CHAPTER

25

Safety and Ethics in Biotechnology and Bioengineering: What to Follow and What Not to

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25.1 INTRODUCTION

Biotechnology is a scientific discipline, which consists of development of living organisms to make new products/services or to modify products or processes for specific use and benefit of mankind. Genetic engineering differs from biotechnology because it uses isolation and insertion of genetic material or DNA, thereby it reprograms the life of an organism or better known as genetically modified organisms (GMO). Both these fields often overlap with each other depending upon the use of techniques and their applications. Omics-based approaches such as proteomics, metabolomics, and pharmacogenomics have added more weight to advances in these fields (Jeanette and Emon, 2016). A wide range of applications of biotechnology and bioengineering involve the areas of health care and medicine, agriculture, transgenic plants (edible vaccines), industrial, and environmental uses. These developments have significantly reduced the global constraints and have benefitted the society by providing novel resources. Many lifesaving drugs and vaccines have been developed and are under development with the use of recombinant technology, monoclonal antibodies, and protein engineering techniques.

At the same time, the developments of biotechnology and bioengineering have raised eyes of researchers, policy makers, economic representatives, law, politics, and even common man. Some issues of ethical and social concerns have been triggered from different corners of the society including public, researchers, government, and nongovernment

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organizations. Especially, genetic engineering of living beings, plants, animals, and human has generated issues and safety concerns. Diverging views and many ethical discussions have been expressed with mediatic announcement of creation of genetically engineered (GE) crops (soya and tomato), cloning of sheep and other animals, or research on human embryos. The guidelines pertaining to animal and human research have been established and documented for proper utilization of benefits of these two fields (Shankar and Simmons 2009).

25.1.1 Addressing Ethical Issues

The word "Ethics" has been derived from "Ethikos" in Greek language, which means "arising from a Habit" to analyze good or right in human conduct. Ethics is an act of defining right or wrong within moral limits. Ethical aspects cover crops animals, medicine, stem cells, and medicines. The use of biotechnology and bioengineering has raised a number of ethical and social issues such as:

- Who owns GMO? Can such organisms be patented like inventions?
- Are genetically modified (GM) crops and foods safe to eat and are without any harmful effect?
- Are GE crops safe for the environment and ecosystem?
- Who controls an individual's genetic information, its privacy, and safeguarding issues? Whether this will categorize them on the basis of genetic mutations.
- How far should we go to ensure that we will be free of mutations? What will be the influence on future generations?
- Should a pregnancy be ended if the fetus has a mutation for a serious genetic disorder?
- Storing, Collection, and Safe processing of samples, all these issues need to be addressed.
- What about the risks obtained by an individual/animal during a research study?

Till date the technically sound answer to these concerns is not available and depends on moral values, dignity, justice, safety, welfare, humanity, biodiversity, health, and security (www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926844.pdf). Usually the ethical values or code of conduct conflict with each other and produce dilemmas for public, policy makers, and researchers. Awash in predictions and uncertainties, we need to devise and follow appropriate controls and should frame precise laws for using research and development in the favor of society.

25.1.2 Organizations Framing Research Ethics in Biotechnology and Bioengineering

Several organizations all over the world like US Food and Drug Regulatory agency that regulates the FDA regulates the safety of food and drugs for humans and animals. A number of organizations, e.g., World Medical Association (Helsinki Declaration), Nuffield Council of Bioethics (2002), Council for International Organizations of Medical Sciences (CIOMS, 2002), Indian Council for Medical Research (in India) and The United Nations

Educational, Scientific and Cultural Organization's declaration on bioethics and human rights (2005) have developed framework of regulatory guidelines to help and guide researchers in the controversial arena of human using advanced biotechnology (Ethical Guidelines for Biomedical Research on Human, 2006).

25.1.3 Ethical Concern in Agriculture

Biotechnology has contributed to sustainable agriculture in many ways, such as increased resistance against stresses including pests and diseases, against abiotic stresses, bioremediation of polluted soils, improvement in quality and productivity, enhanced nitrogen fixation, improvement in fermentation technology, and improved levels of nutrients in crops. It has increased sustainability in agriculture by reducing the dependence on agro chemicals. Pyramiding of genes in a systematic manner helps to improve the quality and quantity of crops such as tolerance to stresses, productivity, and nutritional quality. GE crops or GM crops differ from conventional crops because of genetic modification due to genetic engineering involving one or a few well-characterized genes into a plant species or it can introduce genes from any species into a plant. Whereas most of the conventional methods of genetic modification used to create new varieties (e.g., artificial selection, forced interspecific transfer, random mutagenesis, marker-assisted selection, and grafting of two species) to introduce many uncharacterized genes into the same species. It can transfer genes between species, such as wheat and rye or barley and rye.

Statistical results in year 2008 showed that approximately 30 GE crops were grown on almost 300 million acres in 25 countries (including 15 developing countries) (James, 2009; Ronald, 2011). According to an estimate in year 2015, >120 GE crops (including potato and rice) have been grown worldwide (Stein and Rodriguez-Cerezo, 2009).

There is no doubt that GM crops have created greater possibilities to ensure future food security; especially for small-scale agriculture, associated concerns towards negative and ethical concerns have been increasing (Azadi and Ho, 2010). A diversity of views and opinions related to risks and benefits is available on whether GM crops should be used. There are other questions: Will there be adverse effects of GM crops to obtain medicinal product will endanger their original species on Earth? What will be the effects on environment or ecological balance? What will be the effect on economic condition of farmers? It has been observed that technological advances often bring disproportionate disadvantages to small-scale farmers (Belcher et al., 2005). There will be financial growth of the firms, such as Dupoint and Monsanto, which invest in genetically contrived herbicide-resistant crops (Comstock, 1989; http://www.biofortified.org/2011/02/organic-infighting-over-ge-alfalfa/; https://www.ethics.iit.edu/publication/ethics&biotechnology.pdf). The most debated ethical issue is of market monopoly by the big companies and threatening of small farms (Amin, 2009). Major impact will be on rural economies of the developing countries with the redistribution of benefits in a pattern from small to large and better-off farmers. All these will result in increasing commercialization of science only for profit and will reduce the social benefit of mankind. This will also put a question on scientific purity and public trust on scientists (Thompson, 1997). Moreover, the burden of justification falls on scientists who introduce innovations bringing foreseeable adverse effects. These

situations are needed to be addressed by governing bodies at the international and national level to distribute equal benefit of modern biotechnology and bioengineering, so that fruits of innovations and products in these fields should be accessible to all regardless of economic status and scientific purity should be maintained (Amin, 2009).

25.1.3.1 Sustainable Agriculture

Bt (*Bacillus thuringiensis*) is a soil bacterium, which is used to produce an insecticidal toxin within plants and microbial pesticide. Bt (*Bacillus thuringiensis*), a type of cotton crop, was developed and used after conducting several toxicity and allergenicity tests (Thompson, 1997; European Food Safety Authority, 2004). The genes encoding insecticidal toxins were transferred to many other crops such as cotton, soybean, and rape, to breed pest-resistant crops. As a result of this, fewer chemical pesticides were used and this provided environmental and economic benefits leading to sustainable agriculture production and increased biological diversity. Marvier et al. (2007) found that along with Bt crops nontargeted invertebrates (such as insects, spiders, mites, and related species that are not pests targeted by Bt crops) were more abundant in Bt cotton and Bt corn fields when compared to conventional fields managed with insecticides (Marvier et al., 2007). This crop when commercially introduced in 2002 as a trial in India (especially in Maharashtra and Andhra Pradesh) failed to achieve the target. The environmentalists and the Green Peace Corp observed that as these crops produced the insecticidal toxins later in their life cycle, the Bt transgenic crops planted on a large-scale might increase the resistance of pests to the Bt toxins (Uzogara, 2000). Ultimately, Bt pesticides may lose their efficacy and can result into heavy economic losses. The US Environmental Protection Agency (EPA) was sued in year 1997 by a coalition of consumers, environmentalists, and farmers using organic farming methods for allowing the genetically modified planting of crops (corn, cotton, and tomato) to produce an insecticidal Bt toxin. They demanded that EPA revoke 11 registrations issued to five companies to cease granting such permissions and complete a statement to find out the environmental impact of Bt crops so far (Ronald, 2011; Wadman, 1997).

25.1.3.2 Transgenic Plants

Transgenic plants are able to produce medicine of desired therapeutic value. They consist of elements of two different species. Transgenics helps scientists to develop organisms that express a novel trait not found in a species normally; for example, potatoes (protein rich) or rice that has elevated levels of vitamin A (known as "golden rice") (James, 2009; http://www.goldenrice.org). These may be used to save endangered species, e.g., American Chestnut tree, currently being repopulated by Chinese–American chestnut hybrids specifically engineered with a genetic resistance to the chestnut blight (the deadly fungus that nearly decimated native populations in the early 1900s) (http://www.nytimes.com). Transgenic have also been used to develop novel vaccines such as edible vaccines. A transgenic plant project, known as the "glowing plant project," incorporated a gene from a firefly into a houseplant, resulting in plants displaying a soft illumination in the darkness. This was to create trees that could illuminate streets and pathways, thereby saving energy and reducing our dependence upon limited energy resources. However,

this has sparked a heated debate related to potential environmental consequences via using highly GE plants into natural ecosystems (The Daily Beast, 2013).

25.1.4 Impact of Biotechnology and Bioengineering on Animals

The use of cutting edge technology in these fields has created revolution and has touched the field of veterinary science. These are evidenced from the use of research methods for enhancing livestock production, to develop disease models, to develop diagnostic procedures, and for preclinical evaluation of adverse effects, vaccines, growth hormones via manipulating or modifying the animal genome to bring out desired traits (Kinter and Valentin, 2002; Berger, 2005). Selective breeding has produced physiologically and genetically stable strains to be used as models for certain human disorders such as cancer (Berger, 2005). Some disease are created in animals by special surgical procedures, via administration of toxins, by molecular biology techniques, e.g., knock in and generalized knock out (Levine et al., 2004; Rees and Alcolado, 2005). Many countries have imposed legal restrictions on animal experimentation (Kromka, 2003). Several times unfavorable impact of these advances of biotechnology have been observed on socioeconomic status, e.g., bovine growth hormone (BGH), a product of genetic engineering used in dairy, increases the milk yield of a cow by 30%. Therefore, this undoubtedly has major influence on the dairy industry (Feenstra, 1993; Liu and Xue, 1998). Then the question is regarding quality and safety of milk produced using this method and "inhumane" treatment of cows. The use of BGH threatened to displace a disproportionate number of disadvantaged farmers. The most affected were farmers of small- and medium-sized with small herbs and high debts loads, without highly mechanized and intensively managed operations (Comstock, 1989).

Scientists have claimed that consumption of GE food is safe, based on the view that this food gets destroyed in stomach by acid and enzymes. However, studies have shown that GE food is not completely destroyed or acted upon by stomach acids and enters into systemic circulation after absorption and digestion. Moreover, our defense system is not capable of removing these GE food from the cells.

25.1.4.1 Transgenic Animals

The major ethical issues in transgenic animals are whether it is ethical or unethical alteration of the natural order of the universe. The genetic make-up of an individual is modified for a specific purpose, without predicting in advance whether there are any side-effects that may cause disease to the animal (http://www.bbc.co.uk/ethics/animals). Can we use animals or creatures as a commodity? Disease model or suffering may last for a long time in these animals as researchers want to conduct long-term investigations.

Another transgenic product, BioSteel, is a silent silk product created by inserting the genes from a silk-spinning spider into the genome of a goat's egg prior to fertilization (http://www.bbc.co.uk/ethics/animals). Transgenic goats are obtained by pronuclear microinjection and somatic cell nuclear transfer. After the maturation of the transgenic female goats, they produce milk containing the protein from which spider silk is made. The fiber artificially created from this silk protein has several potentially valuable uses,

e.g., bulletproof vests. Industrial and medical applications include stronger automotive and aerospace components, stronger and more biodegradable sutures, and bioshields, which can protect army personnel and first responders from chemical threats such as Sarin gas (Satya, 2007).

The recombinant protein in the milk of transgenic goats is alpha-fetoprotein used in autoimmune diseases, malaria vaccine antigen, antithrombin III with antiinflammatory and anticoagulant properties, tissue plasminogen activator used in stroke, butyrylcholinesterase in treating neurodegenerative diseases, human growth hormone, human granulocyte colony-stimulating factor, and many others have been already developed and used and some are under development stages in clinical trials (Moura et al., 2011).

Transgenic combinations may include plant–animal–human transgenes. The DNA of human tumor fragments is inserted into tobacco plants to develop a vaccine against non-Hodgkin's lymphoma (Dador, 2013). Researchers have developed a flu vaccine using human DNA and tobacco plants (Swaminathan, 2008). Incorporating a human protein into bananas, potatoes, and tomatoes, researchers have successfully developed edible vaccines for hepatitis B, cholera, and rotavirus, the latter of which can cause fatal bouts of diarrhea (Thomas et al., 2002; http://www.actionbioscience.org).

25.1.5 Ethical Concerns of Xenotransplantation

Xenotransplantation is a procedure, which is used to create model of a disease and sometimes might offer a potential solution to organ/tissue shortages for human recipients. Xenotransplantation, or the transplantation of living tissues or organs from one species to another, alleviates the shortage of human organs such as heart and kidney. Pigs have a similar physiology and organ size, making porcine (pig) organs ideal candidates for transplantation into human recipients. Research studies are going on to explore the use of cell transplantation therapy for patients with spinal cord injury or Parkinson's disease. Due to rapid scientific progress in the field of xenotransplantation, it has overcome the major problem of hyperacute rejection, i.e., massive destruction of transplanted organ within 24 hours (Ekser and Cooper, 2010). The pigs have been introduced with the deletion of gene alpha 1, 3, galactosyltransferase, so that the endothelium of blood vessels of pigs no longer expresses Galα1,3Gal antigen. Humans have naturally formed antibodies against this antigen (Kolber-Simonds et al., 2004; Smetanka and Cooper, 2005; Zeyland et al., 2013).

A number of ethical concerns have been raised regarding xenotransplantation (Smetanka and Cooper, 2005; Melo et al., 2001). These involve risk of transfer of infection, such as cytomegalovirus, Epstein–Barr virus, and hepatitis B or C, and sometimes even HIV illegal trade in sale and purchase of organs, in case of allotransplantation where the organ is transplanted from an individual to other (same species). In case of xenotransplantation, informed consent is difficult to take, because the person (in case vegetarian) with end organ failure, after knowing that organ is from pig, may deny for the procedure. Second is the risk of transfer of infection from porcine to human and the possibility of the transmission of a porcine endogenous retrovirus, cytomegalovirus may persist, and the person in clinical trials is required to undergo lifetime surveillance that may be extended to the family members. This will invade the privacy of an individual along with health

risk. A high level of care has to be observed in xenotransplantation; first the animal used should be genetically engineered to avoid the rejection of immune response and should be kept in a healthy and safe environment to avoid risk of transfer of infection. Concerns have been expressed from different communities indicating that animals will be placed at an "additional risk" in case of the use of this technology.

The UK Advisory Group on the Ethics of Xenotransplantation stated that "some degree of genetic modification is ethically acceptable" but that "there are limits to the extent to which an animal should be genetically modified" (Smetanka and Cooper, 2005; Nuffield Council on Bioethics, 1996).

25.1.6 Ethical Issues in Stem Cell Research

Stem cell research has promised a new life to medical science and treatment strategies. The pluripotent stem cell lines, which are derived from oocytes and embryos, are fraught with disputes about the onset of human personhood (Lo and Parham, 2009). Genetic manipulation of stem cells now includes the growth of tissues on scaffolding, or a 3-D printer, which then can be used as a temporary skin substitute for healing wounds or burns. This has become a viable alternative in procedures that involve replacement of cartilage, heart valves, cerebrospinal shunts, burns, grafting of skin, and other organs. However, the reprogramming of somatic cells to produce induced pluripotent stem cells avoids the ethical problems related to embryonic stem cell research (Lo and Parham, 2009). Stem cells from adult and umbilical cord blood cells do not create any ethical concerns and are widely used in research. The use of embryonic stem cells is ethically and politically challenged.

Several other ethical concerns include counseling, collection, banking, informed consent, confidentiality, and privacy. Also, the issue related to patent of stem cells derived from human embryos has been under debate in scientific and legal communities since years. These have been discussed in detail and reviewed by Lo and Parham (2009). Many countries have established guidelines to address these ethical issues and have made rules for working on embryo transplantation, embryo research, surrogate motherhood, and other issues (Saxena et al., 2012). Cloning of human embryos only to be used for therapeutic purpose was made legal in year 2001, after making an amendment in "Human Embryology Act." However, cloning humans for reproductive purposes is illegal and punishable under the act (Asmatulu et al., 2010).

25.1.7 Ethical Issues in Aquaculture Industry

In aquaculture industry, the transgenic fish is a perfect example to be mentioned here. GM food in aquaculture industry has made it a significant contributor of food production in many countries. Almost 35 species of fish have been genetically modified, e.g., trout, catfish, tilapia, and salmon. These are genetically engineered to grow fast, develop large muscles, and tolerate temperature. Increased efficiency and high production levels are offsetting conventional practices in this field particularly in developing countries. The transgenic fish is able to breed with existing species in an uncontained environment. Some are already

marketed in China (Carp), the United States (Salmon), and Cuba (Tilapia). However, Costco, the second largest retailer of GM Salmon fish has stopped selling Salmon.

Genetic modification represents certain unanswerable and sometime uncontrollable uncertainties that represent risks for human health, animal welfare, and environment (Weaver and Morris, 2005). Approximately, 2 million people, involving scientists, fisherman, businessman, and consumers, have opposed the US FDA's approval for GM Salmon due to the risks related to health (as it continuously releases growth hormone), environment, and wild salmon species. Center for Food Safety in November 2015 announced to sue US FDA for this approval (http://www.centerforfoodsafety.org).

25.1.8 Ethics in Biobanking

Human tissues have been derived and stored, distributed, and used for forensic, educational, therapeutic, and research purposes. These have been known under various names such as biobanks, biolibraries, tissue repositories, genetic databases, or DNA banks (Hoeyer, 2008). These biobanks and other sources contain important samples that contain personal health information of an individual may be owned by a private owner or a profit or nonprofit organization. This type of diversity has raised many ethical and legal questions in biobanking. Many ethical dilemmas exist such as ownership, use of donation, processing of sample, storage, and results of research. Commercialization of biobanks will create many issues such as prevention of data exploitation, ensuring justice to participants, balancing costs and benefits, and ensuring and sustaining public trust (Rothstein, 2005; Budimir et al., 2011). The role of ethical review boards working under ethical and legal framework and national legislations is very important, which provide protection to participants and ensure proper use of their sample. Proper coding and storage of biobank samples, with restricted access to personal information, must be ensured to promote the safety and personal integrity of sample donors. Optimal storage conditions should be followed. Specific consideration applies in case its donor is not alive. These samples should not be used in case if the deceased participants did not wish to carry on research on his/her sample after death, respect should be maintained, and sample should be destructed and disposed off. The review discussing ethical concerns in biobanking has been provided by Budimir et al (2011).

25.1.8.1 Biosafety Issues of Modern Biotechnology and Bioengineering

Biosafety can be defined as an asset of actions or concerns to minimize or erase the potential risks to environment or living beings derived from development, implementation, or commercialization of biotechnology or bioengineering or to counteract the negative impact of these two fields. The valuable knowledge of these two fields if used inappropriately can cause serious disaster to mankind and living beings on our planet. For example, GM crops and food are improved in quality than naturally occurring but are associated with some allergic reactions, and consumption of these for long time may lead to development of some fatal diseases such as cancers. The treatments of weeds such as herbicide, stress resistance and pest resistance may escape plants from cultivation system. These modified crops may create a great threat to normal food chain, which may influence

beneficial insects, birds, mammals, and microbes (Buiatti and Christou, 2013). If used for a long time and in large scale, these transgenic plants or crops may harm natural ecological balance more than a nuclear reaction can cause. These biosafety concerns have hindered the growth of biotechnology and bioengineering. Many countries have formulated and documented the laws regarding biosafety issues, e.g., chapter 16 of Agenda 21 adopted at United Nations Conference in 1992 and "International Biosafety protocol" to ensure the safety of development, application, exchange, and transfer of biotechnology (Buiatti and Christou, 2013). International biosafety project report has focused on the benefit and prioritization of biosafety in the developing world for the benefit of biodiversity and to enable consumers to use their right to choose a healthy sustainable environment and to be informed. The precautionary measure requires an integrated system of risk management in biosafety that includes active participation of representatives of public, government, scientific researchers, policy makers, stakeholders, and manufacturers from biotech companies. The other ingredients of this system are education, information, proper waste management of toxic and contaminating products, and adaptive management (http://www.consumersinternational.org). Above all there should be proper analysis of risk and benefit ratio before directly implementing/using any benefit for society. A number of organizations have come into existence across world such as UN Framework Convention on Biological Diversity controls biodiversity loss and Biological Weapons Convention regulates the use of biological weapons in a proper way.

We can use biotechnology and bioengineering to significantly increase the quality of life and can affect the world around us—for better or for worse. If used negatively, it could cause unprecedented pandemic from lapse of biosafety or bioterrorism (Baum and Wilson, 2013).

25.1.8.2 *Adverse Effect on Health of People/Environment*

These include increased disease burden, increased rate of pathogenicity, emergence of a new disease or allergic reaction, pest or weed, and adverse effect on species and ecosystem.

25.1.8.3 *Unpredictable and Unintended effects*

Horizontal gene transfer may transfer the desired gene from a genetically modified organism to potential pests or pathogens and many yet to be identified organisms (Praksh et al., 2011). This may lead to alteration of ecological niche or ecological potential of the recipient organisms (Praksh et al., 2011). The other possibility of gene transfer is that it may insert at variable sites of the recipient gene, resulting into a novel gene that may cause unintended effects.

25.1.8.4 *Impacts on Socioeconomic Welfare of Countries and of Communities*

Application of genetic engineering has enabled to diagnose and cure some genetically inherited diseases (e.g., some cancers and hemophilia). Molecular diagnosis also has impacts on the employment and marriage prospects of human beings. For example, in a research carried out by geneticists at Johns Hopkins University, it was found that Ashkenazi Jews have double the risk of colon cancer. This work led the Jewish groups being targeted as a potential market for commercial genetic tests because of their susceptibility to disease.

25.1.8.5 Impact of Traditional Values and Culture

Because the genetic modification interferes with nature's creation, the concerns have been raised that identification of certain people susceptible to a certain disease or condition might make descendent selection and will disturb the evolution in a normal way. Because it interferes with fundamental laws of nature.

25.1.8.6 Ethical Issues in Medical Biotechnology

The advances in biotechnology and bioengineering have created a revolution by manipulating genetic heritage in the field of manufacturing medicines and in medical sciences such as personalized medicine. The ability to modify and fix mutant genes has provided unbeatable treatment of disease. Also the diagnosis has become precise after identifying the related genetic variants causing the disease. Animal models of human diseases have been developed to understand the molecular basis of disease. Clinical trials have shown the successful use of gene therapy to attack tumor cells of patients with recurrent B-cell acute lymphoblastic leukemia (Baum and Wilson, 2013; Brenner et al., 2013). However, it has raised many ethical issues that need close attention (Kuszler, 2006). Because we can modify living beings for required benefit, there is great potential of ethical regulation (Persson, 2006). Research costs, storage of DNA samples, risk/benefit to the study subject insurance, privacy, employers, providers, and third-party payers are the other issues bubbled to the surface. To address all the concerned issues, scientific communities, medical professional people, related government officers, policy makers, stakeholders along with public should develop an infrastructure so that biotechnogical development should be used only for the benefit of mankind.

25.1.8.7 Protecting Human Beings in Clinical Trials

This major issue has already created debate in year 1999. With the death of Jesse Gelsinger (18 years of age) after participating in a gene therapy trial in Pennsylvania, the institution faced great criticism for failing to disclose crucial information on informed consent documents, relaxing criteria for accepting volunteers, and eligibility criteria (Silverman, 2004). This issue prompted a great deal of curiosity among researchers and regulators, and many institutions came forward to implement new standards.

Each trial/study should be carefully planned necessary for the success of the scientific research, and the study participants should be aware of the risks and benefits of the research study to which they are participating. Patient's privacy and confidentiality is a must during and after the study. After decoding the human genome, the scientists are adept at deciphering genetic composition that has increasingly alarmed the privacy of an individual's information including prospective employer and insurers or others who can mislead this information.

25.1.8.8 Accountability

The accountability to frame and regulate the "public policy and regulatory ethics" in biotechnology is of government and other research communities. Ethical committees should be framed and maintained at institutional and central level. They should report time to time to the central body.

25.1.8.9 Affordability

The sky-rising costs of health care and cost of medicines are a political hot potato and will remain so (Silverman, 2004). As compared to pills and tablets, the cost of a biologic will be 10 times more or even more costlier. Sometimes a patient cannot afford the out-of-pocket treatment, and situation becomes worse if insurers decline to add a biologic to its formulary because of cost. The high pricing of biological/medicines, which are the result of biotechnology or bioengineering provides additional burden, e.g., in case of a chronic disease or the case where an insurer does not cover a particular treatment.

25.1.8.10 Privacy

Protecting privacy is another concerned issue. After decoding human genome, the whole personal information is available just like a Kundli (A document prepared at birth in Indian Hindu religion to forecast the future based on birth), the single nucleotide polymorphisms, susceptibility to disease, the adverse drug reactions that one can experience if undergoes treatment with particular drugs, and many others predictabilities. This creates enormous problems in case an employer comes or an insurer comes to know the details. This should be kept highly confidential to avoid any misuse, or in other words identifiable patient information should not be shared without the patient's consent.

25.1.8.11 Intellectual Property Rights

The inventions made in the fields of biotechnology and bioengineering are patentable. Patents are used to provide exclusivity for the inventor in commercializing his invention. There is an agreement under World Trade Organization known as The Agreement on Trade-Related Aspects of Intellectual Property Rights (IPR) that requires countries to grant patents for inventions, in all fields of technology provided that the invention is new and industrially applicable (Singh, 2000). IPR encourages inventions and their disclosers. The global market of biotechnology agricultural products has increased approximately to 20 from 0.5 billion dollars in 1996. The Organization of Economic Cooperation and Development (OECD) has expressed 7 billion dollars and accounts for about half the world's entire agricultural research investment (Singh, 2000). Issues in patenting GMO allow industries with big setup to have monopoly of genetically modified plants and animals and violate the sanctity of life (Uzogara, 2000). The patent system can also be used to usurp intellectual ownership of "native technologies." For example, Neem tree, known as blessed tree, used from ancient times in India for medicinal values. A US company did some research on Neem tree and got the patent for extracting "Azadirachtin," a potential pesticide. There are more than 40 patents on Neem only in the United States. A number of Patent controversies and court cases have been going on globally on different aspects. These have been discussed by Fialho and Chakrabarty (2012).

25.2 CONCLUSION

The use of emerging techniques in the field of biotechnology and bioengineering is very important to meet the challenging demands of world around us and to improve existing

conditions prevalent. We are at the juncture where on one side we have capability to change the scenario by meeting all the demands of food and medicine, whereas on the other side, there is unprecedented threat to originality of species, their existence, human health, and environment. Inventions are made every day but the critical approval requires proper risk assessment and management with appropriate monitoring methods before it is applicable to society/general public. A broader base is required for discussion on GMO and their impact on ecosystem. The international biosafety regulatory frameworks are sufficient to be stringent to protect against genuine ascertainable risks. Interdisciplinary training and education should be provided to the students, scientists and professors, doctors, engineers, social scientists, workers, lawyers who are working in the research-related areas with main focus on biosafety and bioethics. The best way is consideration of ethical social and economic issues related to research and its implementation in the fields of biotechnology and bioengineering. The precautionary approach will provide new avenues for future research and development in these areas.

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Further Reading

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