biotechnology has triggered many ethical and social reactions from the public opinion, the media and non-governmental organizations. The aim of this document is to provide some insights into the ethical concerns, dilemmas and trade-offs that have been expressed concerning biotechnology.

1.1 General perspective

Biotechnology is "the study and manifestation of living bodies or their components (e.g., molecules, organs, cells and tissues) in order to improve their living conditions."[4] Synthetic biology is a sub-category of biotechnology and is the "designing and combining of biologic molecules such as deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins. Bioethics is "a relatively recent field of academic inquiry that deals with the ethical, legal, social and cultural implications of the biosciences and their application in biotechnology.[5] Quite often, ethical values conflict with one another and produce dilemmas through which the public, researchers or regulators must find their own way. In Bush presidency (America) The Controlled Substances Act (CSA), which criminalizes "the unauthorized manufacture,

distribution, dispensing and possession of substances classified in any of the Act's five schedules," provides that certain drugs be available only by written prescription.[6]

1.2 Historical background

Medical ethics has its roots in ancient Greece with the Hippocratic Oath; bioethics came to the forefront as an issue at the end of WWII with the trial of 23 doctors for human experimentation in the concentration camps. The result of the Nuremberg Trials was a set of research ethics principles for human experimentation established in 1947 which was called the Nuremberg Code.[3] Jan. 2001 parliamentary debate, the Ad Hoc Committee on Gene Technology is set by the Ministry of Science, Technology and Innovation. In its Report, the Committee recommends that the capacity for genetic counseling should match future demand. Laboratories do not need accreditation or license, but individually take part in external quality assessments. Most ethical issues of pre-symptomatic genetic testing on healthy subjects have been expressed in 2001 Advice from the Danish Ethical. The Council of the National Academy of Sciences formed a committee on the conduct of science and reported their findings in 1989.[3] Their report, On Being a Scientist, offers guidelines on how to conduct research using scientific methods while attempting to accurately gather facts and report them without prejudice.[7]

2. THE BIOTECHNOLOGY DEBATE

Biotechnology products are rooted in the perceived risks that these products pose to social and personal values. It is also suggested that the raging biotechnology debate is rooted in three fundamental disagreements as follows:

1. Scientific disagreements

These disagreements are about the types and degrees of risk to human, animal and environmental health. These issues involve empirical questions and are usually resolved by scientific methods. However, they are not exclusively resolvable by the scientific method of enquiry. Sometimes, value judgment is critical in their resolution. For example, handling uncertainties in scientific data and definition of the levels of risk deemed acceptable are both value judgments.

2. Political disagreements

Political disagreements are generally about the social and economic impacts of bio-technology based on the various political viewpoints.

3. Religious, ethical and philosophical disagreements

These disagreements are often faith based and include issues about morality, whether scientists are playing God or whether the biotechnology products are natural.[8]

3. GLOBAL EVOLUTION OF BIOETHICS AND RESPONSIBILITIES

It is crucial to recognize that, as with physical harms, we disagree about non-physical harms because we adopt different ethical frameworks."[9] For Examples Biosafety concerns for the release of GMOs in the environment have been a major issue in the European public mind while, by contrast, they are of little concern to Asian consumers from China, Indonesia and the Philippines (Hoban, 2004). In 2004, over two-thirds of respondents from the United States, Colombia, Cuba, Dominican Republic, China, India, Indonesia and Thailand considered that the benefits of GM crops are greater than the risks. Fewer than 40 percent of consumers agreed to this statement in France, Greece, Italy, Spain and Japan. Although bioethics is more regulated and Institutional Review Boards oversee clinical research, there are still issues arising.[3] It is logical to go to the areas where a condition is prevalent to research the signs, symptoms and progression of the condition as well as its effective treatments. This results in poor and impoverished nations being the subject of the research. This in itself can be looked at as exploitation and the ethics of it can be questioned. One such situation occurred from 1991-1993 in sub-Saharan Africa and Asia in the research of HIV treatments to prevent transmission of HIV to fetuses in pregnant females.[10-12] In India, the government's decision to finally approve commercial release of Bt-Cotton in March 2002, indeed, is a result of pressure from Indian farmers themselves, who concluded their first alliance with industry.

4. BIOTECHNOLOGY AND ETHICS

Since God, humanity and nature are linked, with God being the creators of the other two. Some people see nature as god's creation for the benefits of humans, who therefore can use plants, animals and the ecosystem for their purposes. In order for us to be correctly evaluative of our choices, decisions and act as they pertain to biotechnology, there is a need for certain basic sets of information.

The ethical issues and the passion with which they are debated in the public arena vary among applications. Manipulation of the food chain seems to attract more attention than clinical applications (example xenografts). For example heart valves from pigs have been used in humans without fanfare. However, GM grains have encountered considerable public

opposition from certain quarters. In general, the ethical issues of concern to the public are the impacts of biotechnology on human health and safety, environmental impacts, intrusions into the natural order, invasion of privacy, issues of rights and justice, economic and others. It is important that benefits and risks of biotechnology be considered in making ethical decisions.[8]

The main issues of biotechnology can be summarized in five F's.

- Foods- About half the soybeans and one-third of the corn grown in the United States in 1999 contained foreign genes.
- Fuel- Different types of fuel can be made using biotechnology techniques; for example, yeast ferment corn starch to yield ethanol; bacteria decompose sludge, manure or landfill waste to produce methane and firewood heats in homes.
- Feedstock- Instead of petroleum, bio-renewable materials such as starch from corn or whey from cheese-making can be used to make plastics.
- Fiber- A new example of industrial biotechnology for fiber is bio-pulping using a fungus to convert woodchips to paper pulp while reducing energy use and pollutants.
- Pharmaceuticals- Vaccines, antibiotics and other therapeutic agents produced by microbes, plants or animals fall under this category.[13]

In light of potentials, social dislocations that might arise from the genetics revolution, organizations have developed ethical guidelines for biotechnology. These guidelines attempt to capture a consensus view of value in society. There is of course, a need of ethical guideline for patient physician relationships. These, however have been in existence since at-least the time of Hippocrates, and have modern manifestations in guidelines from professional societies such as American Medical Association and the United Kingdom General Medical Council.

To make all the domains more illuminative, let us consider some examples.

4.1 Btcotton

Btcotton, the first GM crop to be grown in India was given approval for commercial cultivation in March 2002, so this is the first GM crop harvested in the country. Qaim and Zilberman attribute the 87% yield increase they report as being ‘entirely’ due to crop losses avoided by the presence of a single copy of the *Bt gene*. Yield in plants is known to be polygenic and there is no known evidence for a single gene being largely responsible for

yield. Attributing such large effects on yield to just one copy of the Btgene, is untenable and unscientific.[14]

4.2 Btbrinjal

Bt brinjal is being developed in India by M/s Mahyco (Maharashtra Hybrid Seeds Company). No GM brinjal has released for an advanced stage of feed trials in open conditions anywhere in the world. On February 9, 2010 the government of India officially announced that it needs some more trial and time to release BT brinjal.[15]

4.3 Controversy and issues

Scientists have pointed out possible hazards of transgenic cotton and brinjal along with other BT crops. Risks like crossbreeding of other plant species of natural population or general herbivore population or useful insects like bees, beetles and also to endangered species of insects like Monarch butterflies. It is also assumed that toxin effects would be concentrated in terrestrial or related ecosystems. Toxic effects of BT brinjal such as immunological reactions, tissue damage or organ failures were also observed in experimental mice. On the other hand, there are no reports of toxic effects or allergies induced by eating BT brinjal in human population.

Controversies regarding BT crops indicate that issues are more concerned to nutrition, yield and public policy rather than beneficial effects of GM crops. If the yield was not increased in one in ten applications the reasons could be different and the solution for that needs to be find out instead of making a yield an issue or reason to ban BT crops. Attention should be diverted to the reports that have indicated yield increases, pest resistance, economical saving followed by reduced pesticide use and in turn the gift of clean and healthy environment. Scientists or policy makers or farmers must solve the issues instead of criticizing them towards the misunderstandings. Keeping broad views in mind, we should be prepared to adopt GMOs for our betterment. Actually it could be the best solution to resolve food crisis in feminine affected countries of the world.[16]

4.4 Corporatization and IPR

Corporate world have kept aside biosafety issues for criticism but they have made issue of governmental policies regarding commercialization of BT cotton and brinjal. They have not only blamed governments for not backing commercialization of BT crops but also the scientists involved in development of BT crops for self interest. They have pointed towards

low yields of BT crops as compared to normal crops in some cases. Corporate world denied yield increase by plantation of BT cotton and brinjal and labeled the existing yield increase reports as false and manipulated. In doing so, they overlooked wrong agricultural practices or management in cases of low yield of BT crops. It was criticized that BT crops could not meet need of world's hungry population; the matter of overpopulation was deliberately avoided. Some people also suggested that biological diversity and not BT crops are enough to solve world's food crisis. Biosafety protocols and results were also turned down by declaring them unreliable. In market place BT cotton or brinjal like other GM crops were displayed with labels as GM or BT and sold separately with considerable difference in price in such a way that buyers would eventually opt for non BT food. Controversies regarding intellectual property rights (IPR)/patenting issues of BT crops but not hybrid crops have also been a part of heated discussions in corporate and scientific world. If it happens, the losers would be the plant breeders and Corporators relying on each other for benefits by selling hybrid crops or seeds to farmers.[14]

5. OTHER RISING ISSUES

5.1 Effects on the Environment

Herbicide Use and Resistance

Effects on the environment are a particular concern with regard to GMO crops and food production. One area of development involves adding the ability to produce pesticides and resistance to specific herbicides. These traits are helpful in food production, allowing farmers to use fewer chemicals and to grow crops in less than ideal conditions. However, herbicide use could be increased, which will have a larger negative effect on the surrounding environment. One such herbicide that has already been added is Roundup. Crops of Roundup-ready soybeans have already been implemented into agricultural practices, possibly conferring Roundup resistance to neighboring plants.[17]

5.2 Effects on Untargeted Species

Bt corn, which produces its own pesticide, is also in use today. Concerns have been raised regarding adverse effects on Monarch butterfly populations, which are not the original target of the pesticide.[18] Although, the pesticide can protect crops against unwanted insects, they can also have unintentional effects on neutral or even beneficial species.

5.3 Effects on Human Health

Allergies

GMO crops could potentially have negative effects on human health as well. When splicing genes between species, there are examples in which consumers have developed unexpected allergic reactions. Researchers used a gene from the Brazil nut to increase the production of methionine in soya beans. The insertion of this gene inadvertently caused allergic reactions to the soya bean in those with known nut allergies, but no previous allergy to the soya bean, according to the product developer, Pioneer Hi-Bred.[19]

Long-Term Effects

Because GMO technology has been available for such a short amount of time, there is relatively little research which has been conducted on the long-term effects on health.[18]

New Proteins

Proteins which have never been ingested before by humans are now part of the foods that people consume every day. Their potential effects on the human body are as of yet unknown.[17]

Food Additives

GMOs also present us with possibilities of introducing additional nutrients into foods, as well as antibiotics and vaccines. This availability of technology can provide nutrition and disease resistance to those countries that don't have the means to provide these otherwise. The distribution of these foods is more feasible than mass inoculations for current diseases. However, even these possibilities carry with them potential negative effects such as the creation of antibiotic and vaccine-resistant strains of diseases.[17]

6. RISKS AND BENEFIT BY INDIAN FARMERS

At the moment, we are limited in our knowledge about the full benefits and risks of biotechnology. Consequently, we are in danger of either underestimating or overestimating the potential of biotechnology for good or evil. Furthermore, public reaction may be rooted in undue fear or hope stemming from misunderstanding, misinformation or lack of information about various aspects of biotechnology.

● In terms of environment, the public is concerned about contamination from bioengineered organisms or products that could pose a threat to human health and damage natural sources

(forest, water bodies). There is a concern about destroying the aesthetic value of nature and jeopardizing the survival of wild animals by destroying their habitat. The perception is that 'natural' is better, while 'artificial' is inferior. We have a moral obligation to take care of and preserve nature.

● Regarding food safety and health, the concerns include food allergens and toxic compounds introduced as a result of genetic manipulation. For example, the consumers were leery about the use of BGH (bovine growth hormone) in the dairy industry because they were not certain about how cow hormones would affect humans. Aiming plants to protect themselves against pests (eg- use of Bt) is of concern because the toxins they produce might affect humans.

● There is also an issue of developing countries. Since there are unable to acquire new technologies, many of the nations are unable to compete fairly in the international markets. Also, many if the germplasm resources used in plant and animal improvement are derived from these region of the world.[8]

7. CONCLUSION

GM crops represent an important new technology, which ought to have the potential to do much good in the world provided that proper safeguards are maintained or introduced. All those who are involved in developing the new technology, whether they are researchers in the public sector, in agrochemical or agricultural businesses or farmers, or food manufacturers and retailers need to recognize and accept a very broad responsibility to the public.[20,21] They need to ensure that ethical concerns are taken account of, that their new technologies and products are safe for human consumption and avoid further harm to the environment, that the potential of GM technology is harnessed to meet the most urgent food needs of the world as well as commercial benefit, that impartial information is made widely available to the public and that consumer choice is fully respected.[20,21]

8. REFRENCES

1. Johnsen, Albert R. The Birth of Bioethics. 1998; 26-27.
2. Snead, Carter O. Public bioethics and Bush Presidency. Harward Journal of law and public policy., 32: 869.
3. Jurak Sarah, Jurak Emil, Asmatulu Ramazan. Current State of Bioethics Relating to Biotechnology for Engineering Education. © American Society for Engineering Education., 2015.

4. Asmatulu R, Khan WS, Ceylan M. Biotechnology and Bioethics in Engineering Education. Midwest Section Conference of the American Society for Engineering Education. Lawrence. KS., 2010.
5. Kolarovaa TA, Denev ID. Integrating a Bioethics Course Into Undergraduate Biology Education. Biotechnology & Biotechnological Equipment., 2012; 26: 2801-2810.
6. Oregon Gonzales V. Public bioethics and Bush Presidency. Harward Journal of law and public policy., 2006; 243.
7. Committee on the Conduct of Science, "On Being a Scientist," Proceedings of the National Academy of Sciences of the United States of America., 1989; 86: 9053-9074.
8. Gaythwaite DM , Moses V, Cape RE. Intellectual Property and Technical know-how. In biotechnology the science and business., 1991.
9. Parens Erik, Johnston Josephine, Moses Jacob. Ethical Issues In Synthetic Biology., 2009.
10. Angell M. The Ethics of Clinical Research in the Third World. The New England Journal of Medicine., 1997; 337: 847-849.
11. NIH Research Matters, "National Institute of Health (NIH)," 9 June 208. (http://www.nih.gov/researchmatters/june2008/06092008breastfeeding.htm). 2015.
12. Connor EM, Sperling RS, Gelber R. Morbidity and Mortality Weekly Report (MMWR), Zidovudine for the Prevention of HIV Transmission from Mother to Infant., 1994.
13. Singer Peter A, Daar Abdallah S. Bioethics and Biotechnology. Encyclopedia of Life Support System (EOLSS)., 2: 3.
14. Reddy PR. Current Science. National Geophysical Research Institute., 2003; 84. Kaul Pallavi. (Btbrinjalcontroversy.www.slideshare.net/pallavikaul26887/bt-brinjal-controversy). 2010.
15. Bhawsar Sonali. Btcotton and Btbrinjal- controversies and IPR ssues.
16. (biotecharticles.com/issues-Article/BT–cotton-and-BT-Brinjal-Controversies-and-IPR-Issues-622.html). 2011.
17. Bates Timothy W, Blair Anne M, Germe Erika S, Keller Adrienne B, Lavik Gillian E, McMaken A. Kelly. Executive Summary from the Genetically Modified Organism Exploratory Committee. 2014.
18. Losey, John E. Transgenic pollen harms monarch larvae. 1999; 214.
19. Biotech soybean and Brazil nut protein. Pioneer hybrid international., (http://www.pioneer.com/biotech/brazil%5Fnut/default.htm). 2002.

20. Nuffield Council on Bioethics. Genetically Modified Crops. London, Nuffield Council on Bioethics. 1999.
21. Nuffield Council on Bioethics, United Kingdom, The Use of Genetically Modified Crops in Developing Countries. 2003.