

Volume 1 | Number 2 (Fall/Winter 2015)
www.jheaonline.org
ISSN 2474-2309
doi:10.22461/jhea.2.7162



CASE STUDY

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This article appeared originally in The Internet Journal of Catholic Bioethics (Spring 2008).

MICHAEL L. SIMON, M.S.

Saint Joseph's University, Philadelphia, Pennsylvania, U.S.A.

*Address correspondence to: Saint Joseph's University, 5600 City Ave, Philadelphia, PA 19131, U.S.A.

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REVIEW ARTICLE

Should Unclaimed Frozen Embryos be Destroyed or Used for Stem Cell Research?

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MICHAEL L. SIMON, M.S.

Saint Joseph's University, Philadelphia, Pennsylvania, U.S.A.

Abstract: *The research material used in this paper will demonstrate unclaimed frozen human embryos should not be used for stem cell research. A case study will demonstrate ethical issues. The research will include medical, legal and ethical issues surrounding the disposition of unclaimed frozen embryos. The medical issues will state embryos are a clump of cells that can be used for this research and will discuss the success and promise of stem cell research. The medical aspect will also introduce other sources of stem cells. The legal issues discussed surround consent problems for the disposition of the embryos. The ethical issues will consider both philosophical and theological views. An argument using contemporary natural law will be presented supporting the fact that embryos are human and should be respected as such. Finally, a summary of my personal position and argument regarding the disposition of these embryos will be presented.*

Keywords: *natural law, three-point principles, frozen embryo, stem cell research.*

INTRODUCTION

The disposition of unclaimed frozen embryos remains an unresolved debate in the United States. It is of great importance to scientists, philosophers, researchers and health care that this issue is resolved. It is very important to health care, as it will affect cost, distributive justice of care, and the ethics of health care in this century. A study conducted by the American Society of Reproductive Medicine and the Rand Corporation found that approximately 400,000 unused frozen embryos are being stored in fertility clinics. Some couples are unaware they have leftover embryos due to over harvesting practices at fertility clinics. Other couples have stopped paying the storage bill after successful births. Some of these families have relocated, and fertility clinics are unable to locate them. Others have not responded to the fertility clinic's attempts to contact them about their embryos. Couples that are aware have four options available to them to decide what to do, if anything at all, with the remaining embryos. Couples can leave their embryos in storage, donate them to an infertile couple, donate them to research, or allow them to thaw and be destroyed. This is not always an easy decision for couples.

The literature will focus on the unclaimed embryos, and their disposition. A study conducted by the Society for Assisted Reproductive Technology, a Washington, D.C. agency that oversees about 94% of fertility clinics, reported that the nearest estimate of unclaimed frozen embryos in the United States is about 16,000, which is approximately 4% of all frozen embryos in the U.S. The review of the literature presents many different opinions, philosophies, facts, and considerations that affect the resolution of the unclaimed frozen embryos. Contemporary Natural Law and the Three Font Principle will be applied in this debate and will demonstrate only one resolution: unclaimed frozen embryos should not be donated for stem cell research, should not be donated to fertility clinics for other couples, should not be put up for adoption, or be destroyed as medical waste. The decision to allow unclaimed frozen embryos to die a natural death will reflect careful consideration of not only the embryos, but of all interest groups.

CASE

The Arizona Institute of Reproductive Medicine ran an advertisement in the Arizona Republic stating, "If you feel you have embryos or sperm stored with the Arizona Institute of Reproductive Medicine, please contact us immediately...all unclaimed specimens will be destroyed as of July 15." The 69-year-old founder, Dr. Robert Tamis, retired and the clinic workers contacted patients and offered them a choice to have the embryos implanted, transferred to storage at another clinic or be destroyed. A

worker at the clinic stated there were many clients that have not replied or have not been found. Destroying embryos leaves some doctors, ethicists, patients and scientists aghast. The scientific community would like to have the unclaimed embryos for stem cell research. Fertility clinics would like them to be donated to infertile couples. Others believe they should be thawed and discarded. The disposition of these embryos has stirred an intense debate by scientists, ethicists, philosophers, theologians, lawyers and the American public. In 1997, an ethics panel of the American Society for Reproductive Medicine concluded that clinics could destroy the unclaimed embryos after five years. There is no legal precedent for the Tamis clinic. Should unclaimed frozen embryos be donated for stem cell research or be destroyed?

SCIENTIFIC RESEARCH ISSUE

Michael Gazzaniga, Professor of Neuroscience at Dartmouth College, and a member of the President's Council on Bioethics referred to the early human embryo as "a clump of cells...the size of a dot on the letter i." Lee Silver, Professor of Molecular Biology at Princeton University, declared that the human embryo is not really a human life, that "embryo" and "life" has several meanings. Embryonic stem (ES) cells are primitive, undifferentiated cells that have the potential to become any cell; Pluripotent stem cells. These cells are removed from the blastocyst, which destroys the embryo. These cells are important to research, as they have the potential to become any cell. This opens the imagination to a plethora of possibilities for science, especially medicine. In particular, the treatments of diseases, the replacement of tissues and organs, toxicology and medication research and disease prevention, are of great interest to researchers. Currently, the promise of stem cell therapy is hindered by ethical, moral, and legal disputes. Science has found stem cells in many parts of the body that can have the same potential as embryonic stem cells. The discovery of alternative sources of stem cells that are comparable to embryonic stem cells have suffered from incomplete evidence of their biological versatility or have proved too rare or difficult to isolate to be of practical use. These discoveries include everything from menstrual blood, bone marrow, fat cells, amniotic fluid and testicular cells. Most studies, including research with mice, have shown some promise stem cells will be able to cure diseases; scientists remain optimistic. Scientists are just beginning to understand this research. Regenerative medicine envisions cures for Parkinson's disease, Alzheimer's, diabetes mellitus, heart disease, spinal cord injuries and a host of other conditions. The current response to very preliminary findings on the value of stem cell therapy is a resounding familiar tune. In the 1960's, scientists promised a war on cancer; pour money into research to beat cancer. The same is true for AIDS research. We will have a vaccine by the end of the century.

There are other sources of stem cells that scientists believe may be as promising as or better than embryonic stem cells, in that they would be grown for the donor. The donor would not reject the stem cell therapy. Adult stem (AS) cells are found in the placenta, cord blood, amniotic fluid, brain, pancreas, testes, bone marrow and almost anywhere in the body. These stem cells are rare and difficult to obtain. They do not possess the same potential as embryonic stem cells. (AS) cells are multipotent cells, meaning they can self-replicate and can produce two or more different cells. An example of a multipotent cell's ability obtained from blood is it can be directed to become a white blood cell, red blood cell or a platelet. If this approach to stem cell research becomes available, would the treatments be made accessible and affordable to everyone?

Somatic Cell Nuclear Transfer (SCNT) is a process to obtain embryonic stem cells. SCNT is a method of cloning. The nucleus of a donor somatic cell is transferred into the enucleated oocyte. The cell is cultured and allowed to grow into a blastocyst, and then the stem cells are removed. This process of obtaining stem cells has the potential to provide identical genetic therapy for the donor. The donor will not reject these cells, as they are grown from his own genetic sequence. This does create an embryo that has the potential to develop into a human. This is the technology used to create "Dolly". The shortage of oocyte donation impedes SCNT research. Since this approach to obtaining stem cells has the potential to develop into a human, are the cloned persons or organ donors?

Altered Nuclear Transfer (ANT) is similar to SCNT. This involves the transfer of a nucleus of a somatic cell into an enucleated oocyte. Before the nucleus is transferred into the oocyte, key genes are turned off or blocked to ensure that the egg will not produce a viable embryo. ANT does not create an embryo that has the potential to develop into a human; therefore, it is not justified to call it an embryo. This technology also depends on oocyte donation. Women donating their eggs for experimentation also raise ethical concerns such as recruitment, informed consent, and the medical risks of harvesting. Will this be affordable and available to everyone? Are the risks to the women donating their eggs acceptable risks?

Preimplantation Genetic Diagnosis (PGD) is a method of testing In-Vitro Fertilization (IVF) embryos for chromosomal disorders before they are transferred to the uterus. Once the embryo becomes a blastocyst; one of the cells is removed, without destroying the embryo, for genetic testing. The removed cell is called a Pluripotent stem cell that can reformat itself and go on to produce ES cells. The remaining seven cells left in the embryo are transferred to the uterus and can continue to develop into a human. Questions remain concerning potential problems later in life with IVF babies. Babies conceived through IVF have a slightly

increased risk of major birth defects compared to babies conceived naturally. The comparative birth defect rates are: 6.2% for IVF babies and 4.4% for naturally conceived babies. PGD creates ethical dilemmas concerning eugenics. Will this open the door for gene selection to create designer babies?

POLITICAL AND LEGAL ISSUES

For nearly 10 years, stem cell research has been at the center of public attention and the focus of ethical and legal controversies. In Europe, a great diversity of regulations prevails. Some countries completely prohibit human embryo research while others have a liberal position allowing human embryo research. In the United States, the current administration firmly opposes any research involving the destruction of human embryos. Further restricting ES cell research is limiting the research to ES cell lines created before 2001. This moved the political debate to the state level. In 2005, New Jersey announced plans to fund a \$150 million stem cell research institute with plans to raise an additional \$230 million. In the same year, Connecticut pledged \$100 million over ten years to support Stem Cell Research (SCR). California voters approved a \$3 billion fund for SCR and created the California Institute for Regenerative Medicine (CIRM). Distribution of the CIRM grants are held hostage by lawsuits challenging the constitutionality of the ballot initiative and by the National Institute of Health (NIH). Unless Congress passes a law that prohibits human ES cell research, individual states have the authority to pass laws to permit human ES cell research using state funds. The lack of support and oversight from the United States not only hinders the research, it abdicates responsible stewardship to individual states and private investment endeavors.

Legal statutes that guide ownership are confusing and complicated. Most states conclude that frozen embryos are not persons entitled to protection. Frozen embryos, stem cells and the process of isolating stem cells are property that is entitled to protection as property, but not entitled to rights of human beings. The disputes over possession are usually a result of divorce proceedings. Fertility clinics, currently, have couples sign consent for the disposition of unused frozen embryos. The clinic assumes possession of unclaimed embryos that lack prior agreements. The destruction of the embryos could be justified after a specific period of time because permanently frozen embryos are the equivalent of dead embryos. The clinic could not donate them to infertile couples, because of the “reasonable person standard”. What would a reasonable person consent to? A study conducted by the University of Pennsylvania in 2004, concluded 66% of the fertility clinics in the study did not destroy unclaimed embryos. The remaining 34% of the clinics did destroy unclaimed frozen embryos and disposed of them as biological waste.

AS cells, SCNT, ANT and PGD offer alternatives to ES cell research. Research restrictions on human embryonic stem cells in Europe, and more severe restrictions in the United States, inhibit the progress of human ES cell research. Federally funded scientists in the United States are banned from conducting research on human ES cell colonies created after 2001. The success of SCR shows some promise in mice. The success of stem cell therapy that has cured disease in mice may not be successful in human stem cell therapies. Evan Snyder, director of the stem cell program at the Burnham Institute in San Diego, warns, “The major caveat is that the research done with mice is exciting, but, unfortunately, we are starting to learn there is a big difference between mouse and human.”

All of the fore mentioned alternatives have ethical quandaries of their own. Science has yet to agree when a clump of cells becomes human. In 1979, Clifford Grobstein stated that an early embryo could develop into twins prior to 14 days; individualization had not occurred. He reasoned that because the individual was not present, the human being was not present prior to 14 days. Grobstein’s definition is still being used and published widely today by many scientists. Virtually every human embryologist and every major textbook of human embryology state that fertilization marks the beginning of the life of the new individual human being. The United Kingdom Human Fertilisation and Embryology Act (HFEA) permit investigation of therapeutic properties of embryonic stem cells with the provision that no embryo is subject to experimentation after the appearance of the primitive streak or after 14 days. HFEA also permits fertility clinics to destroy embryos after a 5-year waiting period.

PERSONHOOD

The classical definition of a person is a human being regarded as an individual. The term “person” is subject to dispute and re-interpretation based on alternate definitions. In the fields of philosophy, theology and bioethics, the definition of a person may exclude human beings who are incapable of certain kinds of thought, such as fetuses with incomplete brain development, embryos or adult humans lacking higher brain functions. The recognition of status as a person is known as personhood. Philosophically, personhood is defined by characteristics such as consciousness, the ability to reason, self-awareness and a capacity to communicate. Theologically, personhood requires a relational interpretation of what it means to be a person. Personhood is the ability to have relationships with other humans and God. The Catholic perspective describes the human persons as integrated body-spirit beings

created in the likeness and image of God (*Imago Dei*) with four integrated dimensions of human life: biological, psychological, social and spiritual. A human person must be treated with respect in such a way that recognizes his human dignity. In 1973, the United States Supreme Court ruled that a fetus becomes a person, with rights, when it survives outside of the uterus; [though] *Roe v. Wade*. Personhood cannot be defined by any one theory. Characteristics of personhood vary from discipline to discipline. Personhood must be a matter of conscience. The rules of conscience state when making moral judgments with a certain conscience, the judgment is made with no reasonable doubt of the correctness of the judgment. Reliance on the first reflex principle would, in the matter of personhood, solve a doubtful conscience. The morally safer choice would avoid evil and preserve moral goodness. The decision to choose the safer action preserves the integrity of what is perceived to be the truth. In this case, personhood must begin at fertilization.

PHILOSOPHICAL VIEW

The philosophical debate surrounding human embryo stem cell research is the question of personhood. Francis Beckwith states the functions of personhood are grounded in the essential nature of humanness, and because human beings are persons that maintain identity through time from the moment they come into existence, it follows that the unborn are human persons of great worth because they possess that nature as long as they exist. Peter Singer states an early human embryo is not a human individual who is a person. He contends that the potential of a human embryo existing in the laboratory is not the same as the one who is already implanted in the uterus. The embryo in the Petri dish lacks potential whereas the embryo implanted in the uterus has the potential to become a person.

Charles Krauthammer claims unrestricted embryonic research is on a very slippery slope. He states, “You don’t need religion to tremble at the thought of unrestricted embryo research. You simply have to have a healthy respect for the human capacity for doing evil in pursuit of the good.” Humans naturally test limits. He raises ethical issues that eugenics and embryo banking are immoral and may lead to the commercialization of human life. The principles of justice are based on treating all persons with fairness and equity and distributing the benefits and burdens of health care as fairly as possible in society. The benefits of SCR would be made available to all without regard to the ability to pay. The United States does not have a universal health care system. Currently, 16.3% of the United States population does not have basic health insurance. Others are under insured. Insurance companies may not cover therapies offered from SCR. Without federal funding, and therapies being developed by private companies, the cost of treatment may rise. Only those who could afford treatment would benefit from the research. Furthermore, other treatments may not be developed due to cost benefit measures. This would also limit who would benefit from the research. Globally, the unequal resources and the differences in basic health standards would also impede distributive justice.

THEOLOGICAL VIEW

Science and technology have made it possible to intervene in the process of procreation. The Catholic Church is recognized as an expert in humanity with a mission to serve civilization and life. The Church safeguards the values and rights of the human person. The Catholic moral perspective of the human person is conceived in terms of one’s ability to have relationships with other humans and with God. The human person is created in the likeness and image of God (*Imago Dei*), usually referring to the human intellect, the capacity for moral decision making, and the ability to rule over creation as created co-creators and stewards of the gifts of God. In Catholic theology, this doctrine is the foundation for other foundational principles such as human dignity and the sanctity and stewardship of life. The normative implications of human dignity impacts much of the Catholic moral thought as it pertains to a range of human life issues, including health care ethics. Human dignity cannot be granted by society, nor can it be legitimately violated by society. Every human being should be acknowledged as a valuable member of society. The principle of the sanctity of life stems from *Imago Dei* which implies that human life should be treated with great reverence and respect. The principle of stewardship requires human persons to appreciate what God has given them: the earth and human nature. God has given humans limited dominion over creation and responsibility for its care.

Based on the principles described in the Catholic Church’s teaching in *Donum Vitae*, the church states it is morally illicit to produce and or use living human embryos for the preparation of ES cells. The Congregation for the Doctrine of the Faith affirms from the first moment of its existence, the human being is to be respected and treated as a person from the moment of conception. To destroy a life is an intrinsic evil. The destruction of an embryo to prepare therapeutic interventions for another human is not justified. The therapeutic results of SCR cannot employ the destruction of life to reach its goal. A good end does not make right an action which in itself is wrong.

CONTEMPORARY NATURAL LAW AND THREE FONT PRINCIPLE

Natural Law is the rule of conduct which is prescribed to us by the creator in the constitution of the nature with which He has endowed us. According to Saint Thomas, natural law is nothing more than the rational creature's participation in the eternal law. In virtue of his intelligence and free will, man is master of his conduct. Natural law is the foundation of all human laws because it ordains that man shall live in society, society requires authority which possess the power to direct the members of society to the common good. The primary principle of natural law is to do good and avoid evil.

When facing a confusing moral decision, the three font principle aids in considering a moral judgment. The first question asks about the act itself. Consider if the action is initially good, bad or neutral. Next, evaluation of the circumstances may justify the deed. This evaluation includes foreseeable consequences and viable alternatives. Finally, what is the intention of the act? If one element of the act is evil, then the act cannot be a moral act.

Natural Law and the three-font principle applied to ES cell research have only one outcome. Humans seek to do good, and avoid evil; therefore, the act of destroying a human life must be evil. Destruction of a human embryo is evil. The termination of a life goes against natural law. Destroying an embryo to extract cells to promote the well-being of another or a society can be viewed as confusing. The intention is to improve the lives and health of society. This intention is a good intention. The circumstances, in which unclaimed frozen embryos are donated to research for the better good, must be thought out carefully. The consequences may open the slippery slope argument. The act itself is direct killing of a life. Since one of the three principles is evil, the whole act is evil. The good end can never justify the evil means.

CONCLUSION

Making moral judgments and seeking the good in an act is no simple task. There are no right or wrong answers to the questions posed, just moral judgments. When considering the disposition of unclaimed frozen embryos, we, as reasonable, rational, moral beings, must remember the first reflex principle to solve the doubt of conscience. We must follow the morally safer course. This means that life must begin from the very instant of its existence and end at its death. A human embryo is to be respected and treated with great reverence. The safer course in this decision is to say that life begins at fertilization.

The alternative ways to obtain stem cells should make ES cells a moot point. If the alternatives are just as promising as ES cells, then the alternatives should be utilized. The promise of the research at this time does not indicate the need to use ES cells. The alternatives have ethical issues that need to be addressed. The donation of unclaimed frozen embryos to SCR is immoral.

To answer the rest of the question posed is no simple task. If donating unclaimed frozen embryos to SCR is immoral; is simply destroying them immoral, too? It would appear to be that simple. At first, one would think that any destruction of a life would be evil. What should be done with the embryos; keep them frozen for a future time? This question poses more ethical debates. An argument was made stating that the indefinite future of the frozen embryos is equivalent to death; therefore, the embryos are already dead. In my opinion, they are considered a human life and should be respected as such.

The unclaimed embryos cannot be donated to infertile couples if there is no consent agreement made at the time of fertilization. Consent must be given to donate embryos to infertile couples. The "reasonable person clause" would also prevent adoption choices for the embryos. Adopting them also has ethical disputes.

Unclaimed embryos have no future. They have no quality of life. Since the quality of life has been frozen indefinitely, the sanctity of life must be evaluated. Keeping the embryos frozen, with no hope of a future, would indicate the best interest of the embryos would be to stop the treatment. It would be in the best interest of the embryos not to be kept alive without any hope for a future. Cryopreservation in my opinion would be considered extraordinary means. The burden on the society to keep the embryos, at this juncture, outweighs the benefit to the embryos. The embryos should be thawed and allowed to die a natural death, since they no hope for a future. The embryos would be treated with the greatest respect and reverence. Justification through the above moral principles, allows the unclaimed frozen embryos to thaw and die a natural death. Legislation should be developed to help facilitate acceptable waiting periods for the embryos to be claimed before removing them from Cryopreservation. Statutes must be developed to set standards to support the clinics' decisions to allow the embryos to thaw.

This point of view may show dissent from the teaching of the Catholic Church. The guidelines for dissent describe four points to consider: affirm the teaching of the Church, be concerned by the means, contribute toward reformulating the teaching and count the cost. The Catholic Church teaches taking a human life is evil. The destruction of a human embryo is taking a human life and therefore is evil. In the case of unclaimed frozen human embryos, allowing them to die a natural death with dignity is not direct killing. The United States Conference of Bishops has developed directives for Catholic Health Care Services. The directives that

discuss the care for the dying describe extraordinary means. Cryopreservation would be considered extraordinary means for these embryos. This would be congruent with the teaching of the church regarding quality and sanctity of life issues. The moral principle of best interest also applies to this decision. The means to allow them to die naturally is not evil; it is a fact of being human. The church would debate this decision; therefore, this would contribute toward reformulating the teachings of the church. Finally, the cost would be no different than a spontaneous abortion due to a miscarriage of a pregnancy.

Unclaimed frozen embryos should not be donated to SCR; they should be allowed to die with dignity.

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