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BIOTECHNOLOGY AND HEALTH: ETHICAL CHALLENGES FOR INDIA

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Introduction

There is no universally accepted definition for the term Biotechnology. In this paper, I will refer to it in a fairly broad way as outlined by the UN Convention on Biological Diversity, which referred to the term as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[1] An alternative definition, also broad, which lends itself to more easy interpretation is "the processes and products (usually of industrial scale) offering the potential to alter and, to a degree, to control the phenomena of life—in plants, in (non-human) animals, and, increasingly, in human beings."[2] The second definition goes on to explain some terms more explicitly by giving examples of the processes (e.g. recombining genes) and products (e.g. new drugs or vaccines).

The role of biotechnology in health care has already been well established for diagnostic purposes, for risk assessments of individuals, to predict future health-related outcomes, in the field of

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[1] Convention on Biological Diversity. Article 2. Use of Terms. http://www.cbd.int/convention/articles/default.shtml?a=cbd-02

[2] "Beyond Therapy. Biotechnology and the Pursuit of Happiness." A Report of the President's Council on Bioethics, Washington D.C., October, 2003, 2. www.bioethics.gov

reproductive medicine and for therapeutic purposes[3]. Countries across the world have started investing heavily in the biotechnology-health sector.[4] India's involvement in the Biotechnology research space started relatively early; in the period 1991-1993 it was the only country in the developing world which had scientific publications in excess of 200 in the area.[5] Since those early days, much has changed and much more can be done with biotechnology and health care. There is, however, need for introspection and caution. For instance, 'The Universal Declaration on the Human Genome and Human Rights' adopted on 11 November 1997, recognises in its preamble that "research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole" but cautions that "such research should fully respect human dignity, freedom and human rights" in addition to ensuring that there is no discrimination based on "genetic characteristics."[6] One of the challenges in addressing the issues related to biotechnology and health care is the speed of progress in the field. Thus, ethicists and the public at large appear to react to emerging issues in this field, often with divergent voices. As one commentator put it "Biotechnology races ahead, ethics follows and popular opinion lags behind..."[7]

The tremendous promise of Biotechnology needs to be tempered by the understanding of how we can best use this for the common good, while respecting the dignity of human life and recognising that the decisions that we make today have enormous consequences for future generations. As was succinctly put in 'A Report of the U.S. President's Council on Bioethics' in 2003, we run tremendous risks if we seek to fulfill our deepest desires through Biotechnology —

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[3] P.M. Bhargava, "The Social, Moral, Ethical, Legal and Political Implications of Today's Biological Technologies: An Indian Point of View," *Biotechnology Journal* 1 (2006) 34–46.

[4] L. Zhenzhen, Z. Jiuchun, W Ke, H. Thorsteinsdóttir, U. Quach, P.A. Singer, A.S. Daar, "Health Biotechnology in China: Reawakening of a Giant," *Nature Biotechnology* 22 (2004, Supplement: DC) 13-17.

[5] H. Thorsteinsdóttir, A.S. Daar, P.A. Singer, "Health Biotechnology Publishing Takes-off in Developing Countries," *Int. J. Biotechnology* 8 (2006) 23-42.

[6] The Universal Declaration on the Human Genome and Human Rights, 11 November 1997 http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

[7] A. Robinson, "Ethicists Race to Keep Pace with Advances in Biotechnology," Canadian Medical Association Journal 167 (2002) 289.

"There is an old expression: to a man armed with a hammer, everything looks like a nail. To a society armed with biotechnology, the activities of human life may seem more amenable to improvement than they really are. Or we may imagine ourselves wiser than we really are. Or we may get more easily what we asked for only to realize it is much less than what we really wanted."[8]

This paper attempts to discuss the ethical challenges posed by biotechnology in the field of medicine and health care, with a focus on India. My approach has been to discuss the multiple issues broadly — each of which could be debated in considerable detail. I have laid no specific emphasis to Catholic views on Biotechnology and its ethical implications. However, as a practicing Catholic, my views may be seen by some as having an inherent bias consonant with my faith.

The Application of Biotechnology in Medicine and Health Care

Biotechnology has considerable potential in the area of health and health care. The list below is not exhaustive, but representative of some of the areas that biotechnology has been used to impact the practice of medicine.

- Pharmacogenomics is a field of medicine which attempts to determine how genetic inheritance of certain traits in an individual affects the response or non-response to drugs. It has been known for some time that some drugs work in some individuals and not in others. The promise of pharmacogenomics is that of 'personalised medicine' — where individuals will be given medication with the knowledge that these are particularly effective to their genetic make up. Proponents of 'personalised medicine' argue that individuals will be spared a 'trial' of medication, only to determine that the medicine does not work for them. At the heart of this approach is, therefore, some genetic testing. This carries with it certain ethical issues:[9]

o How, for instance does one manage incidental, nonphramacogenomic results (i.e. results that were not the primary aim of the investigation but which emerge positive)

o What should be done if there is a discovery of a genetic variant that has implications for other family members? Should they be informed? Does the practitioner have a duty to these 'third parties'?

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[8] "Beyond Therapy. Biotechnology and the Pursuit of Happiness."

[9] Brothers KB, "Ethical Issues in Pediatric Pharmacogenomics," *The Journal of Pediatric Pharmacology and Therapeutics* 18, 3 (2013) 192-8.

Do the family members have the right to refusal of genetic information that they did not seek in the first place.

- Manufacture of drugs / vaccines: the traditional approach to the manufacture of drugs has involved organic chemical processes. With biotechnology, genetically modified organism or cells are used to produce pharmaceuticals and replacement hormones. While on the face of it, there seems little in the way of ethical dilemmas, the recent debate on the development of new antimicrobials highlights certain ethical issues.[10] We would largely agree that the development of new, more effective drugs with fewer side effects for the infectious diseases that we continue to face in our world is a generally good thing. However, this development is largely in the hands of private enterprise, driven by motives of profit. Drugs are thus bought by individuals who can afford them and the development of drugs is driven my market forces rather than wider needs. Private industry would see the development of new antimicrobials as constituting rather large risks with limited gains, particularly, since the development of antimicrobial resistance would lead to obsolescence and a relatively short period for financial gain. This would explain the wide disparity between the development of drugs for infectious disease and those of chronic lifestyle diseases such as diabetes and cardiovascular disease. Since developments in Biotechnology are controlled by a small but powerful lobby, there is suspicion that the focus is on increasing consumer dependence and then controlling availability.[11] Thus, biotechnology and drug development do not necessarily go hand in hand to solve the health issues of the majority.

- Genetic testing: There is also the continuing debate on the need to understand that individuals should not be reduced to their 'genetic identity'. There are also concerns about how genetic information can be kept confidential and whether these results can be exploited by health insurers and employers.

- Stem cells:[12] Stem cells have two broad characteristics. First, they have the ability to replicate or renew themselves. Second, they can

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[10] A.E. Aiello, N.B. King, B. Foxman, "Ethical Conflicts in Public Health Research and Practice: Antimicrobial Resistance and the Ethics of Drug Development," *Am J Public Health* 96, 11 (November 2006) 1910-4.

[11] J.C. Polkinghorne, "Trends in Biotechnology," Nr. 18 1/00 http://www.genethik.de/ethical.htm accessed Sept 2, 2013

[12] A. Liras, "Future Research and Therapeutic Applications of Human Stem Cells: General, Regulatory, and Bioethical Aspects," *Journal of Translational Medicine* 8 (December 10, 2010) 131. doi: 10.1186/1479-5876-8-131.

move from their undifferentiated state to develop into cells of different lineages. Embryonic stem cells are seen during the embryonic stage and depending on the stage of embryonic development can form various kinds of cells, while adult stem cells are typically found in the adult tissues and organs and are capable of developing into the cells of the tissue where they are located. One of the implications for stem cells is stem cell therapy — the transplantation of live cells into an organism in order to repair a tissue or to restore lost or defective functions. It has been reported that human embryonic stem cells are used in 13% of cell therapy procedures, foetal stem cells in 2%, umbilical cord stem cells in 10%, and adult stem cells in 75% of treatments. Ethical issues related to embryonic stem cells include, among others, donor consent, oocyte collection and the issue of destruction of human embryos. This is particularly an issue with those who believe that life starts at the moment of conception and that there can be no moral or ethical grading of human dignity throughout the course of human life. Guidelines on the use of embryonic stem cells around the world range from total prohibition to controlled use. For those who do not subscribe to the view of the sanctity of life of embryos there are other ethical considerations regardless of the source of stem cells. The high cost of cryopreservation, means that cord blood banks, for instance, will be accessible only to the population with the means to pay for it; this runs counter to the ethical principles of social and distributive justice.

- Gene Therapy: the principle of the method is that a gene is introduced into a virus vector which then accesses a human cell. The gene in the virus vector is incorporated into the human cell and then makes a protein which helps treat certain genetic or acquired diseases. There are potentially two types of gene therapy:

  - In somatic gene therapy, the genetic makeup of the recipient is changed but this is not passed on to the next generation.

  - In germline gene therapy, the genetic changes can be passed on to the offspring.

There is a general sense that there should be a moratorium on germline gene therapy for two reasons; safety and ethics. Some scientists believe that the first issue, i.e. of safety, could well be addressed in time.[13] The second issue, however, is difficult to

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[13] I.M. Verma, "Germline Gene Therapy: Yes or No?," *Mol Ther.* 4, 1 (2001) 1.

address. The notion of 'designer' babies, possessed of specific physical / intellectual traits leads to a host of moral dilemmas — the concept of 'self', the idea of health and disease, the idea of 'nature' and man's role as a part and modifier of it, indeed, the very nature of society. What may have been seen to be fanciful in Aldous Huxley's Brave New World [14] are now areas of active debate.

- Reproductive therapies: Proponents of these techniques (perhaps the best known is *in vitro* fertilization, although other techniques have since emerged) indicate that they are aimed at providing 'choices' for people who suffer from infertility, for same-sex couples and for single women to form biological families. The use of the techniques is justified by some on the grounds of procreative liberty and procreative autonomy.[15], [16] However even proponents of these techniques, indicate that these techniques:[17]

o Have largely developed outside the realm of public policy and debate

o Are driven by market forces

o Are associated with widespread abuse in terms of sex selection and excessive payment to women to provide eggs.

o Require a critical analysis of ethical dilemmas

Groups opposed to these forms of reproductive assistance, including the Catholic Church, argue that every human being is entitled to life and dignity from conception till death.[18] The number of embryos 'sacrificed' in the process, or the freezing of embryos for future use is in contravention to this fundamental principle, and treat embryos as biological or laboratory material with no right to dignity. Additional issues include the genetic selection of offspring and sex selection.

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[14] M.H.B. Schermer, "Brave New World Versus Island—Utopian and Dystopian Views on Psychopharmacology," *Med Health Care Philos* 10, 2 (June 2007) 119-28.

[15] J.A. Roberston, "Reproductive Liberty and the Right to Clone Human Beings," in *Medical Ethics at the Dawn of the 21st Century*, *Annals of the New York Academy of Sciences*, Vol 913, ed., R. Cohen-Almagor, 198-208.

[16] J. Harris, "Clones, Genes, and Reproductive Autonomy. The Ethics of Human Cloning," *Medical Ethics at the Dawn of the 21st Century*, 209-217.

[17] F. Coeytaux, M. Darnovsky, S.B. Fogel, "Editorial: Contraception: Assisted Reproduction and Choice in the Biotech Age: Recommendations for a Way Forward," 83 (2011) 1-4.

[18] *Dignitas Personae*, 12.

- Genetically modified crops: Although undernutrition of a substantial proportion of children and adults remains a visible social and health problem in India, and some argue that genetically modified crops could help address the problem, I will not be dealing with this further in this paper, as this deserves specific attention, given its complexities.[19]

What are the Ethical Challenges?

While Biotechnology holds tremendous promise for good, there are important considerations that need to be debated. Paul Crooks refers to the Ethics of Biotechnology as "The New Eugenics."[20] While society has rightly reacted to the Holocaust and excesses of Nazi Germany to recreate society framed to warped human ideation of societal 'improvement', or 'enhancement', eugenics has, in fact, continued with the one-child policy, sex selection and genetic screening *in utero*. This has been succinctly put by the U.S. President's Council on Bioethics:

> In a previous Council report, on human cloning, we emphasized how cloning-to-produce-children alters the very nature and meaning of human procreation, implicitly turning it (at least in concept) into a form of manufacture and opening the door to a new eugenics. Sex selection raises related concerns. The salient fact about human procreation in its natural context is that children are not *made* but *begotten*. By this we mean that children are the issue of our love, not the product of our wills.[21]

The issue of sex selection is a particular ethical issue for India where there is a worsening sex ratio and where the girl child is already discriminated against.

Another issue is what primacy we place on the scientific endeavour and technology Vs. the broad implications of the techniques and on the relationship between science and industry. McLean argues in a section of her paper entitled "We Can, But Must We?" that there is suspicion that "science is at the mercy of the technological imperative" and that in this view "ethics takes a quietistic turn; at worse, it becomes completely irrelevant. A mantra of "if we can, we

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[19] "Genetically Modified Crops: The Ethical and Social Issues," Nuffield Council on Bioethics, http://www.nuffieldbioethics.org/sites/default/files/GM%20crops %20-%20full%20report.pdf

[20] P. Crooks, "The New Eugenics? The Ethics of Biotechnology," *Australian Journal of Politics and History* 54 (2008) 135-143.

[21] "Beyond Therapy," 68.

inevitably will" places troubling limits on our critical thinking and moral imagination. We must recognize that the possible — however captivating, however daunting — is not inevitable."[22] In this context, we need to guard against being driven by the overriding issue of national pride and the need to be a part of a select group of biotechnologically advanced nations. While the promotion of science of itself is not an issue, I believe that there is an equal responsibility to debate the social and ethical consequences of scientific advances.

The placement of personal autonomy on an ethical pedestal does little justice to those who have remained disempowered by virtue of history, social prejudice or socio-economic condition. With specific regard to biotechnology, autonomy of choice assumes the access to knowledge, the ability to understand it and discern its immediate and long term implications while making a fully 'informed' choice. Even among the educated, access to information in a form that is easily understood in all its ramifications is hard to come by in the face of rapidly changing technology and science that is continually evolving its own syntax to cope with its changing needs. How much more difficult is it in a country like India, where we still grapple to ensure informed and understood consent for conventional epidemiological research[23] and where we have large numbers illiterate, socially disadvantaged and on the fringes of decision making? Ethical literacy varies considerably across countries and within them, as does the level of public debate about such issues. Even when public deliberations are held, we need to ask ourselves whether the scientific /medical/ industrial fraternity seeks this to validate their own ethical stands or to challenge them. The notion of the individual as an autonomous agent is based on the premise that individuals choose what they value and that they attribute meaning to their existence. However, mankind exists in a cooperative world where individual decisions have ramifications for others, not only in their close proximity but those far removed. With rights come duties and responsibilities — and the latter, unfortunately, are less frequently debated upon.[24] "Science and technology are the most important

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[22] M.R. McLean, "A Framework for Thinking Ethically about Biotechnology," http://www.scu.edu/ethics/publications/submitted/mclean/biotechframework.html; Accessed Sept 2, 2013.

[23] D. Rajaraman, N. Jesuraj, L. Geiter, S. Bennett, H.M. Grewal, M. Vaz, "Study Group TB," *BMC Med Ethics* 12, 1 (February 15, 2011) 3.

[24] S.R. Benatar, A.S. Daar, P.A. Singer, "Global Health Ethics: The Rationale for Mutual Caring," *International Affairs* 79 (2003) 107-138.

instruments to make life more valuable; they provide the means to individuals to liberate themselves from the tragic dimensions of nature, particularly the absurdities of disease, aging, and death."[25] However, how "individual autonomy could be guaranteed in a field which is evolving, and which to a large extent is unclear, at least to the lay person, in terms of its risks and social implications."[26]

There is little doubt that much of the advances in Biotechnology particularly in its translation is driven by the need for profits. This increases the likelihood of innovations being driven by market forces rather than by actual need. There is also the likelihood that the involvement of large industry can lead to monopolisation resulting in a loss of control and the fear of rising prices in the future, although one of the current arguments for biotechnology in the pharma sector is its ability to deliver drugs at lower costs. An important issue is also the relation between scientific activity and industry — "how the market may penetrate into scientific activity and how scientific activity may benefit from the existence of a market."[27]

In India, the poor majority still have limited access to quality health care. The genomics and biotechnology revolution could potentially widen the disparities not only between rich and poor countries, but between populations within a country. In this context, it is important that a Consultation on Genomics policy, while outlining the need for India to commit itself to progress in this field also highlighted the need to "engage the public and ensure broad-based input into policy setting; ensure equitable access of poor to genomics products and services; deliver knowledge, products and services for public health."[28] This strikes at the heart of equity and the need to ensure Distributive and Social Justice.

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[25] H.A. ten Have, "Genetic Advances Require Comprehensive Bioethical Debate," *Croatian Medical Journal* 44 (2003) 533-537.

[26] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights: The International Legal Framework," *EUI Working Papers LAW*, No. 2006/17, http://www.iue.it/

[27] H. Secara, "Biotechnology and Health Care. Regulations, Limits, Controversies," 5th International Focus Programme Essay Competition, http://www.coe.int/T/DGHL/Monitoring/SocialCharter/Activities/FocusEssayWinnerSecara2013_en.pdf

[28] T. Acharya, N.K. Kumar, V. Muthuswamy, A.S. Daar, P.A. Singer, "Harnessing Genomics to Improve Health in India: An Executive Course to Support Genomics Policy," *Health Research Policy and Systems* 2, 1 (2004), http://www.health-policy-systems.com/content/2/1/1

For the individual, Biotechnology holds the promise of 'personalised medicine' and the likelihood of reduced costs.[29] 'Personalised medicine' envisages the prescription of therapies particularly suited to an individual based on their genetic make up. For me, the usage of this term in this context is a misnomer. It reduces the person to his/her genetic make up. For those of us trained at a different time, personalised medicine, meant treating the whole person, not the symptoms or the disease alone; understanding the individual as part of his/her interactions within a family/ community. Use of the term in its current sense usurps a more holistic use of the term and suggests a reframing of 'human identity' devoid of its rich interactions and dependencies beyond the self.

The use of Biotechnology for applications beyond therapies also raises ethical concerns. "Biotechnology offers exciting and promising prospects for healing the sick and relieving the suffering. But exactly because of their impressive powers to alter the workings of body and mind, the "dual uses" of the same technologies make them attractive also to people who are not sick but who would use them to look younger, perform better, feel happier, or become more "perfect."[30] The notion that human beings can somehow be perfect – freed from the 'bondage' of disease and infirmity of any kind is not new. As ten Have quotes in his paper, Marquis de Condorcet (1743-1794) had expounded this optimism over 200 years ago "…the perfectibility of the human being is in reality indefinite."[31] Even if individuals do not change their concept of 'perfection', the widespread use of genetics in medicine can result in a "new conceptualization of 'normality' based, rather than on a natural definition of a state of physical and mental wellbeing," to a "genetic connotation which includes the hidden predisposition to some health impairment."[32] Given the immediate priorities of sickness and ill-health of the poor, including in India, it is likely that those who seek this greater 'perfection' will be the wealthy, leading to a wider disparities and the creation of classes of 'haves' and 'have nots' with regard to biotechnological access. Thus,

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[29] T. Kievits, D. Niese, L. Tengbjerg Hansen, P. Collins, S. Le Gledic, A. Roediger, A. Heathfield, A. Hallersten, "Personalised Medicine: Status quo and Challenges," *EuropaBio*, http://www.europabio.org/sites/default/files/report/personalised_medicine_status_quo_and_challenges.pdf

[30] "Beyond Therapy."

[31] H.A. ten Have, "Genetic Advances Require Comprehensive Bioethical Debate."

[32] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights."

Benatar suggests that used unwisely, biotechnology may, like other forms of power benefit only a privileged minority.[33]

The ethical debate with regard to Biotechnology is too often, medicalised. The commodfication of body parts and indeed of individuals could well be partly a result of this.[34] The medical profession needs to adopt a broader outlook on its societal responsibilities and its responsibilities towards future generations. The emphasis on the ‘here and now’ needs to be weighed against consequences spread out in space and time. As McLean writes “Many indigenous peoples speak of responsibilities that extend to the next seven generations. There is moral wisdom for us in that approach.”[35] Doctors are often accused of playing God — reductionist ethical debates based solely on utilitarianism ignore other prevailing views, which see utilitarianism as being “too instrumental and hubristic.”[36]

McLean outlines 5 sets of questions to translate ethical reasoning into practice.[37]

1. What benefits and what harms can be predicted for biotech innovations in both the research and application phases, and which courses of action will result in the best consequences overall?

2. Who are the ethically relevant stakeholders, and what rights do they have? Which course of action protects those rights? Is human dignity respected?

3. Which option treats everyone the same unless there is an ethically justified reason to treat them differently?

4. Which course of action seeks the common good?

5. Which option best develops virtues? And which virtues, such as trust and compassion, might be particularly relevant to biotech development and human health?

Since Biotechnology and its application has given rise to divergent ethical views based on religion and culture, some have argued that a human rights and legal approach might be able to bridge divergent ethical positions. A human rights approach could, for instance, focus on a set of rights such as, 1. Human dignity, 2. Non-discrimination, 3.

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[33] S.R. Benatar, A.S. Daar, P.A. Singer, “Global Health Ethics,” 109.

[34] H.A. ten Have, “Genetic Advances Require Comprehensive Bioethical Debate.”

[35] M.R. McLean, “A Framework for Thinking Ethically about Biotechnology.”

[36] P. Crooks, “The New Eugenics?,” 137.

[37] M.R. McLean, “A Framework for Thinking Ethically about Biotechnology.”

Self determination, 4. Rights pertaining to the human body such as life, health etc., and economic and social rights including equitable benefit sharing.[38] While this approach certainly has a place in the discourse on the ethics of biotechnology, it has its limitations as Francioni points out: "for instance, in the absence of a consensus on when human life begins, a rights based approach would not be able to resolve divergent views on the dignity of the human embryo."[39]

International and National Legal Frameworks for the Use of Biotechnology

There have been several International Declarations that have set ethical and legal standards pertinent to the discussions of this paper. These include:

1. The Universal Declaration on the Human Genome and Human Rights (1997)
2. International Declaration on Genetic Data (2003)
3. Universal Declaration on Bioethics and Human Rights (2005)

The Universal Declaration on the Human Genome and Human Rights adopted on 11 November 1997 recognises among other things, that,[40]

- Research concerning the human genome, should not prevail over the respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people (Article 10).
- Practices which are contrary to human dignity, such as reproductive cloning of human beings shall not be permitted (Article 11)
- That benefits derived from scientific advances including those concerning the human genome "shall be made available to all" and the applications of research "shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole" (Article 12)

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[38] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights."

[39] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights."

[40] Universal Declaration on the Human Genome and Human Rights. http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html accessed Sept 2, 2013

Article 13 outlines the conditions for the exercise of scientific activity including the responsibilities of researchers: "meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their finding." Articles 14, 15 and 16 outline the responsibilities of States including freedom in the conduct of research with the caveat that they consider "the ethical, legal, social and economic implications of such research," ensure that research is not used for non-peaceful purposes and set up "independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications." Articles 17 and 18 call for cooperation between States to ensure benefits to all.

The International Declaration on Human Genetic Data (16 October 2003)[41] recognises the sensitive nature of genetic data:

> they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information, the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups.

Among the many articles of the Declaration,

- Article 3 cautions that "a person's identity should not be reduced to genetic characteristics."

- Article 6 focusses on the storage of genetic data: "It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures."

- Article 7 discusses the issue of Non-discrimination and non-stigmatization and states among its other recommendations that,

> Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.

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[41] The International Declaration on Human Genetic Data http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

The Universal Declaration on Bioethics and Human Rights (19 October 2005)[42] stems in part from "the rapid developments in science and technology, which increasingly affect our understanding of life, resulting in a strong demand for a global response to the ethical implications of such developments." While the focus of the declaration is broad, there are articles which have a specific bearing on ethics related to Biotechnology. For instance:

- Article 14 addresses the issue of Social Responsibility and Health including the social determinants of health such as poverty, nutrition, water, etc. It does, however, also refer to "access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good." This is relevant because as discussed elsewhere in this article the control of biotechnology in the hands of a minority of people, lends itself to increasing disparities, and increasing lack of health access.
- In consonance with the other declarations outlined earlier in this section, this declaration also emphasises that "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries" (Article 15).

Finally, Article 16 cautions against the application of ethics for the 'here and now': "The impact of life sciences on future generations, including on their genetic constitution, should be given due regard."

In India medical research including those involving products derived from the use of Biotechnology are governed by existing laws including Schedule Y of the Drugs and Cosmetics Rules, 1945[43] which is amended periodically. Broad ethical guidelines for the conduct of medical research are codified in the guidelines drawn up by the Indian Council of Medical Research.[44] With specific regard to Biotechnology, India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th day of June, 1992 and Cartagena Protocol on Biosafety to the Convention which came into force on the 11th September, 2003. More recently, The

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[42] Universal Declaration on Bioethics and Human Rights. http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

[43] http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf

[44] http://icmr.nic.in/ethical_guidelines.pdf

Biotechnology Regulatory Authority of India Bill, 2013 was introduced in the Lok Sabha of Indian Parliament on April 23, 2013 by the Minister for Science and Technology, Mr. S. Jaipal Reddy (Bill No 57 of 2013).[45] The Bill aims to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures. The Bill covers, among other things, human and veterinary products and industrial and environmental applications. The Bill envisages 'A Risk Assessment Unit' which will appraise applications for proposed research, transport or import of an organism or product, before final approval is granted and 'A Biotechnology Advisory Council' which will render strategic advice to the Authority regarding developments in modern biotechnology and their implications in India. While such a Bill is clearly a necessity, there has already been considerable criticism of the Bill — some argue that the substance of the Bill is promotion of Biotechnology rather than the regulation of it, that the Bill does not address the real needs and welfare of the people[46] and that it serves monopoly interests in the Biotechnology sector.[47]

While global frameworks are important, it is questionable to what extent these will be effective since, they are in the main, directive rather than legally enforceable. They seek to facilitate the development of law which can harden into more detailed and exacting standards.[48] In addition, global Declarations such as the Universal Declaration of Human Rights which could contribute to the development of some commonly held ethical principles are undermined by the non-compliance of oppressive regimes, the lack of ratification from certain powerful nations which see these instruments as counterproductive to their national interests, and a selective approach to those accused of abuses of human rights in international tribunals.[49] At a national level we need to combine

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[45] THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA BILL, 2013. http://www.prsindia.org/uploads/media/Biotech%20Regulatory/Biotechnology%20Regulatory%20Authority%20of%20India%20Bill.pdf

[46] Policy Brief for Parliamentarians. THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI) Bill 2013. A threat to our Food and Farming! Policy brief series: No. 19; 2013 June-August

[47] BRAI Bill, 2013 - India's Monsanto Promotion and Protection Act. http://www.greenpeace.org/india/Global/india/docs/BRAI-Monsanto-briefing.pdf

[48] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights," 8.

[49] S.R. Benatar, A.S. Daar, P.A. Singer, "Global Health Ethics," 117

regulations, laws and guidelines with a system of monitoring that will ensure compliance. We also need to engage in a wider debate with all divergent views in society — seeing Biotechnology as a scientific or medical issue, diminishes the debate.

Conclusion

It is difficult to discuss comprehensively the ethical issues related to such a rapidly and continually evolving field. However, it is clear that a sustained discourse on the subject is not merely desirable, but a necessity. The challenges are enormous but the implications of our decisions extend beyond us. Perhaps it is appropriate that in seeking to move forward, we take a step back and reflect:

> In wanting to become more than we are, and in sometimes acting as if we were already superhuman or divine, we risk despising what we are and neglecting what we have.
>
> In wanting to improve our bodies and our minds using new tools to enhance their performance, we risk making our bodies and minds little different from our tools, in the process also compromising the distinctly human character of our agency and activity.
>
> In seeking by these means to be better than we are or to like ourselves better than we do, we risk "turning into someone else," confounding the identity we have acquired through natural gift cultivated by genuinely lived experiences, alone and with others.
>
> In seeking brighter outlooks, reliable contentment, and dependable feelings of self-esteem in ways that by-pass their usual natural sources, we risk flattening our souls, lowering our aspirations, and weakening our loves and attachments.
>
> By lowering our sights and accepting the sorts of satisfactions that biotechnology may readily produce for us, we risk turning a blind eye to the objects of our natural loves and longings, the pursuit of which might be the truer road to a more genuine happiness.[50]

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[50] "Beyond Borders," 298.