# **Ethics of Stem-Cell Research: A Framework for Ethical Dialogue Regarding Sources of Conflict**

Francis C. Dane, James V. Finkbeiner Endowed Chair in Ethics & Public Policy, Saginaw Valley State University

#### Abstract

A framework for dialogue concerning stem-cell research is presented. Based on the ethical principles that are applied to all research involving human subjects--respect for persons and their autonomy, beneficence and nonmaleficence, justice, trust, and fidelity and scientific integrity—the framework is used to argue that we must move beyond single-issue discussions in order to avoid including stem-cell research in the list of topics for which attitudinal positions have become too polarized to enable rational discussion. Neither a favorable nor unfavorable position toward stem-cell research is adopted; instead, an effort has been made to present the ethical issues to be considered as individuals, separately or collectively, work toward attaining an informed, rational position on the ethics of stem-cell research.

## Introduction

One need hardly point out that Darwin's (1859) "Origin" produced controversy from its first appearance. Equally obvious is the fact that, however much value scientists place on evolutionary theory as an explanatory mechanism, the theory remains controversial outside of scientific circles and within nearly every venue in which scientific circles overlap with other areas of inquiry. The controversy exceeds even that of Galileo's (1632/1967) heliocentric viewpoint in his *Dialogue*, prompting Stephen Gould to claim the controversy has reached the point at which "the very integrity of education hangs in the balance" (Alters and Alters 2001, p. 1). Indeed, evolution may well be the only scientific theory about which scientists have felt compelled to write a book to inform educators about how to deal with "a war within scientific classrooms" (Alters and Alters 2001, p. 14). Public attitudes about evolution, similar to those concerning abortion and capital punishment, have become polarized such that most people hold a position that allows little latitude for rational consideration of informational contrary to their position (Deaux, Dane, and Wrightsman 1993). The purpose of the present paper is to present a framework for discussing the ethics of stem-cell research in hopes of preventing its joining the ranks of polarized attitudes.

I do not wish to imply that stem-cell research is not yet controversial. Indeed, the variety of governmental positions on various types of stem-cell research provides but one indication of extent to which disagreements exist within the worldwide community, and sometimes with a single nation. The General Assembly of the United Nations failed to reach agreement on a treaty regarding somatic cell nuclear transfer, also known as SCNT (Caulfield and von Tigerstrom 2005). Caulfield and Bubela (2007) report that Ireland and Austria forbid any research involving embryos while Italy is moving toward a similar ban. United Kingdom, Japan, Sweden, and South Korea, in contrast, allow virtually all types of stem-cell research, while France and Canada allow some types of stem research; SCNT was, however, recently made a criminal activity in Canada. The President of the United States froze embryonic stem-cell research funding, including SCNT (Bush 2001), after which California voters responded by approving a \$3 billion bond to fund fetal stem-cell research, including SCNT (Californians approve stem cell research funding 2004). Aramesh (2007) reports that Iran permits stem-cell research, including SCNT, and notes that Muslim scholars prohibit only research directed toward reproductive cloning. (The latter position is in line with virtually all bioethicists.) These disagreements notwithstanding, most political jurisdictions have no explicit policy regarding stem-cell research; in all jurisdictions, the absence of a framework for dialogue prevents many from considering rationally the ethical aspects of stem-cell research. If we are to reach consensus regarding the ethics of stem-cell research, we must have a single framework, a common language with which to discuss differences.

It is important that any framework for discussing the propriety of stem-cell research be presented at the conceptual or principled level. Ethical discussions are not about whether or not a rule or law has been broken; such are moral, legal, or administrative decisions. Instead, ethical discussions are about whether or not a rule or standard is worthwhile or about which of several, incompatible rules should be given priority (e.g., Dane and Parish 2006; Schroeder 2000; Singer 2000). As has been illustrated, rules can change from one jurisdiction to another or, as noted below, from one set of religious rules to another. Principles, in contrast, tend to be more generalizable, more applicable to a wider variety of situations, locations, and topics. Consider, for example, the variety of religious positions regarding the beginning of human life, which range from conception to an infant's first cry to as long as several years after birth (Morowitz and Trefil 1992). Shifting to a more principle-based framework enables one to determine how to protect the autonomy of an individual (Kant 1788/1997) independent of fixating upon an concrete, operational definition for establishing a single point during a continuous developmental process.

It is equally important that any framework for dialogue be amenable to every type of stem-cell research. It is inefficient to argue the same principles once for research on adult or umbilical cord stem cells, a second time for research on fetal or embryonic stem cells, and yet a third time for stem cells produced from SCNT. More important than efficiency is the fact that all types of stem-cell research have the same basic research goals of furthering knowledge in cell biology, molecular biology, endocrinology, and other scientific areas, as well as the same therapeutic goals with respect to surgery, fetal medicine, transplantation medicine, immunology, etc. (Kiessling and Anderson 2007; Theise 2003). Thus, common goals for research, basic and applied, require a common framework for evaluating the propriety of that research.

## **Principles of Human Subjects Research**

Beginning with the Nuremberg Code (Nuremberg Military Tribunal 1949), medical researchers who included human subjects in their research began developing a set of principles that eventually would be applied to all types of human-subjects research, including noninvasive

3

research, such as medical records or behavioral observation, as well as research with more indirect human involvement, such as research on tissue samples (Gorman and Dane 1994). As development continued, the primary principles were eventually laid out in what became known as the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). Eventually, five principles were established and widely adopted across multiple disciplines in which research with human subjects occurs (e.g., Dane 2006). The principles are respect for persons and their autonomy, beneficence and nonmaleficence, justice, trust, and fidelity and scientific integrity. The principles now guide the conduct of all human-subjects research and have been incorporated in governmental regulations worldwide (Office for Human Research Protections 2007). I argue that these principles also serve as a comprehensive framework for a dialogue on the ethical considerations concerning stem-cell research.

#### Respect for Persons and their Autonomy

Voluntary, informed consent was established as the primary and essential condition under which humans should be involved in research (Nuremberg Military Tribunal 1949), but it was soon realized that an inviolate principle would prevent those unable to give consent from benefiting from research; neonatal and pediatric medical research, for example, would be impossible or would merely involve generalizations from adult research. The principle, while remaining essential and primary, came to include consent by proxy (World Medical Association 1964); parents or other legal guardians could give permission for their charges to participate in research.

Whether one's beliefs include attributing personhood or some similar quality to zygotes, stem cells, or the product of SCNT, it is clear that such cells are themselves incapable of

4

providing consent to research; cells do not have independent autonomy. It is therefore essential that parents/guardians or donors be given the opportunity to provide voluntary, informed consent. In the case of SCNT, donors should be informed of the eventual procedures to be applied to their cellular material. Without such consent, application of additional ethical principles becomes moot. However, voluntary consent, albeit by proxy, is merely the beginning of the ethical debate that should be engaged.

# Beneficence and Nonmaleficence

This principle goes beyond "do no harm" (nonmaleficence) to include a requirement to accomplish some good (beneficence) through research; there must be promise of a net social benefit before any research is undertaken. Although the potential benefits of stem-cell research are sometimes overstated (Theise 2003), they can be stated without hyperbole and are substantial (Kiessling and Anderson 2007). The dialogue, however, must also include the harms (real and potential) that result from stem-cell research and the extent to which the potential social benefits outweigh those harms.

Although there is no agreement about when a developing zygote attains ensoulment, personhood, etc., there are individuals who believe that such takes place prior to the blastula stage and much stem-cell research, therefore, constitutes an insult to their beliefs. This harm, while not physical, must be incorporated into the cost-benefit analysis required by this principle; to do otherwise would lead to a much greater potential harm, a lack of respect for all religious or cultural beliefs. Because scientific research is perhaps the most global enterprise of humanity, it is not logical that any one set of beliefs should be held paramount or determine a common definition of harm; to do so also would lead to a lack of respect for other religious and cultural beliefs.

#### Forum on Public Policy

Another potential harm, particular to SCNT but applicable to all stem-cell research, is the potential for stem-cell research to lead to research directed toward reproductive cloning, which, as noted above, is almost universally considered unethical (Blackford 2007). The potential for techniques to be applied to reproductive cloning, therefore, must also be included in the cost-benefit analysis of stem-cell research.

#### Justice

When applied to research, the principle of justice refers to a fair distribution of risks and benefits realized from a research project, program, or area. It is unethical, for example, to include only prisoners or other institutionalized individuals in research merely because they are conveniently recruited, unless the research results will benefit only those individuals. Similarly, a fair distribution of risk would seem to require those countries or regions in which stem-cell research is not allowed to be willing to forego, or at least wait "last in line," for any therapies that are developed from the locally prohibited research completed in other countries. Otherwise, the prohibitive countries or regions are unjustly allowing others to accept the risks associated with stem-cell research while reaping risk-free benefits. However, many individuals residing in prohibitive locations are "voting with their feet," either traveling to other locations for experimental therapies and/or placing themselves on waiting lists for yet-to-be-developed therapies (Enserink 2006; Thompson 2006). Those establishing policy, and those who wish to inform policy makers, must rationally consider the justice of any given policy concerning stemcell research.

#### Trust

Trust applied to research, including stem-cell research, centers around the extent to which powerful institutions and individuals meet the responsibilities assigned by those who empowered

6

them. Taxpayers and other donors, for example, expect that educational and other knowledgedeveloping institutions will, in fact, educate and develop knowledge. In the United States, for example, the National Institutes of Health and the National Science Foundation represent a research structure designed to serve as the "primary Federal agency for conducting and supporting medical research" (National Institutes of Health 2007) and "to promote the progress of science; to advance the national health, prosperity, and welfare ..." (National Science Foundation 2007), respectively. We must consider the extent to which allowing or prohibiting stem-cell research would enable these institutions to fulfill their missions. As well, each political jurisdiction must consider the extent to a prohibitive position on stem-cell research results in a loss of scientists to other, permissive jurisdictions (Kahn 2001). Similarly, permissive jurisdictions need to be prepared for the emigration of scientists interested in pursuing careers in stem-cell research.

In addition, those who support such institutions should expect that neither the institutions nor the knowledge developed through them will be used for political purposes (Cf., George and Cohen 2006). Much like the controversy concerning evolutionary theory (Alters and Alters 2001), stem-cell research has resulted in numerous, unfounded claims, on both sides of the controversy, that are produced for political purposes rather than to enhance understanding or enhance rational dialogue about ethical issues (Gilbert, Tyler, and Zackin 2005). Such claims undermine the trust that institutions and individuals are obligated to maintain.

## Fidelity and Scientific Integrity

The principle embodied in the above phrase refers to the obligations of scientists by virtue of their being scientists; specifically, scientists have a dual obligation to develop new knowledge and to consider the ethical implications of that activity (Cook 1981; Dane 1990;

Mindick 1982). To the extent that we are training molecular biologists, immunologists, and other scientists whose disciplines may involve stem-cell research (Kiessling and Anderson 2007), we need to consider how faithful we are to their training with respect to prohibiting them from conducting research in the very areas in which they are trained. Of course, no one should be required to engage in research he or she finds morally distasteful, but the obverse involves respecting individual's decisions to fulfill the responsibility engendered from reception of training. A position with regard to stem-cell research must be consistent with a position regarding training individuals in areas dependent upon stem-cell research for advancement of knowledge.

#### Conclusion

The five principles that have long been associated with research involving human participants--respect for persons and their autonomy, beneficence and nonmaleficence, justice, trust, and fidelity and scientific integrity--provide a framework with which to engage in rational dialogue concerning the ethics of stem-cell research. Far from being as simple as the discussion of whether or not zygotes or blastulae are "persons" or have souls, the ethical issues regarding stem-cell research comprise a significantly more complicated milieu that includes the very foundation of scientific enquiry. Those who wish to simplify the debate do a disservice to society. Stem-cell research is controversial, and we owe it to ourselves to consider the full range of ethical implications in our attempts to resolve the controversy.

#### References

Alters, Brian J., and Sandra M. Alters. 2001. *Defending evolution in the classroom: A guide to the creation/evolution controversy*. Sudbury, MA: Jones and Bartlett.

Aramesh, Kiarash. 2007. An Islamic view to stem cell research and cloning: Iran's experience. *The American Journal of Bioethics* 7 (2):62-63.

- Blackford, Russell. 2007. Slippery slopes to slippery slopes: Therapeutic cloning and the criminal law. *The American Journal of Bioethics* 7 (2):63064.
- Bush, George W. 2001. Fact Sheet: Embryonic Stem Cell Research. Washingston, DC: Office of the President of the United States.
- Californians approve stem cell research funding. 2004. USA Today, November 3.
- Caulfield, T., and Tania Bubela. 2007. Why a criminal ban? Analyzing the arguments against somatic cell nuclear transfer in the Canadian Parliamentary debate. *The American Journal of Bioethics* 7 (2):51-61.
- Caulfield, T., and B. von Tigerstrom. 2005. Globalization and biotechnology policy: The challenges created by gene patents and cloning technologies. In *Globalization and health: Challenges for health law and bioethics*, edited by B. Bennet and G. F. Tomossy. New York: Springer.
- Cook, Stuart. 1981. Ethical implications. In *Research methods in social relations*, edited by L. H. Kidder. New York: Holt, Rinehart and Winston.
- Dane, Francis C. 1990. Research Methods. Pacific Grove, CA: Brooks/Cole Publishing Company.
- ———. 2006. Ethical Issues in Statistical Analyses: An Argument for Collective Moral Responsibility. C-Stat News 2 (3):1, 3, 4.
- Dane, Francis C., and David C. Parish. 2006. Ethical Issues in Registry Research: In-Hospital Resuscitation as a Case Study. *The Journal of Empirical Research on Human Research Ethics* 1 (4):69-75.
- Darwin, Charles. 1859. On the Origin of Species by Means of Natural Selection, or the Preservation of Favoured Races in the Struggle for Life. London: John Murray.
- Deaux, K., Francis C. Dane, and L. S. Wrightsman. 1993. *Social psychology in the 90s*. 6 ed. Pacific Grove, CA: Brooks/Cole Publishing.
- Enserink, Martin. 2006. Selling the stem cell dream. Science 313 (5784):160-163.
- Galilei, Galileo. 1632/1967. *Dialogue Concerning the Two Chief World Systems, Ptolemaic and Copernican.* Translated by S. Drake. 2 ed. Berkeley, CA: University of California Press.
- George, Robert P., and Eric Cohen. 2007. A Clarifying Five Years: Stem-cell politics under a microscope [Website]. National Review Online, August 9 2006 [cited May 31 2007]. Available from http://article.nationalreview.com/?q=ZTYzNDU4MjgwNDE1MzFhYjk4YzMyZDdlYWIwMmVmZDc=.
- Gilbert, Scott F., Anna L. Tyler, and Emily J. Zackin. 2005. *Bioethics and the new embryology*. Sunderland, MA: Sinauer Associates.
- Gorman, Holly M., and Francis C. Dane. 1994. Balancing methodological rigour and ethical treatment: The necessity of voluntary, informed consent. In *Animal and Human Experimentation*, edited by P. P. DeDeyn. London: John Libbey & Co.
- Kahn, Jeffrey P. 2007. *Stem cells and a new brain drain* [Website]. CNN.com, July 9 2001 [cited May 31 2007]. Available from http://archives.cnn.com/2001/HEALTH/07/23/ethics.matters/.
- Kant, Immanuel. 1788/1997. Critique of practical reason. Translated by M. Gregor, Cambridge Texts in the History of Philosophy. Cambridge: Cambridge University Press.
- Kiessling, Ann A., and Scott C. Anderson. 2007. *Human embryonic stem cells*. 2 ed. Sudbury, MA: Jones and Bartlett.
- Mindick, B. 1982. When we practice to deceive: The ethics of metascientific inquiry. *The Brain and Behavioral Sciences* 5 (2):226-227.
- Morowitz, H. J., and J. S. Trefil. 1992. *The facts of life: Science and the abortion controversy*. New York: Oxford University Press.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Washington, DC: Author.
- National Institutes of Health. 2007. *About NIH* [Website] 2007 [cited May 31 2007]. Available from <u>http://www.nih.gov/about/index.html#mission.htm</u>.
- National Science Foundation. 2007. *NSF at a glance* [Website]. National Science Foundation 2007 [cited May 31 2007]. Available from <u>http://www.nsf.gov/about/</u>.
- Nuremberg Military Tribunal. 1949. Trials of war criminals before the Nuremberg military tribunals under Control Council Law No. 10. Vol. 2. Washington, DC: U.S. Government Printing Office.
- Office for Human Research Protections. 2007. International Compilation of Human Subject Research Protections, edited by U.S. Department of Health and Human Services.
- Schroeder, William R. 2000. Continental Ethics. In *The Blackwell Guide to Ethical Theory*, edited by H. LaFollette. Cambridge: Blackwell.
- Singer, Peter. 2000. Writings on an ethical life. New York: HarperCollins.

# Forum on Public Policy

Theise, N. 2003. Stem cell research: Elephants in the room. *Mayo Clinic Proceedings* 78:1004-1009. Thompson, Andrea. 2006. A barbaric kind of beauty. *Daily Mail*, August 7. World Medical Association. 1964. Declaration of Helsinki. *British Medical Journal* 313 (7070):1448-1449.

Published by the Forum on Public Policy Copyright © The Forum on Public Policy. All Rights Reserved. 2006.