

# **The Urgency for Legal Regulation of the Practices of Cloning and Stem Cell Research**

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## **Introduction**

"The ability to turn blood into liver would be the envy of the alchemists of former times. Turning stem cells into 'therapeutic gold' will probably rest on our ability to identify the mechanisms by which tissue-derived stem cells respond to environmental cues and execute new developmental decisions."<sup>1</sup> \To develop legislation for such an area as cloning and stem cell research is a governmental nightmare. An ethical minefield coupled with the rapid advances in the area ensures most governments place the issue on the long finger until it can be ignored no longer. The Irish government has indeed fallen foul of this rule. The issue has come before them in a European context recently and this alone caused a major storm. With no domestic legislation in the area and an increasing bio pharmaceutical presence in this country it is an area which must be legislated for, and soon. After all "controls, regulations and safeguards are far better than a free-for-all"<sup>2</sup>.

On February 23, 1997, Dolly the Sheep was cloned by Scottish scientists. It was from that point that genuine ethical concerns were raised about the possibility of cloning humans. With so much publicity surrounding the field of genetics and its related areas it is little wonder that much of the terminology inherent with the area is confused and it is difficult for the lay person to determine one practice from another. It is true that cloning and stem cell research are very much related but from a procedural and an ethical point of view the differences between the two are quite significant.

## **Cloning**

There are two main categories of cloning, reproductive cloning and therapeutic cloning.

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<sup>1</sup> Stuart H. Orkin, *Nature Medicine*, November 2000, Vol. 6, Number 11, p. 1212 at 1213.

<sup>2</sup> An Tainiste, Mary Harney quoted in Fionán Sheehan, *Fianna Fáil Split deepens over stem cell research*, *The Irish Examiner*, 26<sup>th</sup> November 2003.

**Reproductive cloning** is the technology used to generate a specimen that has the same nuclear DNA as another currently or previously existing specimen, be it animal or human and may simply be defined as a way of producing a genetic twin of an organism without the need for sexual reproduction. Dolly the sheep was created by reproductive cloning technology. The process involves the transfer of a cell nucleus to an unfertilized egg, the nucleus of which has been removed and its development stimulated by a small electrical current. Once the cloned embryo reaches a suitable stage it is transferred to the uterus of a female host where it continues to develop until birth. This process does not create an identical twin of the creature that supplied the nucleus, only a genetic twin. There are many inherent risks with this type of cloning with scientists believing that errors or incompleteness in the process cause the high rates of death, deformity, and disability observed among creatures cloned.

**Therapeutic cloning** or embryo cloning is the creation of human embryos for use in research. The goal of this process is not to create cloned human beings, but rather to harvest stem cells that can be used to study human development and to treat disease. The creation procedure is the same as for reproductive cloning, the transfer of a nucleus of one cell to the unfertilized egg, the nucleus of which has been removed. The difference is in the procedure after this. While the intention in reproductive cloning is that the embryo be implanted and develop into a human baby, in therapeutic cloning the embryo is allowed to develop for about five days, until the blastocyst<sup>3</sup> stage is reached at which point the stem cells are harvested for research.

### **Stem Cell Harvesting and Research**

Stem cells are of reported importance to medical researchers as they can be used to generate virtually any type of specialized cell in the human body. The fertilized egg is allowed to divide for 5 days, at which point the stem cells are extracted from the egg. It must be noted that the extraction process destroys the embryo, which raises a variety of

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<sup>3</sup> The 'blastocyst' is a hollow, fluid-filled ball of cells.

ethical concerns. Many researchers hope that one day stem cells can be used to serve as replacement cells to treat heart disease, Alzheimer's, cancer, and other diseases.

For the most part embryonic stem cells for research are obtained from embryos donated by persons with an excess following a course of IVF treatment and so these embryos are destined to be destroyed anyway. But where the numbers of IVF surplus embryos being donated are insufficient there are instances where embryos have been cloned for the purpose of harvesting stem cells for use in research.

As the embryo develops it goes through several stages. Following fertilization the embryo is a single cell. This is comprised of half male genetic material and half female genetic material. This zygote undergoes a series of cell divisions. When the developing embryo has divided to about 100 cells it is known as a blastocyst. Of these cells in the blastocyst, some go on to form both embryonic cells, which may develop into a human baby under the right circumstances, and non embryonic cells which go on to form such things as the placenta and the umbilical cord. It is impossible to say what percentages of these blastocyst cells form which tissue. Within the blastocyst is a population of cells from which embryonic stem cells can be harvested. At this stage the cells are still relatively undifferentiated<sup>4</sup>. There is no trace of human structure such as a nervous system. At about 14 days after fertilisation, and only following implantation, the cells begin to become differentiated into more specialised cell types, and the "primitive streak", from which the central nervous system eventually develops, begins to appear<sup>5</sup>.

### **The Current Law**

As it currently stands Ireland has no legislation which bans or regulates the practices of cloning and stem cell research. In Ireland, should an organization be found engaging in such activities, the matter would be dealt with as being contrary to the Constitution and indeed Natural Law. The Constitution guarantees a right to life<sup>6</sup> and a right to bodily integrity. It would need to be proved that the practices being undertaken are contrary to

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<sup>4</sup> 'Undifferentiated' means the cells have not become specialised and can develop into any type of human tissue.

<sup>5</sup> Scientists in general believe this is the 1<sup>st</sup> stage at which the cells are recognisable as any form of person.

<sup>6</sup> Article 40.3 of Bunreacht na hÉireann 1937.

these rights in order for an injunction, restraining the organization, to be obtained. But this might be too late. Such proceedings take time, certainly longer than it takes to implant a cloned embryo. What would be the remedy to such a situation?<sup>7</sup> With no legislation to determine the boundaries and sanctions, the legal conundrum would begin.

The sole guidelines in relation to this area exist in the governance of the medical professions. The Medical Council of Ireland published its 6<sup>th</sup> edition of its guidelines on ethics in 2004<sup>8</sup> which stated that

The creation of new forms of life for experimental purposes or the deliberate and intentional destruction of in-vitro human life already formed is professional misconduct.<sup>9</sup>

This has the effect of banning medical practitioners from participating in any process relating to the destruction of an embryo for the purposes of stem cell research, or indeed for any reason.

Those embryos which are created must only be used for the purposes of implantation in IVF treatment.<sup>10</sup>

However these guidelines apply solely to the medical profession acting in such capacity and are in no way binding on any member of the scientific community.

There is no evidence at this point to suggest that either cloning or stem cell research is being carried out in this jurisdiction but the bio technology market in this country is currently booming. In such a fast paced research area there is little point in trying to play catch up. The stakes are too high.

## **The EU**

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<sup>7</sup> Because there is judicial recognition that the constitutional right to life encompasses the unborn child, abortion is not a valid remedy.

<sup>8</sup> Medical Council of Ireland, "A Guide to Ethical Conduct and Behaviour", 6<sup>th</sup> edition, 2004

<sup>9</sup> Ibid at p. 35

<sup>10</sup> Ibid

This issue is ongoing at European level but it must be stressed that any decisions taken by the EU in relation to the funding of such research will not be imposed on any of the member states. The issue before the EU is whether or not to allow funds under the 6<sup>th</sup> Framework Programme to be applied to cloning or stem cell research.

It has decided that funding may be given to stem cell research projects but only where the embryos used are those which are left over from IVF treatment, and would otherwise be destroyed. There will also be other stringent pre requisites which will all need to be satisfied before an ethics review group, before any funding for a particular research project will be approved. Embryonic stem cells can only be derived from embryos that are donated for research by parents who gave their fully informed consent. The parents donating these embryos shall be forbidden from making any financial gain. Research will be funded only when it is demonstrated that it meets important research objectives. There must be no adequate alternative available to researchers. Traceability of stem cells and anonymity of donors must be guaranteed. Finally, the EU will not fund human embryonic stem cell research in a particular country where such practice is forbidden by that Member State.

### **Other Jurisdictions**

Other jurisdictions have recently put legislation in place to regulate the practices in their own country. There are striking differences between the positions taken by different countries in their regulation of the area. These differences largely reflect contrasting cultural and religious traditions. Reproductive cloning is either illegal or prohibited in all countries which have relevant legislation.

In Britain the use of embryos and creation of embryos for use in stem cell research and other areas of genetic research are permitted under the Human Fertilisation and Embryology Act 1990. This legislation was enacted primarily to regulate the practice of *in vitro* fertilisation, but the regulatory authority<sup>11</sup> set up by the Act is also empowered to license research on human embryos. Under the Act research on embryos older than fourteen days is prohibited. All research must be undertaken under license from the HFEA. A license may not be granted unless two tests have been satisfied: first that the

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<sup>11</sup> The Human Fertilisation and Embryology Authority (HFEA)

use of embryos is necessary and they cannot be obtained by other means and, second the research must be necessary or desirable for one of the specified purposes.

In the United States, President Bush has authorized federal funding for research on human embryonic stem cells, but only if they were derived from stem cell lines established before 9 August 2001<sup>12</sup>. It is generally up to individual states to put in place their own regulations in relation to research on embryos and therefore funding is the sole method of regulation of such practices from a federal point of view. Some states have no regulations in place and therefore little control on what takes place in private research facilities.

In Australia, the House of Representatives Standing Committee on Legal and Constitutional Affairs, following a two year enquiry, published a report recommending a ban on the creation of embryos solely for research purposes, allowing the extraction of stem cells from spare IVF embryos and banning reproductive cloning.

### **Recommendations**

It is a slight anomaly but even though stem cell research and cloning are inextricably linked the two are very much separate and distinct yet each stands alone without the other. The decision to regulate these practices is difficult, as the area is fraught with many scientific, religious, ethical and legal matters.

### **Reproductive Cloning**

Bunreacht na hÉireann 1937 guarantees the right to life of all citizens<sup>13</sup> and upholds the family as the primary institution of society.<sup>14</sup> The constitutional and social implications of permitting such a practice are endless.

Dolly the Sheep was hailed a scientific success story. But she was sheep number 277. The previous 276 perished from abnormalities at different stages of development or were simply discarded. Putting this on a human scale, the implications are terrifying. We are human beings, not scientific guinea pigs.

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<sup>12</sup> This is the date of the Act and so the creation of further embryos past this date will not qualify for funding. The research is not expressly banned in the USA.

<sup>13</sup> Article 40.3.2 of Bunreacht na hÉireann.

<sup>14</sup> Article 41.1 of Bunreacht na hÉireann.

In this jurisdiction the constitution describes the family as the primary social group in society.<sup>15</sup> Cloning does not subscribe to a mother or father in the conventional sense. The closest the clone would conceivably come to a family would be a series of ambiguous relationships. These are concerns are merely the tip of the iceberg, an iceberg submerged in very murky waters. What rights the clone would have? Would it have any of the rights of a normal person? Would it merely be treated as the results of an experiment, to be discarded or destroyed once it has yielded all of the useful scientific evidence it can?

Reproductive cloning is a dangerous game. It is no longer an issue of animal testing or lab rats; it is a matter of human life. To endorse such a practices or not make it a grave crime would be making a mockery of the sanctity of human life,<sup>16</sup> the right to bodily integrity<sup>17</sup> and the concept of the family<sup>18</sup>, all guaranteed by the constitution. It would be a failure of the state to uphold the fundamental rights guaranteed to all by the Constitution. Reproductive cloning is wrong-full stop. It has been banned or criminalized in all other jurisdictions and this ought to be the position here. It is recommended that any efforts to carry out such a procedure within this jurisdiction be punishable as a criminal offence with a severe sentence attached.

### **Stem Cell Research using Surplus IVF Embryos**

The decision as to whether or not this type of research ought to be permitted is more difficult. As already pointed out stem cell research involves the harvesting of embryonic stem cells from an early embryo in order for research as to their efficacy to be carried out. Scientists believe these stem cells may hold the key to providing cures to degenerative diseases such as Parkinson's' disease, Alzheimer's' disease and cancer. The moral and legal issues in this area derive from the fact that the harvesting of the stem cells destroys the embryo. Therefore the question which must be asked in respect of this type of research is- Are these early embryos afforded the right to life?

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<sup>15</sup> Ibid.

<sup>16</sup> Article 40.3 of Bunreacht na hÉireann.

<sup>17</sup> Ibid.

<sup>18</sup> Article 41.1 of Bunreacht na hÉireann.

The Roman Catholic Church claims that all life is sacred and must be protected from the time of conception.<sup>19</sup> The reasoning behind this view is that from the point of conception the embryo, in whatever form, is a person and so its right to life should be guarded as with all other persons. This is a somewhat romantic view and one which society cannot reasonably claim to subscribe to. It is a fact that a very high percentage of conceived embryos perish in the body prior to implantation and indeed even in more advanced pregnancies where a woman miscarries or the pregnancy fails through complications there is no public mourning of the loss of these embryos or babies. Of course this is not to suggest that such a loss is not traumatic for the family, it is a time of great grief. But nonetheless society does not hold the death of an embryo in early development in near the same regard as a baby in the late stages of pregnancy or post birth.

It is also worth noting that the 'morning after pill' is permitted in this jurisdiction. This pill effectively destroys the embryo.<sup>20</sup> In permitting the use of the morning after pill the government and society are suggesting the right to life is not absolutely given to the very early embryo.

The embryos used are destined for destruction, not because they are an experiment but that they are left over from IVF treatment, a legal procedure. At the point of their creation they were intended for life but this life is contingent on being selected for implantation. Since they are never going to become implanted and develop into a living person, they are merely to be destroyed. Should their creation not be allowed to serve some purpose?

It is not denied that the IVF embryo is a potential person but should this in itself mean it has a right to life? A person below the age of 18 is a potential voter but this does not extend to them a right to vote. Just as a law student is a potential lawyer but this does not give them a right to practice law. These rights are contingent, respectively, upon reaching 18 or becoming qualified as a barrister or a solicitor. The right to life of an embryo ought to be contingent upon it becoming implanted in the womb of its mother. Furthermore it is widely accepted in the scientific world that the embryo only begins to develop a primitive streak at around 14 days. If the scientific view was to be followed as it seems to be in

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<sup>19</sup> *An Opportunity Not To Be Lost*, Catholic Communications Office, Dublin, 2002.

<sup>20</sup> The 'morning after pill' works in two ways. First it aims to prevent ovulation and thus fertilisation and secondly should the egg become fertilized the embryo is prevented from implanting in the uterus and therefore the embryo dies in the body.



many jurisdictions, the harvesting of stem cells would only be permitted on embryos below 14 days old.

It would be recommended that the scientific view be taken in respect of surplus IVF embryos being made available for research.

Of course the strict line laid down by the EU should be taken with strict laws governing the area. Among other things the donor parents must give their fully informed consent, they must not receive any monetary reward, they must remain anonymous and the organizations conducting the research must undergo strict checks and testing by a board of ethics to ensure that only genuine research projects receive licensing and the activities of these organizations must be constantly monitored by this board to ensure that no rogue activities are undertaken.

### **Therapeutic Cloning**

This area is very much the middle ground between the issue of reproductive cloning and stem cell research using surplus IVF embryos. The public policy considerations in relation to therapeutic cloning are not quite as compelling as with reproductive cloning. Here the cloning process would begin as for reproductive cloning but the development of the cloned embryo would end at the blastocyst stage<sup>21</sup>. The embryo would be created only to harvest stem cells. Generally this type of cloning is only used where there is a shortfall in the amount of surplus IVF embryos being donated but is sometimes used to research the development of early embryo and genetic research.

There are many people who subscribe to the view that this type of cloning is acceptable. The embryo is treated the same way as a surplus IVF embryo in that the stem cells are removed at an early stage which ends development of the embryo. The stem cells are used for valuable research and this is no different than using the embryos left over from IVF. This is not so.

The creation of an embryo for the express purpose of destroying it is contrary to all the laws of nature. It is believed that this type of cloning may be putting the country on a

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<sup>21</sup> The 'blastocyst stage' is reached between the five and fourteen day mark when the embryo is a small, hollow ball of cells.

slippery slope. If the cloning of embryos is allowed, what then if one ‘accidentally’ becomes implanted? Criminal sanctions or not, the damage has been done.

It is not that there is no alternative. Surplus IVF embryos are a viable option and they are created originally for human reproductive purposes. There are those who argue that the cloned embryos would only be used where there is a shortfall in the number of IVF embryos donated but this can hardly be a reason for justifying such a procedure. Indeed it ensures more value is attached to those IVF embryos which are donated and emphasis will need to be placed on refining techniques in order to ensure there is no wasting of donated embryos. For this reason it is recommended that the cloning of embryos for use research be banned and a criminal sanction attached to it, albeit not so severe as the punishment for attempts at reproductive cloning. However this view might be reviewed in the future should the position regarding availability of embryos changes.

### **Conclusion**

“...Rights given by the Constitution must be considered in accordance with concepts of prudence, justice and charity, which may gradually change and develop as society changes and develops and which fall to be interpreted from time to time in accordance with prevailing ideas....The Constitution did not seek to impose for all time the ideas prevalent or accepted with regard to these virtues at the time of its enactment.”<sup>22</sup>

Thus the law must move with the times. This may be a controversial area but regardless of the feelings of the public and the government must be legislated for in one way or another in the very near future.

The Constitution of Ireland upholds the sanctity of life and a failure to expressly ban the cloning of human embryos for any purpose would be a failure to uphold these rights. There are no reasons to clone human. After millions of years it is safe to say the human race has accepted the ritual of conventional reproduction. To interfere with the most natural of processes can only result in bad things. But in recognizing the dangers of modern science the Oireachtas must also acknowledge its rewards. The right to life as guaranteed by the Constitution is a prominent consideration but another consideration

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<sup>22</sup> per O’Higgins C.J. *The State (Healy) v Donoghue* [1976] IR 325 AT 347

must be the benefits of stem cell research. No entity shall be denied the right to life, save for the common good.

The human race has been handed a gift in the discovery of the medical potential of stem cells. But in order to explore the full potential of this therapeutic gold the proper legislation must be put in place. The potential for abuse of all these areas are far too great. Without legislation and a growing bio pharmaceutical presence this jurisdiction will become a cloning playground. Each day Ireland is 24 hours closer to this problem dropping into her lap. Legislation must be forthcoming. This is not the time to be scared of public controversy; it is the time to embrace it.

After all there is little point in closing the stable door after the horse has bolted.

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