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An Interpretation in the Indian Medico-legal and Bioethical Context

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Keywords

UDBHR; bioethics; Indian medico-legal scenario; autonomy and consent; pharmaceutical and reproductive ethics; de-stigmatisation; amendments of medical laws.

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I. Introduction

"Ethics and equity and principles of justice do not change with the calendar."

D. H. Lawrence

Of all the areas in applied and professional ethics, bioethics is the most diverse and it contains debates that are more often philosophically sophisticated. Many of the particular concerns of contemporary bioethics- such as abortion, prenatal diagnosis, cloning, informed

consent and voluntary euthanasia commonly raise deep issues of perennial importance, about when life begins, the value of parenthood, the notion of respect for others and what it means to be human. The Universal Declaration of Bioethics and Human Rights (UDBHR) came into existence as an instrument to guide the legal frameworks, health care providers and professionals to attempt to strike a balance between public health and human rights. The fact that law and morality rests on two different levels pose both as a question and a roadblock towards integrating health, human rights and bioethics under a common paradigm. The search for common rules for different communities in the field of bio-law is arduous. The governments of various countries have endeavoured to bring the bioethical guidelines into the practical realm of law, seeking exhaustive study of international documents like UDBHR and ongoing and emerging situations in the medical arena. UDBHR sets an example on how to embrace co-operation, responsibility and self-reflection and the principles enshrined in it seems to serve as a possible solution for most of the medico-legal and ethical problems that exist. But, there is absence of solid evidence to prove that its ideals are universal in nature. UDBHR also generated many controversies while it was being drafted. There is also widespread opinion that it fails to identify the dynamic nature of socio-economic inequalities, environmental resources and other factors that affect health and bioethics.

Among the poor and developing nations, India occupies an enviable position of possessing a health services system which has an extensive infrastructure, an army of trained personnel and well-equipped institutions for research and education. An overview of the system, however, reveals that despite its professed commitment to serve allespecially the poor- it is riddled with unevenness [1]. There is sharp inequality in terms of resource distribution, participation and proper practical knowledge in bioethics. Since India has no agency till date to track medico-legal cases and bioethical concerns, most of the events go unreported. India needs to take a leap to create a comprehensive legal framework to combat bioethical issues related to pharmaceutical scams, vagueness of informed consent, organ rackets, and non-protection of surrogate mothers and impersonal approach of doctors towards patients. Thus, the researcher modestly attempts to critically analyse the UDBHR, assess the reasons for its failure in implementation, and

identify ways to inculcate, most possibly through public policy, the universally acceptable principles in the Indian legal context in order to ameliorate factors that obstruct law and the society from embracing bioethical principles.

II. Literature Survey

A. Bioethics

Bioethics can be defined as the humanistic knowledge of scientific methodology to handle living organisms in an acceptable survival or a sustainable society within a healthy ecosystem or as a branch of ethics, philosophy and social commentary that discusses the life sciences and their potential impact on our society [2]. A widely used ethical framework for health care consists of four ethical principles: the principles of autonomy, privacy, beneficence and justice [3].

B. Bioethical issues

A significant factor in the emergence of bioethics as a discipline was the critique by many philosophers of paternalistic practices in medicine. This led to a new emphasis on the importance of patient autonomy in medical decision making [4]. Some of the earliest writing in bioethics focused on the ethics of abortion and questions of foetal and moral status of human embryos. Peter has famously argued that mere membership of the human species does not itself confer any special moral status [5]. But, Harris has surveyed a range of ethical objections to human cloning, and argues that the instinctive aversion which many feel towards reproductive cloning lacks any solid ethical foundation. He also argued that current prohibitions on human cloning restrict our interest in procreative autonomy without sufficient reason, and so may themselves violate human dignity [6]. Another topic is reproductive ethics. A recurrent concern in the literature of commercial surrogacy is that such arrangements exploit the surrogate mother. Wilkinson argues that there is good reason to believe a commercial surrogate mother is exploited by the commissioning couple, in the sense that they take unfair advantage of her [7]. Ethical issues about the end of life have been prominent. Because of developments in medical technology and disease control, patients can be kept alive longer and this has prompted

many health professionals and bioethicists to question whether this is always appropriate. Helga Kuhse criticises the claim, on which advocates of the sanctity of life doctrine heavily rely, that there is an asymmetry between killing a patient and letting them die because only the former involves the intentional cause of death [8]. Some bioethicists saw the prevalence of unjustifiable medical paternalism as symptomatic of the insularity of professional role-based ethical standards themselves, and so argued that doctors should reject a professionally generated ethic altogether and rely for guidance solely on broad-based ethical theories such as Kantianism or Utilitarianism [9]. Early discussions of research ethics focused on the importance of informed consent and international statements of the rights of researched subjects such as the Nuremberg Code and the Declaration of Helsinki. Even after clinical trials have shown drugs to be safe and effective, there are further ethical concerns that have been raised about the pharmaceutical industry [10].

C. Bioethics and Public Policy

The most practical side of bioethics is perhaps, its engagement with public policy. The development of democratic public policy on these issues of life and death, reproduction, genetics and biotechnology highlights the tensions between populist and deliberative conceptions of democracy. Populist approaches hold that the will of the majority serves as the appropriate reference point for law-making, because uneducated people are as capable of using their reason to judge what is right and wrong as are educated people [11].

D. The future of bioethics

Bioethics examines and challenges existing and likely future practices in health care, reproduction, genetics, biotechnology and biomedical research. At a broad level, there is a distinction emerging between bioethical issues facing current health professionals and bioethical issues involving future applications of various biotechnologies, some of which remain fairly speculative. There will continue to be ethical debates about more familiar issues in clinical practice along with discussions about the pros and cons of moves towards greater transparency and issues involving stem cell research, embryo selection

decisions in pre-implantation genetic diagnosis and so on. Whichever directions eventuate, bioethics has now become an established field of enquiry and clearly has an exciting future ahead [12].

III. Reading the UDBHR

A. Background of Global Bioethics

The term "bioethics" was coined in 1926 by Fritz Jahr in an article about a "bioethical imperative" regarding the use of animals and plants in scientific research. In 1970, the American Biochemist Van Rensselaer Potter used the term to describe the relation between the biosphere and a growing human population. The scientific advancements of the last few decades have opened up doors in many different fields like reproduction, organ transplants, sexuality, surrogacy etc. This has had a significant social consequence: facts have turned into choices. Human beings are now left with the option of choosing life and death. The scientists are even waging a war against human aging. Millions of venture capital dollars are being dumped into longevity research and there are ongoing debates about the 'Right to life v. Right to die'. In such a situation, we can essentially apprehend the intrusions into right to privacy and dignity of an individual. Law has not been able to keep up the pace with science. The international conscience demanded universal ethical rules after the disastrous events of human experimentation during World War II without consent, resulting in death, permanent impairment, trauma and disfigurement of the subjects. Subsequently, Nuremberg Code, Helsinki Declaration and UDHR came into existence to ensure that the worst past doesn't repeat. In Newcrest Mining (WA) Ltd v. The Commonwealth [(1997) 190 CLR 513], it was held that; "The central ideas of the UDHR were incontestably influential in the subsequent development of the United Nations treaty law; the emergence of customary international law; and the incorporation of variations on the UDHR language in national constitutions, legislations and common law." UN continued to strive towards upholding international humanitarian law on many fronts and the chief of it has been the United Nations Economic, Scientific and Cultural Organisation (UNESCO). It is the think tank of the UN. Initially, the discussions on any international standards related to bioethics primarily focused on health care issues. But, the advent of

biotechnology, had presented the UNESCO with the opportunity to delve deeper into the Bioethical concerns. To fulfil the perceived responsibilities of UNESCO in the field of bioethics, an International Bioethics Committee (IBC) was formed in 1993 and it was asked to examine the bioethical questions of international concern. The Universal Declaration on the Human Genome and Human Rights was adopted unanimously at UNESCO's 29th General Conference on 11 November, 1997. The Intergovernmental Bioethics Committee (IGBC) was created in 1998, under Article 11 of the Statutes of the IBC. The International Declaration on Human Genetic Data was adopted in 2003. At the 32nd session, the General Conference considered that it was opportune and desirable to set universal standards in the field of bioethics and invited the Director-General to continue preparatory work on a declaration on universal norms on bioethics, by holding consultation with member states, the other international organisations concerned and relevant national bodies and to submit a draft declaration at its 33rd session. The drafting of the text took place between April 2004 and January 2005. On October 19, 2005, at the UNESCO General Conference, the member states by resolution adopted the Universal Declaration on Bioethics and Human Rights (UDBHR) unanimously.

B. What does the UDBHR promise?

UNESCO's UDBHR has laudable goals in its ambit. It is the first document to set global standards in biological and medical ethics. UDBHR respects human dignity, human rights and fundamental freedoms (Article 3). The word "dignity" comes to us, via the Latin dignus and dignitas, from Greek and Roman antiquity, in whose literature it means something like "worthiness for honour esteem." Human dignity forms the basis of human rights in the 1948 UDHR as it is considered central to human identity. Thus, human dignity is the recognition that human beings possess a special value intrinsic to their humanity and as such are worthy of respect simply because they are human beings. While the prior documents only accorded respect to autonomous persons, the UDBHR considered and inculcated the plight of all those who could not exercise autonomy. After covering the existing persons, UDBHR moved forward and embraced the respect and dignity for future persons, in the era of genetics and assisted

reproduction. Integrating the human rights framework into bioethics is meaningful because most basic human prerogatives are relevant to biomedical activities, for instance the rights to life, physical integrity, privacy and access to basic health care [13]. The UDBHR has tried to cover the basic fundamental freedoms and rights that are desirable to all human beings- all persons must be treated with due respect (Article 3, 5, 8 and 9), be treated justly and equitably (Article 10), to enjoy the highest attainable standard of health (Article 14) and not to be subjected to discrimination and stigmatisation (Article 11). UDBHR also includes considerations about the environment, biosphere and other living beings (Article 17) because of the fact that it is no longer possible to advance science and technology without reflecting on the impact of our actions on our environment and other living beings. Thus, by focusing on common principles and shared values, the UDBHR has established global standards that could be used by both developing and developed countries. UNESCO understands that not all of its member states have adequate infrastructure to uphold bioethical values and therefore, sets benchmarks which are universal in nature to address such gaps.

C. The polarisation of promises and results: a critical view

There has been several criticism and controversies regarding the draft process and sharp conflicts in terms of opinions about the contents have made the world wonder if the UDBHR really would achieve its primary intended objectives. The researcher does not go into the problems of process as I understand that the declaration was unanimously adopted in 2005 at the general conference. The focus is on rooting out the differences in promises and results. The main obstruction is the usage of abstract language throughout the declaration. In order to set forth universal guidelines for the member states whose resources vary, simple language should have been used as in UDHR. The UDBHR lacks conceptual clarity, for what is implicit in abstract language? Abstract terms and clauses will be spoilt over by numerous interpretations and subsequent conflicts will question the synchronicity of principles and objectives. Bioethicists and scholars have rightly pointed out some examples- Can the statement on the freedom of scientific research and the need to respect human dignity be read apart from recent debates on stem cell research?, Can the

injunctions on human solidarity in Article 13 or the statement on protecting the environment or Article 29 on the assessment and management of risk be read apart from the vast inequities of wealth and power? These doubts will certainly shed light on the conceptual errors wherein the UNESCO and the IBC specifically failed to consider the social, economic and cultural disparities among its member States. How can we formulate universal principles by ignoring the context in which they are going to be applied? How can one call such principles universal if it lacks universal applicability? So, there has been a serious mistake of presuming universality disregarding the structural inequalities. Unfortunately, the Bioethics Declaration simply relies on concepts of universality, rights, persons, and equality that derive from the logic of fraternity and Enlightenment philosophies of man's common sense. As feminist philosophers have demonstrated, these concepts are not innocent and inevitably reflect a certain history of power [14]. Rawlinson and Donchin rightly opines that the formidable task of articulating 'universal principles' requires a critical recognition of the implication of Enlightenment concepts of persons, rights and equality in the hegemony of particular racial, cultural, and sexual identities [15]. The interests of the individual should have been placed higher to societal interests. The reality of human rights and bioethics being placed on different levels cannot be ignored either. Richard Ashcroft, Head of the Medical Ethics Unit at Imperial College, comments, "Human rights statements are positive declarations of what is obligatory, whereas bioethics documents are frequently exploratory or speculative in nature, arguing about what may or may not be permissible or necessary." To be frank, the expectations of the international community about bioethical guidelines were not met. Already, being a declaration, having no legal binding in terms of legal status, UDBHR will not prevent any ethical lapses from being committed. So, it would have been better if brisk, yet powerful language was used to write down the declaration. The guidelines should have been such that it will influence the governments to incorporate them in their policies, by making them realise the dire need for bioethics. But, it also does not mean that UDBHR has no scope of applicability through public policy. The scope of implementing the guidelines in the Indian context will be discussed in coming sections. The researcher very well accepts the truth that declarations cannot

cover all possibilities. UDBHR has however succeeded to call attention of the countries to bioethics. It may lack rigour and accuracy, but the principles pave way for the States to formulate public policies and programmes related to bioethics. Hence, the Bioethics Declaration remains an important advance for the international community.

IV. Bird's eye view of the Indian medico-legal and bioethical scenario

A. The Constitutional framework of medical law and bioethics

In a developing society as in India, steeped in unbridgeable and ever widening gaps of inequality in status and opportunity, law is catalyst and rubicon to the poor to reach the ladder of social justice. The Constitution of India which was adopted by the Constituent Assembly on 26th November, 1949, came into force on 26th January, 1950. It is the longest and most detailed Constitution in the world. Even though health as a sector does not appear in many places of the Indian Constitution, there are indirect and tacit references to health of people and the role of State. As held in Paramanand Katara v. Union of India (AIR 1989 SC 2039), "the human life is more valuable and it must be preserved at all costs and members of the medical profession are ethically bound to provide necessary medical care to the patients. There can be no second opinion that preservation of human life is of paramount importance. This is so on account of the fact that once the life is lost, the status quo ante cannot be restored as resurrection is beyond the capacity of man". In India, the right to health care and protection has been recognised since early times. India is a founder member of the United Nations and has ratified various International Conventions promising to secure health care rights of individuals in the society. Part III of the Indian Constitution guarantees fundamental rights to persons against the State. The preamble to the Constitution of India, which strives to provide for a welfare state with socialistic patterns of society under Article 21, guarantees the right to life and personal liberty. It states that: "No one shall be deprived of his right to life and personal liberty except according to the procedure established by law."

Because of the vibrant interpretation given by the Apex Court to Article 21, it has become the thrust and throb of the Constitution itself.

It is a well accepted fact that the foundation of bioethics is the protection of human dignity. The framers of the Constitution were well aware of the concept of dignity and they incorporated the term in the preamble. According to Kelsen's pure law theory, the Constitution is the basic norm. He was aware that in some legal orders, it can be difficult to draw a line between constitutional and other norms. So, in 1964, he relativised the idea of "Constitution", holding that each relatively higher legal norm is a 'constitution' in relation to any norm created under its authority. The Constitution of India takes care of every section of the society. The liberal approach of the Apex Court in the interpretation of Constitution has resulted in derivation of various rights from Article 21, the most important of which is the right to live with human dignity. In Kharak Singh v. State of Uttar Pradesh (AIR 1963 SC 1295), the Supreme Court held that, "By the term 'life', is meant more than mere animal existence and the inhibition against its deprivation extend to all those limbs and faculties by which life is enioved."

Article 14 ensures that there can be no valid law which arbitrarily denies to persons the right to health. Article 38(1) lays down the basis for human rights. It summarises that in order to secure socio-economic justice to the people and to promote their welfare, the State is under a constitutional duty to take effective steps to provide proper health care and to ensure a life of dignity to them. Article 39 enumerates that the State shall, in particular, direct its policy towards securing, inter alia, that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength and that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity. Article 43 enjoins upon the State to make endeavour to ensure a decent standard of life and full enjoyment of leisure and social and cultural opportunities. Article 47 places responsibility on the State to raise the standard of living of its people and improvement of public health by ensuring proper health care and health facilities as among its primary duties. Article 48-A further provides that the "State shall endeavour to protect and improve the environment and to safeguard the forests and wildlife of the country."

Thus, it is evident that the right to public health is considered at the top of Indian Constitutional agenda and the State is duty bound to ensure it to all in all circumstances. The Apex court has beautifully explained this aspect of Constitution in *State of HP* v. *Umed Ram Sharma* (AIR 1986 SC 847), wherein it held; "the jurisprudence of personhood or philosophy of the right to life envisaged under Article 21, enlarges its sweep to encompass human personality to its full blossom with invigorated health. Thus, the right to life with human dignity covers within its fold, some of the finer facets of human civilisation which makes life worth living. It includes the quality of life as understood in its richness and fullness by the ambit of the Constitution."

B. Human rights and Bioethics in India

The United Nations has explained that "the denial of human rights and fundamental freedoms not only is an individual and personal tragedy, but also creates conditions of social and political unrest, sowing the seeds of violence and conflict within and between societies and nations." The concept of human rights, to the core embraces certain universe of values significant to the protection of human dignity which apply beyond the national borders and the cultural divides [16]. Locke opined that man is born with a title to perfect freedom and an uncontrolled enjoyment of all the rights and privileges of the Law of Nature and by nature he has the power to preserve his property-life, liberty, and estate, against the injuries and attempts of other men. The United Nations since 1945 has tried to secure the promotion and protection of the Human Rights [17]. The International Bill of Human Rights consists of the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, and the International Covenant on Civil and Political Rights and its two Optional Protocols.

Article 12-35 of the Indian Constitution ensures various human rights guaranteed by the UDHR in its most sacrosanct manner. Though there is no explicit implication to the declaration in any of the provisions is the Constitution, yet the Supreme Court now follows an approach to evaluate fundamental rights in the light of UDHR. In Chairman, Railway Board v. Chandrima Das (AIR 2000 SC 988), the Apex Court had made reference to the provisions of the International Bill of Rights and observed that "the applicability of the universal declaration

of human rights and the principles thereof may have to be read, if need be, into the domestic jurisprudence." Section 2(d) of the Protection of Human Rights Act, 1993 has defined the human rights "to mean the rights relating to life, liberty, equality and dignity of the individual guaranteed by the Constitution or embodies in the International Covenants and enforceable by Courts in India." Thus, the judiciary applies all such international instruments to uphold the human values and rights. Now, the prime focus is on strengthening the legal mechanism in consonance with the international standards.

Unlike in the West, where the medical professional emerged largely as a part of an entrepreneurial profession, which was only later brought into a nationalised service, in India, modern medicine was "built up" by both the colonial and the independent Indian State as the vehicle of modernity and welfare. Considering the recent advances in life-sciences, bioethics has many roles to play, namely, to raise the questions about non-ethical practices among health care institutions, to compete with the new bioethical problems and to challenge the public health issues and the deliverance of health care facilities among economically underdeveloped parts of the world [18]. The Indian Council for Medical Research (ICMR) formulates, coordinates and promotes biomedical research in India. In 1980, they formulated the first national ethical guidelines. They also have designed curriculum for implementing bioethics in medical schools. The ethical principles that guide bio-research in India are essentiality, voluntariness, nonexploitation, privacy and confidentiality, precaution and risk professional competence, minimization. accountability transparency, maximisation of the public interest, totality of responsibility and compliance [19]. A number of laws have been enacted to protect the health interests of the people including the Fatal Accidents Act, 1855, the Indian Medical Degrees Act, 1916, Dangerous Drugs Act, 1930, Drugs and Cosmetics Act, 1940, Pharmacy Council of India Regulations 1952, the Indian Medical Council Rules 1957, the Medical Termination of Pregnancy Act, 1975, the Dentist Code of Ethics and Regulations 1976, Narcotic Drugs and Psychotropic Substances Act and Rules, 1985, The Pre-Natal Diagnostics Techniques Act, 1994, the Transplantation of Human Organs and Tissues Act(THOTA), 1994 etc. Moreover, the ICMR publishes ethical guidelines for the health providers and medical professionals

periodically. Further, there are various NGOs working towards unearthing pharmaceutical scams, protesting against unethical practices of medical professionals in clinical medicine and trial and demanding IPRs for tribal and rural people who have protected various medicinal herbs and plants, which are continuously being tried to be stolen and experimented upon, without their permission.

C. Bioethical issues in India that demand urgent attention

It is well known that bioethics evolved in the West as a result of a series of scandals and public outcry over the misuse of authority and control by the medical profession. There are several bioethical concerns in India, and if each of it has to be gone through in depth, it will necessitate writing of separate and elaborate research papers. Considering the constraints, the researcher focuses on prime bioethical issues that demand immediate attention, unless which the public health care system in India may collapse in few years.

• The forgotten 'Informed Consent' in clinical trials: In any field affecting man, research is necessary as it provides data to improve the health of human beings and this appreciable objective demands encouragement and motivation at all levels of participation. "Informed consent" is a concept that is required at clinical trials as well as treatment of individuals. Informed consent implies that a person from whom consent is sought should have adequate reasoning ability, a clear understanding of the facts, a good idea of the choices available, an appreciation of the implications and comprehension of the consequences, and he/she should be able to voluntarily choose a particular option. Despite significant economic advances and strides in education, India still remains a feudal society with a great differential in power between doctors and patients. Informed consent is just looked upon as a necessary burden of legal documentation procedure and its ethical side is ignored. Further, human experimentation in India is seen to take place without the "informed" consent of individuals and big pharmaceuticals test their drugs on rural patients who are mostly illiterate and untaught about the basic medicines given to them for even common illness. As reported on 25th April, 2013, the Central government informed the Supreme Court of India that as many as

2644 people, called subjects, died during the clinical trials of 475 new drugs on human beings in the period of 2005-2012 (7 years) and only 17 of the medicines were approved for marketing in India. Clinical trials of two drugs- Bayer's Rivaroxaban and Novartis's Aliskiren vs. Enalapril- accounted for maximum number of deaths [20]. The former was first used for human trials in 2008 resulting in death of 21 of which it claimed that only five were related to clinical trial but it has till paid compensation to kin of only two. Two years later, the same drug was again put on human trial and this time 125 deaths were reported.

• Is there patient or subject Autonomy? Laws overriding the decisions in surrogacy and organ transplants: The age-old paternalistic model in clinical medicine has changed into a contractual relationship between physician and patient. The established philosophical tradition argued that knowledge is always good in itself and that ignorance deprives people of their choice and consequently, their autonomy. Western philosophy and individualistic societies set great store by personal autonomy. They often assign less value to health than to autonomy. On the other hand, many in India tend to value health more than personal autonomy [21]. One disease which captured the attention of the medical professionals all over the world in early 1900s and throughout the first half of the 20th century was solid organ failure. With the advent of advanced medical technology in transplant procedures, an end stage organ failure patient got a ray of hope to lead a healthy and prolonged life by undergoing organ transplant. With the revolutionary changes brought about in social, political and scientific fields of human activity, human organ transplant as a curative medical technique gained public acceptance in India too. While the technology expanded possibilities of organ transplants, the number of organ donors does not increase correspondingly and this gap in demand and supply of transplantable organs results in illegal trade in organs. To make the regulation of organ transplant procedure with all the incidental paraphernalia meaningfully effective, periodic amendments have been made to the THOTA, 1994. We know that we all have a duty to act at all times in the best interests of human kind. This includes respecting the autonomous choices made by persons regarding the treatment of their body after their death. Autonomy is a kind of deliberated

self-rule which makes us to act according to our own wishes on the basis of informed choices, thought and decision, freely and independently [22] (p. 158). THOTA 1994 provides that a person can make a wish to donate his organs/tissues or can also register his objection for such donation after his death. As per the Act, even if the deceased had consented to donation of organs during his life-time, the wishes of his near ones are given priority over the deceased's wishes and organ retrieval cannot be done without the consent of the near relatives. In such a situation, autonomy of the deceased is not respected. In India, religious beliefs generally discourage practices such as stockpiling and collecting organs from cadavers [23]. Though all religions permit donation, people still are unwilling to donate organs. Reproductive tourism, an important subset of the medical tourism industry, has become a USD 500 million industry in India [24]. In light of the booming and unregulated nature of the surrogacy business, its ethical aspects need to be evaluated. The Western Liberal feminist perspective of considering surrogacy as an exercise of reproductive choice and of women's economic autonomy do not apply to Indian Surrogates, owing to the socio-economic realities which determine their choice. In India, surrogates mostly come from poor families whose husbands might have died or absconded. Further, the female literacy rate in India is also low. The principle of "Equal pay for equal work" has not yet been entirely established in the country and the economic prospects of surrogacy push them to this business. But, it is pertinent to note that commercial surrogacy is culturally stigmatized by the conservative Indian attitude towards sex and procreation. Surrogate mothers are usually thrown out of their homes and communities. In such a scenario, the existence of voluntary choice or autonomy on the part of these women is contentious. It is debatable whether women are choosing freely to become surrogates, or that their will is socially and economically constructed [25]. A conspicuous paradox manifests itself when one compares reproductive rights and reproductive health facilities available to a common woman in India when compared to a woman who has volunteered to be a surrogate. The World Health Organisation (WHO) gives a

working definition of the term sexual and reproductive rights as the "highest attainable standard of sexual health, including access to sexual and reproductive health care services." UNICEF has observed that due to social and economic inequalities and shortages in primary health facilities, India's fight to lower maternal mortality rates is failing. For every maternal death in India, an estimated 30 more women suffer injury, infection and pregnancy-related disabilities [26]. In Jaitun v. Maternity Home, MCD, Jangpura & Ors (W.P. No. 10700/2009), the Delhi High Court emphasized that there has been a complete failure of public health care system and a failure in implementation of government schemes designed to reduce maternal and neonatal mortality by encouraging institutional delivery for poor pregnant women. Medical services are denied to poor women because they are unable to demonstrate their BPL Status for medical services. The Court observed that the Indian government should be facilitating their access to these essential services and therefore, it is stressed that 'no woman, more so a pregnant woman, should be denied the facility of treatment at any stage irrespective of her social and economic background.' The judiciary is sensitive to the plight of the poor and destitute pregnant women, but the implementation at the ground level is lacking as highlighted by the courts themselves.

• Absence of adherence to Pharmaceutical ethics: Another alarming bioethical issue is- 'Ethical violations by the Pharmaceutical industry in India'. According to the World Health Organisation (WHO), 35 percent of the fake drugs sold all over the world comes from India and it occupies the counterfeit drug market of nearly Rs. 4,000 crore and 20 percent of drugs sold in India are fake. Subsequent to a research study by the National Institute of Biologicals (NIB) conducted during 2014-2016; it was revealed that more drugs of poor standards were found in government hospitals as compared to the pharmacies of the market and most of such fake drugs are made in extremely polluted atmosphere [27]. The Standards created by the Pharmacy Council of India are regularly violated. It is saddening that the Government hospitals which are the only resort of the Indian poor to access health care fails to provide the common masses with reliable and authentic drugs. In a shocking disclosure, some drugs companies were

caught red-handed writing scientific recommendations of their own products and submitting them to the Drug Controller General of India (DCGI) after getting them endorsed by top doctors for a quicker marketing approval. Usually, scientific recommendations are submitted by experts after they have studied a drug's content [28].

V. Significance of the study: the dire need to analyse the situation

Law and medicine join a common pilgrimage towards all pervasive welfare of human life. Because bioethics and law are so strongly connected, even a bare reading of the UDBHR requires basic understanding of law. There have been so many discussions and criticism against the draft process and contents of the UDBHR, but its relevance cannot be overlooked. It has set global benchmarks for all and it is for the countries to adopt the principles into the domestic law and customise it as per their legal and ethical conditions. UDBHR has undoubtedly broadened the scope of bioethics. India is a developing country and it has been a laboratory of various landmark legal and jurisprudential experiments. It has got almost all of the bioethical issues covered under separate laws. But, the recent development of civil society and widespread awareness regarding the medico-legal and bioethical problems has unearthed several scams, corruption, blatant violations of ethics and laws. There is an asymmetry in the existence and implementation of laws. India has sufficient space to incorporate the universal principles of bioethics in its public policy. Thus, this paper gains importance considering the fact that the principles laid down by the UDBHR if correctly revised and modified and applied in the Indian context can create wonderful and enviable results.

VI. Data collection and methodology

The current study is descriptive and analytical in nature. The researcher has made use of both primary and secondary resources. The study is a unique combination of empirical, non-doctrinal mode of research based on field work by way of personal interviews of the bioethicists, legal experts and health care professionals as well as secondary source based analysis of Indian medico-legal context, the existing and emerging

bioethical concerns and the interpretation of the UDBHR. To make this work original and authentic, attempts were made to gather views of eminent legal experts regarding the scope of applicability of the UDBHR through public policy in India. Sincere efforts have been made to collect secondary data in the form of medical and law journals, resource books, research studies, ICMR Guidelines and independent media reports.

VII. Delimitations and limitations of the study

By delimitations and limitations, the intention is to bring out those characteristics that limit the scope, i.e. to define the boundaries of the enquiry as determined at the time of conscious exclusionary and inclusionary decisions that were made throughout the development of its proposal and execution. The first limiting step was the choice of the problem itself; while formulating the proposal basic focus; many aspects were thought of like collecting data from patients of different hospitals and research centres and documenting separate testimonies. Implicit are the problems that could have been chosen, but were screened off from practical bound feasibility point of view.

Lack of prior research studies on the scope of application of UDBHR in India was another limitation. In fact this is the first time a research is being done on interpreting UDBHR in the Indian context. In fact, this limitation has always been the motivational factor to explore the unexplored area. Absence of an agency to track medicolegal and bioethical issues in India posed another roadblock to extract out the real position of medical laws and their implementation. Smaller sample size is a usually a limitation, but not in this kind of qualitative research.

VIII. Findings: scope of applicability of UDBHR in Indian context

A. Is the UDBHR applicable to India?

As far as India is concerned, there is no contradiction between the individual and the social good and natural rights and development. India recognised that there are certain unalienable rights that are inherent to the concept of the dignity of man. India firmly believes that

a country's overall performance and its resolve to translate into reality the enjoyment of rights by its people is of paramount importance [29] (p. 34). The Bioethics Declaration provides legal and political guidelines which proposes to have universal applicability. The plural perspectives and multidisciplinary approach of the integrative bioethics construct a perfect methodological framework for a theoretical justification and an in-depth explication of the most important and the subtlest recommendations of the declaration. Although, the UDBHR technically has no legal authority, it is not unusual for such statements to become incorporated in national legislation and court rulings. There are 3 broad reasons why UDBHR becomes applicable to the Indian legal context. Firstly, India is an active member of the UNESCO and any declarations, treaties or resolutions passed by it shall become binding on India. Further, India also has an international responsibility to follow bioethical guidelines, considering its scientific advancements moving ahead in the quickness of light years. Secondly, India is a founder member of the United Nations, and has ratified various International conventions promising to secure health care rights of individuals. The UN adopts large number of declarations, resolutions and other statements that are not treaties; they do not have parties to them, they are not ratified and their legal effect is less certain. However, as they are products of the UN system, they are considered to be highly influential and there is an argument that compliance is a necessary consequence of membership of the UN. In this context, Article 51 of the Indian Constitution needs to be looked at. Article 51 states that the "State shall endeavour (a) to promote international peace and security, (b) maintain just and honourable relations between nations, (c) foster respect for the international law and treaty obligations in the dealings of organised people with one another and (d) encourage settlement of international disputes by arbitration." Thirdly, Section 2(d) of the Protection of Human Rights Act, 1993 recognises that the human rights include the rights relating to life, liberty, equality and dignity of the individual guaranteed by the Constitution or embodies in the International Covenants and enforceable by courts in India. Thus, India has no bar from adopting the guidelines put forth by the UDBHR and in fact, must take the responsibility to implement it in the domestic law.

B. Translating the UDBHR into public policy: the tug of war between law and morality

Ethics has claimed a right to criticise legal arrangements and recommend changes to them. Many debates about law, when they are not merely debates about how legal precedent mechanically applies in a particular situation, are also ethical debates. The work of ethicists is in many ways both oriented towards the law and influenced by law. Conversely, many legal concepts like the right to privacy, dominate moral discussions. The perceptions of ethics (moral philosophy) vary from a society to another. The relationship between bioethics and public policy has become a rather broad subject that asks a rather simple question; namely, which moral imperatives that arise out of the study and consideration of bioethical issues should be reflected in public policies that govern us all. Being social animals, it is unavoidable for us to establish rules of conduct that are thought to serve the collective interests of individuals. These rules must, however, be constantly reviewed and perhaps revised and updated. As Jhering rightly opines, "The relation of law to morals is the cape horn of jurisprudence. The juristic navigator who would overcome its perils ran no little risk of fatal shipwreck." In a given community at a specific time, there is a continuous interaction among the various types of norms signified by the terms law, morals and ethics. Members of a community are in a position to change the relationship between law and ethics. These norms are not clearly distinguishable from each other. None of the regimes can maintain a complete normative monopoly [30]. Despite the enormous achievements made in science and technology, this century has produced a very high level of apprehension about the future unlike the past ones. It is true that science has given us a gigantic set of opportunities, but, it also has raised the levels of moral responsibility that falls on our shoulders. The same phenomenon demanded the set of bioethical guidelines for the Countries to adopt and follow.

The best and optimal way to achieve the feats of bioethics in any country is to implement the principles through the public policy. The overall impact of public policy on the shape and scope of the scientific agenda has become so widespread that, we barely notice it in special sense. Public policy influences science through the problems it deems worth solving, the methods it finds acceptable and the resources it

makes available for the task. The Bioethics Declaration gives us abstract concepts which are for the respective States to interpret, break down into understandable chunks of rules and draft public policies in accordance to them. It is a strenuous, yet worthy process. In India, most of the bioethical issues arise due to the patriarchal set up of the society and the religious influences on an individual's decisions. It can be seen in instances of people denying becoming organ donors, stigmas on surrogate mothers etc. We are in a chaos wherein we do not know how to place morality and law on the same levels. Law seems to be compulsive, so the only alternative is to inculcate updated moral concepts into the grass root levels of society, which public policy alone can do. Thus, one of the greatest responsibilities placed on us is to consider the social and human repercussions of our rapidly accumulating new knowledge and the appropriate stance of public policies with respect to these matters. Indeed, the more dependent we become on new science and technology, the more essential it is to generate renaissance after renaissance in moral philosophy.

C. Solutions for bioethical issues in India

In our own time, of course, we must both celebrate and contend with the fact that science and technology are advancing at a rapid pace. We may see the science undermining our faith in existing arrangements. India is in such a situation. Organ transplants, surrogacy, and global pharmaceutical companies coming into India has changed the medical field and further raised several complex questions in the context of ethics and absence of proper laws. This is a serious issue. But, UDBHR sets forth certain principles that serve as the best solution to most of these bioethical concerns worrying the Indian State.

The principles of autonomy and informed consent: Paternalism cannot be considered as morally wrong in entirety. But, if certain acts attempt to maximise welfare by disregarding autonomy, it will be wrong. The concept of consent arises from the ethical principle of patient autonomy. Under the THOTA, 1994, the provision of free will of the deceased is nothing but a misnomer because in spite of his opting for the organ donation, his wish becomes secondary to the wishes of his family. Despite the open declaration of his consent and wish to donate organs after his death, it is the approval of family which is needed for such a donation. The ethical and religious constraints also pose a

challenge. The grief-stricken family opposes organ donation as they apprehend that the corpse may be mutilated. Again, surrogacy contracts pose a sufficiently great number of risks to personal autonomy to justify their impermissibility like surrogate's loss of control over her body and daily activities during pregnancy. Non-protection of surrogate mothers is a big issue. Currently, there is no specific legislation to deal with surrogacy and India relies on rules and guidelines issued by ICMR. The Surrogacy (Regulation) Bill of 2016 has reinforced the legendary constitutional historian Sir Ivor Jennings' comment: "The truth is that the rule of law is apt to be rather an unruly horse...if analysis is attempted, it is found that the ideas includes notions which are essentially imprecise [31]. Also, there are several flaws in the bill like anti-liberal and unscientific regulation, exclusion of live-in couples and homosexuals, banning of commercial surrogacy, and camouflaged regulatory designs. Thus, the organ transplants and surrogacy are being discouraged by the State itself, which is a bad socio-medical indicator. Other bioethical issues like researches done on human subjects and clinical treatments shed light on the complex questions of informed consent. There is inadequacy in human subject protection in India. The State also has failed to impart shared decision making, i.e. to direct the doctors to decide the extent of information to be conveyed only after carefully assessing the individual's beliefs and choices. Most of the doctors see informed consent's legal aspects alone. Thus, the challenge is to change the prevailing culture within medicine and health care. Article 5 of the UDBHR considers the importance of autonomy and individual responsibility and also covers the persons who are unable to exercise autonomy. Article 6 specifically elaborates the ethical and legal aspects of consent. Both these articles serve as the yardstick to measure and evaluate the Indian laws in the topics of informed consent and autonomy. They also enable the State to draft and amend the laws accordingly adhering to bioethical principles.

• Weighing the aspects of benefit and harm. Preventing harm is present in the Hippocratic Oath. So, issues regarding the minimising of possible harm and maximising of potential benefits to patients is not of recent origin. India has a well-established pharmaceuticals industry, but its ethical aspects give us a jerk. Since last century, there has been a rise of human experimentation in Asia, and specifically in India. There has been widespread abuse and

exploitation of the subjects, and causing harm and even death as a result of adverse drug reactions for which no compensation is usually paid. It is thus opined that the local populations are used as guinea pigs with double standards in operation [32]. Inspections into the laboratories are unorganised and fragmented. Severe violations are reported ranging from low hygiene to inadequate control systems to store data. Despite elaborate rules regarding acceptance of a new drug, they are very easily violated and remain unquestioned. There is an imbalance between benefits and harm. Article 4 of the UDBHR needs to be followed not only in ethical paradigm, but also in legislations and their implementation. Only then shall the utilitarian ethics of maximising benefits and minimising harm be achieved.

• Social responsibility of the State to promote health: Reproductive rights: The Indian medical tourism industry promotes itself by the slogan, "First world treatment at Third world price." However, the health care provided to India's poor continues to be of third world standards. The last few decades witnessed policy makers preoccupying with pregnancy and contraception-related services and failing to recognise and address the fundamental problems. Recently, WHO published some disturbing facts about the state of pregnant women in India; it revealed that at least one woman every five minutes, dies during pregnancy and child birth and this can be attributed to the absence of proper emergency obstetric care, missing trained mid-wives, lack of management capacity in health system, and lack of comprehensive maternal care services [33]. Unethical nature of trials of contraceptives on women is also frequently reported. Reproductive rights are the fundamental rights of every woman. Article 14 of the UDBHR provides the best guideline for India to ensure reproductive health of women, wherein it holds that the Governments should advance 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. India should abide by that principle in order to regulate reproduction-related issues and ensure healthy environment and adequate resources to pregnant women.

• De-stigmatisation: Article 11 of the UDBHR states, "No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms." Globalisation and changes in the forms of governments in various countries have resulted in unfamiliar and unappreciable phenomena, such as homophobia, xenophobia, ethno-centrism etc. The health sector also subsequently suffered from inhumane and impersonal approaches of professionals, researchers towards their patients and subjects respectively. India is not free from stigma and discrimination. Stigma prevails when one is made to feel inferior to another and considered to be below other fellow beings. Dignity is an intrinsic human quality and thus, cannot be alienated. So, stigma in broader sense is the slaughter of human dignity. This interpretation stems from Kantian philosophy, according to which respecting the dignity of others is not making it just a means; all rational beings are subject to the law that each of them should treat him/herself, and treat everyone else, never as a mere means, but always at the same time as an end in itself. Kant opines that this is not just a relative value or a price, but rather an internal value that is, dignity [34]. When a woman does not have the right to bodily integrity in reality, when her body is invaded against her will, when her choices are judged by the prejudiced society, it is unlikely that she can play an active role in decision making. Commercial surrogacy has been attacked in many ways like harm to surrogates, their children; the commoditisation of surrogates and women in general; and the exploitation of women, especially those who are poor or vulnerable in some other way [35]. Further, a survey conducted in 2012 by the Delhi Women's group, Sama revealed that Indian couples were prepared to pay more for a light-skinned surrogate from the right caste [36]. The practice of surrogacy is rising among the Indians, but many of the communities still consider it unacceptable. Studies of surrogate mothers have reported that they are often stigmatized because surrogacy is widely believed to involve sexual intercourse [37]. Further, stigma also exists in the context of organ donations. In India, the consent of nearest relative is required for a hospital to obtain organs from a body and it is a major roadblock as relatives are often uncomfortable about organs being harvested [38]. All these issues can be put to an end if the Principle of Non-discrimination and Non-stigmatization is weaved in through the laws and programmes in India. It will ensure that surrogates and organ donors are protected from societal ostracisation. The State and the civil society can initiate national-level awareness drives about the myths and realities of organ donation and surrogacy. The prospects of organ donation should be included in as a subject right from the school curriculum as it is the right way to shape a new generation who strongly rely on reasoning and logic rather than myths and stigma.

IX. Recommendations/ Suggestions

A. An efficient public health care system: the need of the hour

India's health care system is already in a crisis. The poverty induces the masses to approach government hospitals which provide free health care to them. But, unfortunately and alarmingly, there is just one government allopathic doctor for every 10,189 people. Adding to it, there are dead and mutilated animals, rotting corpses and infections in the hospitals and laboratories. It then makes the poor rush to private hospitals which drain their pockets and households and render them ever poorer. Further, the system is becoming more and more unequal. There is no agency to track medico-legal and bioethical issues in India. To uphold bioethics, an efficient public health care system becomes the dire need of the hour.

B. Amending the laws

The Indian laws discussed in the previous sections need to be seriously and meticulously reviewed and amended. The State should ensure that they adhere to the bioethical principles. The UDBHR provides the accurate path to amend the laws, especially issues involving consent, benefit and harm, autonomy etc.

C. Bringing law and morality under the same roof

The final suggestion, though not easily achievable, is to restructure the perceptions about morality and bring them under the ambit of law. Bad impressions and prejudices towards organ donors and surrogates points out the unacceptable imbalance between law and morality in India. It is impossible to equate law and morality. However, the images of morality can be modified from grass root levels, by inculcating the acceptable values amongst the children at the schools. It is easier to build a new reasonable generation than running behind self-deafened society and norms. Optimism lies in seeing the initiatives of various NGOs to protect and promote bioethical values in the citizens. It is pertinent to note that law and morality can also not be separated. As Jeremy Bentham quoted, "Law has the same centre with morals, but it has not the same circumference." The challenge and prospect lies in the task of deciding that central point.

X. Conclusion

All national and international efforts in achieving health care must be supported by positive action of the forward looking legislature, dynamic executive and independent judiciary. The harmonious blend of ethics and law is needed to reach the International bioethical standards, by the turn of this century. Socially committed bioethics defends diversity, not allowing it to be suffocated by the hegemonic perspective. The UDBHR remains to be a significant contribution to global bioethics. The last but the most important question remains as to who will take the initiative? The emerging trends of citizens' protests against ethical violations and the rising contribution of Indian scholars and students to the area of bioethics give hope. It is vital to remember that it is the poor, the illiterate and the common people of India who took it to the streets with protests whenever their democratic rights were threatened. The media is also in its full swing in making the people about the bioethical issues in India. Considering the extraordinary complexity of the Indian medical scenario and texture of ethics and culture, the researcher concludes that the principles enshrined in the Bioethics Declaration has the potential to lead India in achieving its constitutional goals of health and international responsibility towards ensuring equity, liberty and justice.

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