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Developments in Biotechnology: Ethical Perspectives

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Introduction

Several new developments in biotechnology have been introduced in our generation, for example, organ transplants, chemotherapy for cancer treatment, cyclosporin to reduce reaction of immune system, in-vitro fertilization and embryo transplant, research with fetal tissue, and implantation of fetal tissue, research upon human embryos not yet implanted in the womb. Many other new techniques or therapies could be cited. Clearly, all these developments are possible, but are they beneficial for individuals and for the human community?

Discerning whether these new developments are beneficial for individuals and the human community is the work of ethics. Ethics is not an arcane discipline, separate from science and scientists. Rather it is an integral part of scientific endeavor, and a responsibility of every scientist, because scientists and sciences should not seek to develop and produce the possible unless it is also beneficial for human beings and for society. Because scientists have ethical deliberation as part of their responsibility, they often benefit from collaboration with people who devote more time to ethics. Ethicists provide information to scientists which enables them to make beneficial decisions in regard to the effect of medicine and science upon culture and individual persons. Thus, an ethician is something like a midwife; not intimately involved in the generation or birth of new developments of medicine and science, but facilitating generation and birth by providing information and insight which help scientists and physicians make decisions which are beneficial for individuals and the human community.

In this presentation, I shall select one new development of biotechnology, research on human embryos, and use it to illustrate potential ethical approaches to biotechnology. I shall present the ethical

evaluations of research on human embryos offered by four different scientific study groups,[1] point out the different conclusions reached by these study groups, and make some observations concerning their ethical methodology. The scientific study groups which have published reports on this topic are:

a) Committee of Inquiry into Human Fertilization and Embryology (The Warnock Committee) in the United Kingdom, 1984;[2]
b) The Senate Select Committee on The Human Embryo Experimentation Bill, Australia, 1985;[3]
c) The Bioethics Summit Conference representing seven member countries of the Economic Summit Conference, 1987;[4]
d) A study prepared by the Ministry of Justice in West Germany, 1988.[5]

I. Embryos and Research

The human embryo results from penetration of a mature ovum by a sperm, the chromosomes from male and female combining to form a new and unique genetic identity.[6] Embryo research in general refers to research performed upon a fertilized ovum, in any stage of development, up to the observation of human form. Various other terms may be used to describe specific stages of development in the embryo; for example, morula, zygote, blastocyst or fetus. Though it is possible to conduct research upon the embryo in any stage of development, the stage of development under discussion by the scientific study groups is the initial time of development, up to about 14 days of existence. Moreover, in this study we are concerned with research upon embryos which have been generated in vitro, that is, resulting from union of ovum and sperm in a petri dish and with no intention of transferring the fertilized ovum into a womb. The source of embryos for this type of research is two-fold. Some result when more embryos are generated in vitro than can be transferred safely into the woman's womb. These are called "spare" or "extra" embryos. However, the fertilization of ova with the express purpose of using them for research is also countenanced by some researchers. At present, embryos generated in vitro may be sustained outside the womb for about 10-14 days, however, we can envision this time being extended indefinitely through the proper technology. In discussing the living entity resulting from union of sperm and ovum, some wish to use the term "pre-embryo" to avoid the ethical discussions arising from the term "human embryo." The term pre-embryo was used, for example, in the Warnock Committee Report. As one member of the Warnock Committee indicated, the term was introduced to avoid contention over the issue proposed for study.[7] If there were such a thing as a "pre-embryo", justifying research upon it would be much easier than justifying research upon human embryos. But the term pre-embryo is not a stage of pre-human development. As the Australian Committee stated: "No marker event in the development of the human embryo carries such weight that different principles should apply to distinguish the

fertilized ovum from that which all would agree is a human subject."[9] Hence, once fertilization occurs, the scientific designation for the resulting entity is "human embryo".

The Australian Committee also outlines the scientific knowledge concerning the human embryo:

> While it may not be possible to achieve agreement, either among scientists or others, on the complete set of attributes of this entity formed from the fusion of sperm and ovum, it may be of assistance to establish those attributes for which there is general agreement; that is, to achieve a minimum description of the human embryo. Two universally accepted attributes are that the fertilized ovum has 'life' and that it is genetically human (i.e., it is composed of genetic material entirely from the species *Homo sapiens).* It is also generally agreed that it is an entity (a centrally organized unit which has a purposeful independent function as opposed to an organ or tissues). It also has developmental potential (whether that may progress to little more than cleavage, or to birth and on to subsequent adulthood).[9]

What is Research?

Research is generally understood to involve the testing of a hypothesis with no foreseen certainty of the result, permitting conclusions to be drawn and thereby contributing to generalizable knowledge.[10] The generalizable knowledge derived from research is expressed in theories, principles and statements of relationship. For our purposes, the most important distinction in regard to embryo research is whether it is therapeutic or non-therapeutic. Therapeutic research is designed to provide a curative or diagnostic benefit for the subject of research. Non-therapeutic research does not provide a benefit to the subject, but rather is designed to provide new knowledge which may benefit some other subject in the future.

Thus, if this categorization is applied to research involving human embryos, *therapeutic research* on an embryo is carried out with the aim or object of acting in the best interests of the embryo which is the subject of the procedure, for example, correcting genetic defects. Obviously, therapeutic procedures may also produce knowledge which is beneficial to others, or helpful in other fields of medical practice or research, but this is not the primary purpose of the procedure, taken as a total human action. At present, there do not seem to be any research projects designed for embryos which will never be introduced into a womb which could be designated as therapeutic, or beneficial for the individual embryo.

Non-therapeutic experimentation does not directly benefit the individual embryo undergoing the procedure. Rather, knowledge gained from this type of research may ultimately benefit future embryos by advancing the understanding of human generation or by improving medical therapy for genetic deprivation. For example it was claimed in hearings before the various study committees that such non-therapeutic research would provide valuable information in regard to:

- verification of the technique of freezing of ova;
- verification of the technique of microsurgical injection of sperm nuclei into ova;

— development of new contraceptives;
— diagnosis of genetic and developmental abnormalities;
— the study of embryo toxicity and teratogenesis;
— the study of carcinogenesis;
— treatment of disorders through transplantation of embryonic tissue cultures;
— genetic engineering;
— reduction in the number of spontaneous abortions.

The scientific validity of some of these examples was questioned by other witnesses. But all witnesses agreed that non-therapeutic experimentation on an embryo is, at least for the present, intrusive and destructive of that embryo.

II. How Do Various Scientific Groups Evaluate Embryo Research from an Ethical Perspective?

All the aforementioned study groups admitted that an embryo is a discrete entity, is genetically human and "must be accorded great respect."[11] Moreover, there is no disagreement among the study groups in regard to therapeutic research upon human embryos. If the research is therapeutic — that is, if the human and social future of the embryo is respected and curative or diagnostic results are intended — then the research would be acceptable.

In regard to non-therapeutic research upon embryos however, great disagreement exists. The Australian study group declared:

> The Committee concludes that the respect due to the embryo from the process of fertilization onwards requires its protection from destructive non-therapeutic experimentation. The Committee recommended that the principle protecting the embryo from destructive non-therapeutic experimentation be adopted by the Senate in its consideration of this matter.[12]

In Germany, the thinking of many scientists and legislators is in accord with this statement. The Ministry of Justice for example, recently recommended legislation which would make it a criminal offense to engage in any research that could be considered non-therapeutic for a human embryo.[13]

The United Kingdom study group recommended that non-therapeutic research be permitted up to 14 days from fertilization.[14] The International Committee recognized the "preciousness of the human embryo" but allowed non-therapeutic research if it were "regulated by appropriate guidelines administered by a competent authority.[15]

III. Why Different Evaluations?

Why the difference of ethical evaluation for non-theraputic research upon human embryos? The difference does not rest in a radical disagreement over the nature of the human embryo, nor is there disagreement in regard to the value of the knowledge which might be gained from this type of research. There is severe disagreement however in

regard to protecting the human embryo from harm and destruction if useful scientific knowledge can be gained from research. What rights of the embryo must be respected in face of the rights of the human community to scientific knowledge? In discussing this conflict of rights, some scientists use a utilitarian approach, emphasizing the good of knowledge to be attained, rather than the good of the subject involved in the research. In this system, the goal of ethical deliberation is to "balance rights"; no inalienable rights of the individual being recognized. Using this system of ethical evaluation, Dame Mary Warnock declared: "In a calculation of harm and benefits the very early embryo need not be counted."[16]

Opposed to this method of ethical evaluation is an outlook which considers the human being worthy of respect, and protection, even if acquiring new knowledge must be delayed or sacrificed. In this system of ethical evaluation, some goods or rights are considered so significant that they cannot be balanced with other rights nor be sacrificed for other goods. These rights are not granted by the human community but are considered to be from nature and prior to consideration by the human community. The Helsinski Statement of the World Health Organization, the original statement in regard to the ethics of research summed up this ethical approach when it stated: "Concern for the interests of the subject must always prevail over the interest of science and society."[17] Moreover, the respect for the individual as the bearer of inalienable rights is also the basis for the "United Nations Declaration on Human Rights"[18] a document which would assure world peace if followed by all nations who have endorsed it. Several other documents on research dating from the post-World War II era are based upon this embryo theory.[19] "To sum up 'the problem' (in regard to embryo research) is not the relation of science and religion, it is which ethical principles are relevant. We have utilitarian principles on the one hand and the idea of human dignity on the other."[20]

How shall we evaluate research upon human embryos and all the other new developments in medicine and science? I submit that utilitarianism leads to a complete destruction of human worth and individual value. The results of sacrificing individual human worth to any other good are clearly related by Robert Jay Lifton in *The Nazi Doctors*.[21] Note well, I am not accusing anyone of acting like a Nazi or being a Nazi. But I am saying that we learn from the Nazi epoch that utilitarianism not only violates human rights, it dehumanizes people. The horror depicted in *The Nazi Doctors* is not only in the slaughter of innocent people in concentration camps, but more significantly, that this slaughter was performed by physicians who sacrificed the good of the individual for the good of the State. Thus, people with brilliant minds and attitudes of service to humanity brutalized themselves and betrayed their profession because they sought a good which demanded the rejection of individual worth. They "balanced" the good of human worth with the good of the country and human worth lost.

One reading the ethical reports of the study groups which approved non-therapeutic research will discern a desire to approve limitations upon

this form of research. Thus, human cloning, the creation of chimeras between human and animal embryos, and trade or commerce involving embryos is usually disapproved. It seems the study groups wish to avoid the slippery slope which might result from the initial approval of destructive research upon innocent human beings. But once one embraces utilitarianism, there is no slippery slope. Logically, when one accepts the principle that the interests of the human subject need not prevail over the interest of science and society, then one has no reasonable argument for rejecting procedures which at first glance may seem to be brutal or inhuman.

Conclusion

Briefly, it seems the basis for disagreement in regard to the ethical evaluation of non-therapeutic research on human embryos is not radical disagreement in regard to the nature and worth of the human embryo; rather disagreement results from ethical methods. The ethical theory which places the good of the patient or subject before the good of science or society is part of the heritage of medicine. Theory which sacrifices the good of the individual patient or subject of research for the good of knowledge or the good of the State not only violates the worth and rights of the patient or subject, it also dehumanizes the person performing the research. While embryo research is only one specific example of new frontiers in medicine and science, the dichotomy between respect for individuals and a willingness to sacrifice human beings to attain other goods applies to many other innovative therapies, procedures, and protocols. Everything which is possible is not necessarily beneficial. When assessing benefit, we must be careful to respect the inalienable rights of individuals.

References

1. In 1975, a U.S. group, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, published a study concerning research on fetuses resulting from abortions. The study group from the United States for the most part rejected non-therapeutic research on fetuses in the uterus or outside the uterus. However, it provided for exceptions to this norm if a special approval be given by a review board and the Secretary of the Department of Health, Education and Welfare. This study group completed its work in 1975, before the potential for generating embryos outside the womb was developed. Thus, they were not concerned with the topic of our study. However, the recommendations of the Committee were rendered moot as a result of the ban on federal funding for research on living fetuses resulting from a Presidential order.

2. "Report of the Committee of Inquiry into Human Fertilization and Embryology," Department of Health and Social Security, London: Her Majesty's Stationery Office, July, 1984.

3. "Human Embryo Experimentation in Australia," Senate Select Committee on Human Embryo Experimentation Bill, Canberra: Australian Government Publishing Service, 1986.

4. "Toward an International Ethic for Research with Human Beings," International Summit Conference on Bioethics, Medical Research Council, Ottawa, Canada, 1988.

5. "Europe Split on Embryo Research," David Dickson, *Science*, v. 242, p. 1117; Nov. 25, 1988.

6. "Human Embryo Experimentation in Australia," p. 7.

7. Davies, David, *Nature* v. 320, 20 March 1986, p. 208.

8. "Human Embryo Experimentation in Australia," p. 25.

9. *Ibid*, p. 8.

10. "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research". The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. DHEW Publication, No. (05)78-0012; 1978, p. 2.

11. "Summary Report of International Bioethics Summit Conference;" *Bulletin*, Institute of Medical Ethics, May, 1987, supplement n. 6.

12. *Op. cit.*, p. xiv, n. 8.

13. *Loc. cit.*

14. Warnock, Mary, "The Warnock Report," *British Medical Journal*, vol. 291, 20 July, 1985, p. 197.

15. *Doc. cit.*

16. *Op. cit.*

17. "Declaration of Helsinki," 1964 and 1975, World Medical Association, cf. *Encyclopedia of Bioethics*, IV, p. 1769.

18. United Nations, 1948.

19. Cf. "Nuremburg Code," 1946; "Responsibility in Investigations on Human Subjects," (Great Britain) 1963; "Ethical Guidelines for Clinical Investigation", A.M.A., 1966; *Encyclopedia of Bioethics*, New York: The Free Press, 1978; p. 1764ff.

20. Anderson, S., Arhaus University Denmark; quoted in News and Comment, *Science*, Nov. 25, 1988, p. 1117.

21. *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (New York: Basic Books), 1986.
