



## HUMAN CLONING: A SOCIO - LEGAL AND ETHICAL APPRAISAL

### I Introduction

THE SUCCESSFUL cloning of Dolly (an adult sheep) by Scottish scientists at the Roslin Institute in 1997 has been considered as a most dramatic example of scientific discovery which has revived the debate that arose in 1966. Nobel Prize winner geneticist Joshua Lederberg advocated for cloning and genetic engineering in a seminal article in the *American Naturalist* in 1966 and again agitated the same in the Washington post in the following years.<sup>1</sup> He sparked a debate with conservative bioethicist Leon Kass, who wrote at the time that “the programmed reproduction of man will, in fact, dehumanize him”. Another Nobel Laureate, James D. Watson, publicized the potential and the perils of cloning in his *Atlantic Monthly* essay, “Moving Towards the Clonal Man” in 1971.<sup>2</sup>

The event was followed soon thereafter by the cloning of twenty two fertile mice by nuclear transfer from adult ovarian cells, by international team headed by Ryuzo Yanagimachi of University of Hawaii, U.S.A.<sup>3</sup> These experiments created wide spread alarm and debate about the possibility of cloning of human beings, and consequent ethical, legal and moral questions relating to human cloning became the subject matter of debate and discussion throughout the world. The issues are, however, not new. Literary imaginations of cloning found in science as true generates possible consequences in form of apprehension and beneficial use of it in society. Indeed, these issues demand a proper informed debate which certainly has not occurred until now. This paper is an attempt to attribute that debate from the socio-legal and ethical perspective and, in so doing, to challenge some commonly held assumptions. To begin with, it is important

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- 1 Joshua Lederberg, “Experimental Genetics and Human Evolution”, 100 (915) *The American Naturalist* 519-531 (1966) cited in [en.wikipedia.org/wiki/Human\\_cloning](http://en.wikipedia.org/wiki/Human_cloning).
  - 2 James Watson, “Moving Towards a Clonal Man: Is This What We Want?” *The Atlantic Monthly* (1971) Quoted in [en.wikipedia.org/wiki/Human\\_cloning](http://en.wikipedia.org/wiki/Human_cloning).
  - 3 Kelly Morris, “Studies Give Boost to Promise of Cloning Techniques” 352 *The Lancet* 293 (1998).



to understand the genetic process of human cloning, in order to understand its impact.

## II Meaning of cloning

The term cloning is an ambiguous one, as it can refer to various processes. It is well known that many plants can clone themselves, and have presumably been doing so since life began. In this paper cloning has been taken in the sense as referred in the report of the Human Genetics Advisory Commission (HGAC) and the Human Fertilization and Embryology Authority (HFEA)<sup>4</sup> in which it is defined as ‘producing a cell or organism with the same nuclear genome as another cell or organism’. This definition assumes that, in this type of cloning, the entire genetic identity of an individual is copied, although this is not strictly true because when Dolly was formed, she inherited not only the geocentric material in the parental nucleus but also the small amount of DNA which exists outside the nucleus of each cell and which in this case come from the donor egg. Accordingly, the definition of cloning used in the above report was not entirely accurate: it is vital that it should be pointed out. Nevertheless, the definition in the report does make clear the general type of cloning to which it applies.

## III Cloning process

The process of cloning indicates the taking of a cutting (as in plant breeding), and also includes nuclear transfer, of genetically identical animals. Nuclear transfer involves removing the chromosomes from an unfertilized egg and replacing them with a nucleus from a donor cell. As it is the transfer of nucleus that determines almost all of the characteristics of the resulting offspring, a clone will resemble its parents, *i.e.* the animal from which the donor cell was taken.<sup>5</sup> The same technique was used in order to create Dolly. The nucleus from egg cell was removed and the same was replaced with mammary cell of an adult sheep. After that an electric current applied which caused the egg, its new nucleus to fuse and develop into an embryo. Later on, the created embryo was implanted into surrogate

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4 Both Commission and Authority established to report on regulation of nuclear replacement from unfertilized egg.

5 I. Willmut, “The Uses and Ethics of Cloning” in David Calhaun (ed)., *Britanica Book of the Year: Events of 1997, 1998*.



Dolly which was only a lamb born from a series of implantation into surrogate ewes.<sup>6</sup> If the same technique applied in human beings, cloning would essentially be through somatic cell<sup>7</sup> of nuclear transfer. The process would involve transferring a human diploid nucleus into a human ovum from which its own nucleus has been removed. The donor nucleus could be taken from a fetal stem cell or adult somatic cell.<sup>8</sup> This process would require - a consenting donor as a source of DNA, nucleation of egg, fusion of DNA, a woman to carry and deliver the child and a person or couple to raise the child.<sup>9</sup> The process of cloning is being perfected in laboratories and the day does not seem far when the successful creation of a human clone will be announced.

#### IV Types of human cloning

There are two commonly discussed types of human cloning: therapeutic cloning and reproductive cloning. A distinction is sometimes drawn between these two terms. The latter is where the intent is to produce more or less identical foetuses and babies and where egg is implanted into the mother. The former type of cloning, by contrast, could be where stem cell lines are developed with a view to medical application. The nucleus of a cell donated by one person would be transferred to an egg mother cell and the embryo would be grown to generate stem cells which could be induced to form whichever type of cell or tissue was required for therapeutic purposes such as brain tissue, muscle or skin. The essential difference is that here the object would not be to treat an existing human being as a source of spare part for another.

A third type of cloning called replacement cloning is a theoretical possibility, and would be a combination of therapeutic and reproductive cloning. Replacement cloning would entail the replacement of an extensively damaged, failed, or failing body through cloning followed by whole or partial brain transplant.

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6 I. Willmut, "Viable Offspring Derived From Foetal and Adult Mammalian Cells" 385 *Nature* 810-813 (1997).

7 Somatic cells are the non-reproductive cell, they contain the full set of 23 pairs of chromosomes in the human body.

8 Jerome P. Kassirer, "Should Human Cloning Research be Off- limits?" 339 *New Eng J Med* 905 (1998).

9 John A. Robertson, "Human Cloning and the Challenge of Regulation" 339 *New Eng J Med* 120 (1998).



## V Beneficial applications of human cloning

Advocates of human therapeutic cloning believe the practice could provide genetically identical cells for regenerative medicine, and tissues and organs for transplantation. Such cells, tissues and organs would neither trigger an immune response nor require to use immune suppressive drugs. Both basic research and therapeutic development for serious diseases such as cancer, heart disease and reconstructive and cosmetic surgery are areas that might benefit from such new technology.<sup>10</sup>

Solter of the Max-Planck Institute for Immunology is of the opinion that cloning provides a revolutionary answer to current problems of rejection in organ transplants.<sup>11</sup> Because some time the patient who needed an organ or tissue transplantation might lack a medically suited donor. As Robertson<sup>12</sup> pointed out, the couples in this situation have often conceived a child in the hope that she would have the correct tissue type to serve, like a bone marrow donor for an older sibling. If the child's disease was not genetic, a couple might prefer to clone the affected child to be sure that the tissue would match. New York University bioethicist Jacob M. Appel has argued that "children cloned for therapeutic proposes" such as "to donate some marrow to a sibling with leukemia" might some day be viewed as heroes.<sup>13</sup> Of course, this raises many ethical questions which have been dealt in the course of the paper.

Cloning could also assist couples who are both infertile due to gametic insufficiency. It could provide a viable alternative to embryo donation. In situation where the male partner lacks gametes, the couple might prefer to opt for cloning, rather than sperm donation.<sup>14</sup> If the husband was source of the DNA and the wife provided the egg that received the nuclear transfer and then gestated the foetus, they would have a child biologically related to each other and would not have to rely on anonymous

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10 "Cloning Fact Sheet" available at [http://www.oml.gov/techresources/Human\\_Genome/elsi/cloning.shtml#organsQ](http://www.oml.gov/techresources/Human_Genome/elsi/cloning.shtml#organsQ). (visited on November 20, 2009).

11 D. Solter, "Dolly Is A Clone And No Longer Alone" 394 *Nature* 315-316 (1998).

12 *Supra* note 9.

13 J.M. Appel, *New York Time Magazine* December 11, 2005 as quoted in [en.wikipedia.org/wiki/Human\\_cloning](http://en.wikipedia.org/wiki/Human_cloning).

14 D. Butter and M. Wadman "Call for Cloning Ban Sells Science Short" 386 *Nature* 8 (1997).



gamete or embryo donation.<sup>15</sup>

Another beneficial application of cloning technology in human beings would be for a couple at high risk of having offspring with a genetic disease. Now a days, couples in this situation may choose an option either to give birth to an affected child, or to undergo pre-natal or pre-implantation diagnosis and abortion, or to discard embryos, or to accept gametes donation or to seek adoption or to remain child less.

Some scientists, including Richard Seed, suggested that human cloning might obviate the human aging process.<sup>16</sup> Preston Estep has suggested the term “replacement cloning” to describe the generation of a clone of a previously living person and “persistence cloning” to describe the production of a cloned body for the purpose of obviating aging, although he maintains that such procedures currently should be considered as science fiction and current cloning techniques risk producing a premature aged child.<sup>17</sup>

In Aubrey de Gray’s proposed SENS (Strategies for Engineered Negligible Senescence), one of the considered option to repair the cell depletion related to cellular senescence is to grow replacement tissues from stem cell harvested from a cloned embryo.

Cloning could be used to enable a couple to clone a dead of dying child so as to have that child live on in some closely related form. It may also be used to obtain sufficient number of embryos for transfer and pregnancy.<sup>18</sup>

Cloning has been accepted as a liberating technology, paving the way for a new family structure. It assists same sex couple in fulfilling their desire for biological offspring. The inability or unwillingness to engage in sexual intercourse ought not to prevent an individual from enjoying her procreative freedom which is a freedom entail right.<sup>19</sup>

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15 Andrea L. Bonnicksen, “Procreation By Cloning: Drafting Anticipatory Guidelines” 25 *Journal of Law, Medicine & Ethics* 276 (1997).

16 “Cloning Touted as Infertility Solution” *Washington Times*, December 11, 1997 quoted in [en.wikipedia.org/wiki/Human\\_cloning](http://en.wikipedia.org/wiki/Human_cloning).

17 Available at <http://www.newscientist.com/article/dn3393-dolly-the-sheep-dies-young.html>. (visited on November 20, 2009).

18 *Supra* note 9.

19 *Ibid.*



## VI Ethical and Sociological implications

Numerous ethical and social concerns have been highlighted in relation to the soundness of cloning apart from the question of safety of procedure, such as :

- (i) Every human being has procreative liberty in form of moral right which has been accepted as human right in International Covenant.<sup>20</sup>
- (ii) Creation of clone solely for the purpose of providing spare parts (*i.e.* organ transplantation) would, from a philosophical stand point contradict human dignity. Kantian principles<sup>21</sup> also emphasize that an individual human life never to be thought of as only a means of an end, but an end itself, at all times. Creating human life for the sole purpose of its serving as a source of therapeutic material would not serve the dignity of the life so created and fails this test.
- (iii) The cloning technology is an inevitable by-product of *in-vitro-fertilization*. If one can go through the trouble of *in-vitro*, with its potentially hazardous mega doses of hormones for the female partner and various indignities for male partner, cloning is simply the next step.<sup>22</sup> When researchers, for the first time, in 1993, duplicated a human embryo, they submitted to the public that human cloning is simply the next step in logical progression that started with *in-vitro* technology and is driven by a desire to relieve human suffering.<sup>23</sup> Thus, cloning is seen as continuous with other reproductive technologies, the ultimate goal being to provide a couple with a biological child they might otherwise be unable to have. This, however, is not an answer itself.
- (iv) Cloning would take to a situation where death of child is not viewed as a single human tragedy, but merely as an opportunity to try to replicate. It is no longer irreplaceable child and using

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20 Arts. 15 (1) and 15 (3) (b) of International Covenant on Social, Economic and Cultural Rights, 1966.

21 Carl J. Friedrich, *The Philosophy of Kant : Immanuel Kant's Moral & Political Writings*, 154-229 (1993).

22 Ehreureich Barbara, "The Economics of Cloning" *Times* November 22, 1993 at 86.

23 Philip E. Dewitt, "Cloning – Where Do We Draw the Line?" *Times* November 08, 1993 at 64.



the cloning to replicate the children encourages to devalue children as inter changeable commodities.<sup>24</sup>

- (v) The process of cloning is likely to lead to severely disabled children. Bioethicist Thomas Murray of the Hastings Centre argued that it is absolutely inevitable that groups are going to try to clone a human being.<sup>25</sup> But they are going to create a lot of dead and dying babies along the way.<sup>26</sup> It is likely that there would be a great number of failures in the creation of living human clone, such as clones without viable immune systems or other gross genetic failures.
- (vi) In Aubrey de gray's proposed SENS (Strategies for Engineered Negligible Senescence), one of the considered options to repair the cell depletion related to cellular senescence is to grow replacement tissues from stem cells harvested from a cloned embryo.
- (vii) Cloning is also a crime against the clone, the crime of depriving the clone of her "existential right" particularly, the right to ignorance of facts about her origin that is likely to be paralysing for the spontaneity of becoming self. This advance knowledge of the reason for her existence destroyed the clone's chances of authentic growth, of answering the fundamental existential question, "who am I".<sup>27</sup> The report of National Bioethics Advisory Commission (NBAC) also expressed this concern about the interest of the clone and its individuality.
- (viii) From religious point of view, some Islamic scholars argue that cloning testifies resurrection *i.e.* revival of life, however, it is not seen as a creative act, rather it is considered destructive and satanic act as it bungles with divine creation.<sup>28</sup>

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24 George J. Annas, "Why We Should Ban Human Cloning" 339 *N. Eng J Med* 123 (1998).

25 Available at <http://www.scholieren.com/werkstukken/20448> (visited on November 20, 2009).

26 Codification Division, Office of Legal Affairs, United Nation (2005-05-18). "Ad-hoc Committee on an International Convention Against the Reproductive Cloning in Human Being" available at <http://www.un.org/law/cloning>. United Nation <http://www.un.org/law/cloning/> (visited on January 8, 2007).

27 *Supra* note 24.

28 Sheikh Mohammed Shihabuddin Nadvi, *Cloning Testifies Resurrection* 189 (1997).



- (ix) Cloning to be used as an alternative means of reproduction in cases of infertility - has not been accepted by and large. Critics like Annas argue that cloning cannot be a treatment of infertility. This replication technique changes the very concept of infertility itself, since all humans have somatic cells that would be used for asexual reproduction and therefore one would be able to replicate herself asexually. However, *in-vitro-fertilization* has been a technique whereby otherwise infertile couples can reproduce sexually. Some British pioneer jurists and surgeons are of view that infertility does not justify cloning.<sup>29</sup>
- (x) Cloning challenges present day human kinship and familial structures. Who may be treated as parents of clone? Proponents of genetic reductionism argue that a clone has a full set of chromosomes, like any other else-half of which were derived from the father, and half from mother. In spite of that, the donor is not clone's parent in biological sense, but is simply an "earlier offspring" of the original parents.<sup>30</sup> While this appears to make logical sense, it in fact challenges traditional notions of reproduction and parenthood, and radically redefines them. The argument also fails to explain the clone with the "earlier offspring". Needless to say, this has significant sociological implications.
- (xi) If the course of cloning has been popularly adopted in the society, then it is indirectly curtailment of sexual reproduction and sexual intercourse. Medically, it is an established fact that sexual intercourse has been accepted as therapy for some diseases and for relaxing body and nervous system, like for sleeping, skin etc.
- (xii) On question of the individuality of the clone, the counter appears to be that genetic determinism is scientifically inaccurate. While the genotype of an individual is significant, the importance of the environment in shaping personality and traits cannot be underestimated. Moreover, the nature of parental motivations is more complex than critics allow: often the motives that persons have

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29 M. Wadman, "Cloned Mice Fail to Rekindle Ethics Debate" 394 *Nature* 409 (1998).

30 R.C. Lewontin, "Confusion over cloning" *New York Review of Books* cited in Annas, *supra* note 24 at 123.



for bringing a child into the world do not necessarily determine the manner in which they raise them. Seeing their child grow and develop, they learn that he/she is not merely an extension of themselves.

- (xiii) Some scientists, including Richard Seed, suggests that human cloning might obviate the human aging process.<sup>31</sup> Preston Estep has suggested the term “replacement cloning” to describe the generation of a clone of a previously living person, and “persistence cloning” to describe the production of a cloned body for the purpose of obviating aging, although he maintains that such procedures currently should be considered as science fiction and current cloning techniques risk producing a premature aged child.<sup>32</sup>

## VII Legal Aspect of Cloning

Despite the numerous potential beneficial application of human cloning technology, governments of the world over have come down heavily on the very research, leave alone commercial application of such technology. The reasons flow out of ethical and social concern about cloning and possibility of misuse.

### United States

Following the birth of Dolly, US President Bill Clinton announced an executive ban on federal funding for “human cloning” on March 4, 1997. He also directed the National Bioethics Advisory Commission (herein after mentioned as NBAC) to make recommendations about human cloning. Pursuant to the recommendations of NBAC and the announcement by Richard Seed (had the technology to clone a human being, incidentally turned out to be a hoax), the cloning was banned for a period of ten years.<sup>33</sup> At the time, the fact that Seed was physicist with no expertise in cloning, no institutional affiliation, and no funding, seemed inconsequential compared to what he proposed he could do for a fee. The NBAC’S recommendation of a five year moratorium was in fact enacted

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31 *Supra* note 16.

32 *Supra* note 17.

33 S. 1602 of Prohibition of Cloning of Human Beings Act, 1998.



in California.<sup>34</sup> The impetuously drafted bills in both Senate (the Bond-First Bill) and House (the Ehlers Bill), however, went far beyond restricting the cloning of humans. These bills were to put an end to all cloning experiments that used human cells, in particular, research into somatic cell nuclear transfer technology. These were opposed by dozens of medical organization, (predictably) biotechnology companies, and distinguished scientists.

In 1998, 2001, 2004 and 2007, the United State House of Representative voted whether to ban all forms of human cloning, both reproductive and therapeutic. Each time, there was division in Senate over prevention of therapeutic cloning but absolute ban was accepted in respect to reproductive cloning. Some American states ban both forms of cloning while some others outlaw only reproductive cloning.

Current regulations prohibit federal funding for research into human cloning, which effectively prevents such research conducted in public and private institutions such as universities which receive federal funding. However, there is currently no federal laws in the United States which ban cloning completely, and any such law would raise difficult constitutional questions similar to the issues raised in abortion cases.

### European countries

The European Convention on Human Rights and Biomedicine<sup>35</sup> promoted by the Council of Europe prohibits any intervention seeking to create a human being identical to another human being whether living or dead.<sup>36</sup> The term 'genetically identical' is defined as where a human being shares along with another the same nuclear gene set. It is submitted that if legislation is eventually passed dealing with human cloning, then this definition could usefully be adopted as it deals with the problem of some genes coming from the DNA in the egg cell. The prohibition appears to cover therapeutic as well as reproductive cloning because it provides (article 7) that the prohibition on cloning of human beings covers all

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34 Act of Oct.4,1997 Cal. Legis. Serv. 3790.

35 Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Strasbourg: ETS164) cited in file://G:/cloning\_Legal Aspect.htm. (visited on July 14, 2009).

36 *Id.*, Art. 1 (a).



nuclear transfer methods seeking to create identical human beings. Two countries did not sign the Protocol to the Convention. One was Germany, which asserted that it had its own legislation - Federal Embryo Protection Act, 1990 that completely prohibits experiments on human embryo. Another country which refused to sign the Convention was UK. The reason was given by Baroness Hayman, when she replied to the debate, that “whilst the government fully supporting the principle enshrined in the protocol, it could not sign it because to do so would also mean signing the whole Convention which contained the provisions relating to research on persons not able to give consent which needed to be examined in the light of forthcoming legislation to be introduced by the government following the Law Commission’s working paper “Who decides”?”.

The much of the pressure to legislate at least therapeutic human cloning comes from commercial organizations. The Biotechnology Patents Directive<sup>37</sup> expressly prohibits patenting process for cloning of human beings.<sup>38</sup> Once again the familiar problem of definition rears its head because of the doubt whether an embryo which has not yet reached the age of 14 days is included as a human being? However, large firms may be reluctant to spend even huge sums of money when there is a doubt about patentability. It is noteworthy that in November 1997 UNESCO brought out the Universal Declaration on the Human Genome and Human Rights which provides, in clause 11, that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.

### United Kingdom

The precise legal position in the UK on cloning is uncertain. The starting point is the Human Fertilization and Embryology Act, 1990, which absolutely prohibits certain activities, such as cloning, although there is doubt about precisely what the Act means by this. Other activities, such as the creation of an embryo *ex utero* or the storage of embryos or gametes require a license under the Act. If any activity is not covered by the Act, naturally it is not subject to legal regulation at all, and it may be that this

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37 European Parliament and Council Directive on Legal Protection of Biotechnological Inventions COM97 446 final quoted in file://G:/cloning\_Legal Aspect.htm. (visited on July 14, 2009).

38 *Id.*, Art. 24.



is so in case of human cloning. Since 1990 human cloning was not known, so no requirement was felt to legislate on the subject. The meaning of embryo has been explained in the Act as a live human embryo where fertilization is complete<sup>39</sup> and the term fertilization stated that reference to an embryo includes an egg in the process of fertilization.<sup>40</sup> Section 3(3)(d) of the Act contains a prohibition on cloning *per se* by providing that a license granted under the Act, cannot authorize replacing a nucleus taken from the cell of any person, embryo or subsequent development of an embryo. The difficulty here is that although those words appear to prohibit nuclear transfer cloning, which is what precisely occurred in Dolly's case, is not covered because of the word embryo. The Act, 1990 uses two terms; fertilization and embryo which do not cover what is now understood by cloning. However, the Act allows certain activities under a license, among which is the storing of gametes. Section 4(2) of the Act provides that a license cannot authorize storing of using gametes in any circumstances in which regulations prohibit their storage or use. This may not cover what happened in Dolly's case because cell membrane was used to create Dolly, which was not gamete. The final relevant part of the Act, 1990 is section 8 (a) which provides that the Human Fertilization and Embryology Authority must keep under review the information about embryos and any subsequent development of embryos. Once again, although these words were inserted to enable the HFEA to deal with developments probably unforeseen when this Act was passed. (This question whether human cloning was covered by the Act, 1990 exercised the minds of House of Common Sciences and Technology Committee.) In evidence, Ian Willmut (the creator of Dolly) accepted the point made by chairman of the committee<sup>41</sup> that the crucial thing is that the word embryo be defined in law in such a way that science is clear as to what it actually means. Bulfield put the point simply that 'an embryo cannot be in the process of fertilization because it is only an embryo after fertilization'.<sup>42</sup> A memorandum submitted by the Department of Health<sup>43</sup> stated that it had been agreed with the HFEA to make a joint approach to counsel on the definition of embryo as used in the Act. It also stated that their current legal advice was that if a court was asked to consider the matter it

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39 S. 1 (i) (a) of the Human Fertilization & Embryology Act, 1990.

40 *Id.*, s. 1 (i) (b).

41 Fifth Report, 2 *The Cloning of Animals for Adult Cells* (1997).

42 *Id.*, para 159.

43 *Id.*, para 154.



would be likely to come up with a broad construction which would bring the technique used in the cloning of Dolly within the Act, 1990. The effect is that, at present, any decision on whether to grant a license to permit reproductive cloning rests entirely with a statutory body which, although subject to judicial review<sup>44</sup> and is not subject to any kind of democratic scrutiny or control. Moreover, one may arrive at this position by the extremely dubious route of assuming that the courts will define the term 'embryo' so that it means something which at present it does not. The report recognized that many persons find it unsatisfactory by stating that the government may wish to consider the possibility of introducing primary or secondary legislation explicitly<sup>45</sup> banning reproductive cloning. In response, the government simply stated that it will keep under continuing review the adequacy of the existing safeguards and the possible need for additional legislation, with a further detailed analysis in five years time if necessary. In this regard, the government set up an expert advisory group. Some confusion was also created in between the Human Genetic Advisory Commission and the Human Fertilization and Embryology Authority reports by leveling some forms of therapeutic cloning as cell nucleus replacement. The government asked the expert advisory group to look at the recommendations in the report<sup>46</sup> so that two additional purposes for human embryo research should be added to those which are already in the 1990 Act. This will permit the development of methods of therapy for (i) mitochondrial disease and (ii) for diseased or damaged tissues of organs. These additional purposes would be added by regulations made under section 45 of the Act, 1990 and would not therefore require fresh legislation.

On January 14, 2001 the British government passed the Human Fertilization and Embryology (Research Purposes) Regulations, 2001<sup>47</sup> to amend the Human Fertilization and Embryology Act, 1990 by extending allowable reasons for embryo research to permit research around stem cells and cell nuclear replacement, thus allowing therapeutic cloning. However, on November 15, 2001, a pro-life group won a high court legal challenge, which struck down the regulation and effectively left all forms

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44 *Id.* at 42.

45 *R. v. Human Fertilization and Embryology Authority* (1997) 2 All E R 687.

46 Report of the Committee.

47 Available at <http://www.statutelaw.gov.uk/content.apex?activeTextDocId=2523310> (visited on November 20, 2009).



of cloning unregulated in the UK.<sup>48</sup> Parliament was quick to pass Human Reproductive Cloning Act, 2001<sup>49</sup> which explicitly prohibited reproductive cloning. The remaining gap with regard to therapeutic cloning was closed when appellate court reversed the previous decision of the high court.<sup>50</sup>

The first license was granted on August 11, 2004 to researchers at the University of Newcastle to allow them to investigate treatments for diabetes, Parkinson and Alzheimer diseases.<sup>51</sup> The Human Fertilization and Embryology Act, 2008 a major review of fertility legislation, repealed the 2001 cloning Act by making amendments of similar effect to the Act 1990. The Act, 2008 also allows experiments on hybrid human- animal embryo.<sup>52</sup>

### Australia

Australia had prohibited human cloning,<sup>53</sup> however, in December, 2006 a bill legalizing therapeutic cloning and the creation of human embryos and the stem cell research was passed by the House of Representatives. Within certain regulatory limits, and subject to the effect of state legislation, therapeutic cloning is now legalised in some parts of Australia.

### United Nations

In 1997, UNESCO brought out the Universal Declaration on Human Genome and Human Rights which provides<sup>54</sup> that practices which are contrary to human dignity, such as reproductive cloning of human being, shall not be permitted.

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48 S. D. Pattinson, *Medical Law and Ethics* (2006). Quoted in [en.wikipedia.org/wiki/Human\\_cloning](http://en.wikipedia.org/wiki/Human_cloning).

49 “Campaigners Win Cloning Challenge” available at <http://news.bbc.co.uk/1/hi/sci/tech/1657707.stm>. BBC News. (November 15, 2001) (visited on September 06, 2008).

50 “Lords Uphold Cloning Law” available at <http://news.bbc.co.uk/2/hi/health/2846265.stm>. BBC News Online, March 13, 2003.

51 “HEFA Grants the First Therapeutic Cloning License for Research” available at <http://www.hfea.gov.uk/en/1048.html> (visited on September 06, 2008)

52 “MPs Support Embryology Proposals” available at [http://news.bbc.co.uk/2/hi/uk\\_news/politics/7682722.stm](http://news.bbc.co.uk/2/hi/uk_news/politics/7682722.stm). BBC news on lines. October 23, 2008.

53 The Prohibition of Human Cloning for Reproduction Act, 2002.

54 Art. 11 of UDHR.



On December 12, 2001, the United Nations General Assembly began elaborating on International Convention Against the Reproductive Cloning of Human Beings. A broad coalition of states including Spain, Italy, Philippines the United States, Costa Rica and the Holy See sought to extend the debate to ban all forms of human cloning, noting that, in their view, therapeutic human cloning violates human dignity. Costa Rica proposed the adoption of an International Convention to Ban All Forms of Human Cloning. Unable to reach consensus on a binding convention in March, 2005 a non-binding United Nations Declaration on Human Cloning<sup>55</sup> calling for the ban of all forms of human cloning contrary to human dignity, was finally adopted.<sup>56</sup> The declaration solemnly affirms following:

1. Member states are called to adopt all measures necessary to protect adequately human life in the application of life sciences.
2. They are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.
3. They are further called upon to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity.
4. They are called upon to take all measure to prevent the exploitation of women in the application of life science.
5. They are also called upon to adopt and implement without delay national legislation to bring into effect the above.

### **VIII Conclusion**

It is clear by the above discussion that the debate would by no means be silenced by imposing a moratorium on it. The time is appropriate, however, to consider what kind of policy is required to regulate the use of cloning technology and prevent undue commercial exploitation of the

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55 *Available at* <http://www.bioeticaweb.com/content/veiw/1267/765/lang.es/1>. (visited on October 21, 2009).

56 Codification Division, Office of Legal Affairs, United Nations “Ad-hoc Committee on an International Convention Against the Reproductive Cloning of Human Beings.” *Available at* <http://www.un.org/law/cloning/>. United Nations, <http://www.un.org/law/cloning>.



process. Firstly, the question for consideration is whether state intervention is required? Obvious answer is 'yes' because cloning, while enhancing the rights of a few who take risk to exercise their procreative liberty, the lives of many others may be affected, including that of clone,<sup>57</sup> in utilitarian sense, rights and the interest of the majority should prevail.

On the point of extent of state intervention, opinions ought to be largely divided. Some favour the criminalization of cloning, but it is not easy to determine and fix liability. Whom should the law punish, the proponents of the technology,<sup>58</sup> or the users of the technology? In the latter case, the user's liability is determinable only by a fact-based inquiry. Sometimes, it might be the clone itself, or otherwise the 'parents' of the clone. A sentencing policy would also have to be evolved for the same.

A fundamental question that poses a dilemma to all policy makers in this area is that how does a legal framework develop to govern a subject-matter which is in a constant state of flux. It is required to evolve flexible laws that allow for change along with any change in technology.

The ultimate aim of legal intervention should be to prevent misuse of the technology. A complete ban on cloning research would be futile as research is seldom stopped on account of law. Biotechnology companies are bound to find out loopholes in any rigid law that is enacted. Even if the ban is successfully enforced, it would pre-empt any possibility of tapping on the benefits of cloning. So, it is submitted that regulation, not prohibition may be the answer. The regulation should not be time bound or too specific, and should give room for a co-operative strategy by the regulatory authority, with the research teams.

Annas<sup>59</sup> suggested regulation of cloning on the lines of the 'precautionary principle' in environmental law. According to the principle, the government has to protect the public health and environment from imminent threats of irreversible harm or catastrophic consequences even in the absence of clear evidence of harm. There would be a reversal of burden of proof; the proponents of human cloning would have to prove

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57 Rizwanul Haq, "Ethical, Moral and Legal Issues Involved in Cloning" 1 *Supreme Court Journal* 8 (1998).

58 The jurisprudence which is being evolved by the US courts on the liability of the tobacco industry in cases of chain smokers contracting lung cancer, up to huge pecuniary amounts, poses an interesting analogy.

59 *Supra* note 24 at 125.



that there was some compelling, countervailing need to benefit present or future generations before such an experiment was permitted ( for example, if the entire species were to become sterile). The regulators would not have the burden of proving that there was some compelling reason not to approve it. This regulatory scheme would depend on at least a *de-facto*, if not a *de-jure*, ban or moratorium on such experiments.

Another suggestion given by Jerome P. Kassirer<sup>60</sup> is that of voluntary self regulation. Researchers and users of the technology should impose restrictions on their activities, and ensure transparency with regulatory authority.<sup>61</sup> This suggestion appears to rest on the presumption that the actors concerned have a sense of moral and social duty, and will not detract from their path. One is, however, inclined to treat this as faithful, yet unrealistic optimism. The vast majority of research projects are funded by biomedical companies, their main purpose is to explore the commercial potential of research outcomes. It is difficult to believe that these companies will place social security before their commercial interest in a fair and impartial manner.

The suggestions have also been put that cloning of human being is in the distant future and does not require precautionary legislation because they feel that it is only due to false security reason. It is submitted that such an approach is rather myopic, and should instead seek to address the issues that are bound to surround technological advancement which made cloning feasible in clinical conditions.

Every new idea is ushered by disbelief, and initially dismissed as hearsay, right from ancient time. But sooner or later, once its credence is established, it is seldom questioned. As Wilmut (Dolly's godfather) points out, many religious leaders were initially scandalized by introduction of artificial insemination methods on cattle, a procedure that helped to eliminate sexually transmitted diseases and provided the single biggest advance in livestock breeding.<sup>62</sup> When *in-vitro* technology was being developed in the seventies, it came under tremendous public scrutiny and debate.<sup>63</sup> Present time, apart from few dissidents, the technology has become part of our unquestioned rationale.

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60 *Supra* note 8.

61 *Ibid.*

62 *Supra* note 5.

63 Russel, Scott, *The Body as Property* 198 (1981).



Since then, thousands of babies have been born to infertile couples through this method. It is submitted that skepticism about an idea alone ought not to preempt informed debate. In area of human cloning, the extreme conjures images of wasted embryos and deformed babies, of infinite life, of master races and duplicate of famous scientist, artists and other celebrities. On the other hand, cloning has technology with boundless implications for the treatment of infertility and diseases. There are merits in both the arguments, though the truth probably lies somewhere in between and the debate must go on till science tells all.

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