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**GERM-LINE ENGINEERING AND FUTURE
GENERATIONS: AN ETHICAL AND
LEGAL OUTLOOK**

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“Life is entering a new phase in its history. We are seizing control of our own evolution.” — Gregory Stock

I Introduction

ON SEPTEMBER 14, 1990 researchers at the U.S. National Institute of Health performed the first approved gene therapy procedure on four-year old Ashanti De Silva. Born with a rare genetic disease called severe combined immune deficiency (SCID), she lacked a healthy immune system, and was vulnerable to every passing germ. Children with this illness usually develop overwhelming infections and rarely survive to adulthood. Ashanti led a cloistered existence—avoiding contact with people outside her family, remaining in the sterile environment of her home, and battling frequent illnesses with massive amount of antibiotics.¹

In Ashanti’s gene therapy procedure, doctors removed white blood cells from the child’s body, let the cells grow in the lab, inserted the missing gene into the cells, and then infused the genetically modified blood cells back into the patient’s bloodstream. Laboratory tests have shown that the therapy strengthened Ashanti’s immune system; she no longer has recurrent colds, she has been allowed to attend school.² This case of somatic gene therapy elucidated how gene therapy can be successfully used to cure diseases and give a new life to patients.

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1 Mary Carrington Coutts, “Human Gene Therapy” 4 *Kennedy Institute of Ethics Journal* 63-83 (1994).

2 *Ibid.*



This was claimed as a breakthrough in somatic gene therapy. Although the initial steps in somatic gene therapy have already been taken, research on human germ-line gene therapy is still in its infancy. The capacity to create genetic alteration to our germinal cells will symbolize a key progress in science, because alteration to the first cell of the human embryo are copied into every cell of the body and can thus reach to any tissue. At the same time the issue of germ-line therapy raises considerable ethical and legal issues. This paper deals with the issues raised by germ-line engineering.

II Fundamentals and present status of germ-line engineering

Human genetic engineering has been there for much longer than most people realize. The Greek philosopher, Plato, wrote about genetic engineering in *The Republic*. He stated that “the best men must have intercourse with the best women as frequently as possible, and the opposite is true of the very inferior”.³ This early form of genetic engineering was part of long-standing traditions and this argument was supported by many including Hitler who started of an elaborate eugenic programme. Still these attempts were controversial.

The new addition to the pool of genetic engineering is the technique of gene therapy. Gene therapy is the introduction of genetic material into human patients in order to alter the expression of particular genes. The goal of these alterations is to treat, cure, or ultimately prevent a disease or disability”.⁴ There are two main strategies in gene therapy:

1. Gene addition;
2. Removal of a harmful gene by antisense nucleotide or ribozymes.⁵

It is generally accepted that, whatever may be the strategy followed in genetic interventions, these genetic interventions are distinguished based upon the type of cells that are targeted. Genetic interventions therapy can be targeted to somatic (body) or germ (egg and sperm) cells. Somatic engineering, involves introducing new genes into an already grown person. In somatic gene engineering the recipient’s genome is changed, but the change is not passed along to the next generation. The second type of

3 Randy Moore, *Evolution* 144 (2006).

4 Anthony J. Zuccarelli, “Changing our Genes: Medical Promises and Ethical Threats” 16 *Loma Linda University Center For Christian Bioethics* (September 2000).

5 Meiligan R, “The Basic Science of Gene Therapy” 260 *Science* 926-32 (1993).



genetic engineering, germ-line engineering is the modification of DNA in a zygote, the first cell created from the joining of an egg and sperm.⁶ In germ-line gene therapy, the parent's egg and sperm cells are changed with the goal of passing on the changes to their offspring.⁷

Moving from the cellular level to the level of the organism, there is a further division depending on the aim of the intervention. If genetic engineering is to cure or prevent a medically unacceptable condition, then it is called therapy, while if the aim is to enhance a function or property of the body then it is labeled as enhancement.⁸ Thus the categories: somatic and germ-line therapy and somatic and germ-line enhancement.⁹

Germ-line genetic engineering is still in its infancy. However, it has been instrumental in research involving animals. It has been responsible for producing different types of specially altered animals. Some examples are:¹⁰

- Cows with elevated milk production.
- Sheep which synthesize a valuable hormone or enzyme in the udder and secrete it into the milk. This is an especially convenient source for purifying large scale amounts of medical products.

Germ-line engineering embodies the most profound possibilities and challenges because it promises (some would say threatens) eventually to transform the very being as ever more significant genetic changes are introduced into their genomes.¹¹ This technology will force human beings to re-examine even the very notion of what it means to be human, for as one become subject to the same process of conscious design that has so dramatically altered the world around them. Until recently, germ-line engineering in humans had not been discussed much because it seemed distant, something theoretical and concerned with our children or

6 Francis Fukuyama, *Our Post-human Future: Consequences of the Biotechnology Revolution* 136 (2002).
7 Rashmi Sharma and Ruchi Khajuria, "Gene Therapy : Current Concepts" 6 *JK Science* 62 (2004).
8 B. Hoose, "Gene Therapy: Where to Draw the Line" 1 *Human Gene Therapy* 299-306 (1990).
9 L. Walter "Ethical Issues in Human Gene Therapy" 2 *Journal of Clinical Ethics* 267-274 (1991).
10 Germ-line Gene Therapy available at <http://www.ess.ucla.edu/huge/genetic.html> (visited on February 12, 2009).
11 Gregory Stock, *Engineering The Human Germline* (2000).



grandchildren but not us. But molecular biology has progressed so rapidly that rudimentary germ-line manipulation in humans is already nearly possible, even if not yet with the safety and reliability one demands for human medical interventions.¹²

Germ-line engineering: Promises and pitfalls

Perhaps the most engaging argument in support of germ-line gene therapy is its therapeutic efficacy and usefulness.¹³ It could in principle treat and eradicate genetic diseases eternally. It is clearly effectual than somatic cell therapy because its effects are not limited to the actual persons treated. All of their offspring will be freed from the genetic condition treated with germ line therapy. In addition to this, there might be a number of diseases for which no effective somatic cell gene therapy is sufficient, leaving germ-line gene therapy as the only probable way to cure and eliminate them. Proponents of germ-line therapy argues that in the latter case, medicine has a moral commitment to provide the best existing treatment.¹⁴

Secondly, there is a theoretical consideration in favour of germ-line therapy namely, scientific freedom which allows scientists to choose whatever they want as a subject of their research. Zimmerman argues that “the prevailing ethic of science and medicine is that knowledge has intrinsic value, and that its pursuit should not be impeded except under extraordinary circumstances.”¹⁵

Arguments against germ-line gene interventions are numerous. The most common fear is that since the effects of these manipulations may be inherited by an unlimited number of generations, the possible outcomes might well be considered as irreversible.¹⁶ Another argument against genetic engineering is that of the genetic divide. Further it is argued that

12 *Ibid.*

13 L. Walter “The Ethics of Human Gene Therapy” 320 *Nature* 225-227 (1986).

14 J.C. Fletcher and W. F. Anderson “Germ-line Therapy: A New Stage of Debate” *Health Care Law, Medicine* 26-39 (1992).

15 B.K. Zimmerman, “Human Germ-Line Therapy: The Case for its Development and Use”, 16 *The Journal of Medicine and Philosophy* 593-612 (1991).

16 T. Tannsjo, “Should we Change the Human Genome?” 14 *Theoretical Medicine* 231-247 (1993).



the germ-line gene therapy experiments would involve too much scientific uncertainty and clinical risks, and the long term effects of such therapy are unknown; such gene therapy would open the door to attempts at altering human traits not associated with disease, which could exacerbate problems of social discrimination; as a society, we are already in struggle with class discrepancies.¹⁷

As germ-line gene therapy involves research on early embryos and affects their offspring, such research essentially creates generations of unconsenting research subjects. The doctrine of informed consent is central to medical ethics. It is now a widely accepted legal and moral principle that competent adults are not to be subjected to medical treatment without their consent.¹⁸ In addition, genuine consent requires knowledge of relevant facts.¹⁹ Some have thought that this poses a problem for germ-line genetic engineering because future generations will not have consented to being genetically engineered.²⁰ Gene therapy is very expensive, and will never be cost effective enough to merit high social priority; germ-line gene therapy would violate the rights of subsequent generations to inherit a genetic endowment that has not been intentionally modified.²¹

Besides this there are arguments concerning effects on the gene pool. Experts point out that the gene pool is a joint possession of all members of human society, and should not be subjected to any intentional, artificial, perhaps arbitrary manipulation by a few individuals. The right to be born with one's genome, or genetic patrimony, in fact has been a strongly motivating factor in European discussions on germ-line interventions and has been incorporated into a report of the Parliamentary Assembly of the Council of Europe.²² Intervention at the germ-cell level could eliminate a gene thought to be harmful today, which might be proven to be useful in the future. A present day example of this potential is the case with the

17 S. K. Pandya, "Ethical Aspects of Clinical Trials in Gene Therapy" *Indian Journal of Medical Ethics* 34 (2000).

18 Faden and Beauchamp, *A History and Theory of Informed Consent* 241 (1986).

19 *Id.* at 248.

20 J.C. Fletcher, "Moral Problems and Ethical Issues in Prospective Human Gene Therapy" 69 *Virginia Law Review* 515-546 (1983).

21 Eric T Juengst, "Human Germ-Line Engineering" 16 *Journal of Medicine and Philosophy* 587-694 (1991).

22 Parliamentary Assembly, Council of Europe, *Recommendation on Genetic Engineering* 934 (1982).



gene associated with sickle-cell anemia, which is also protective against malaria.²³

Almost all authors mention the classical slippery slope argument against germ-line therapies.²⁴ According to this argument, once a course of action is followed, it will be impossible to limit its consequences, even undesirable ones. It would be a slippery slope to begin germ-line gene therapy even with the most problem-free curative intention, because no one could inhibit the use for enhancement or eugenic purposes of knowledge learned during this research. Only richer population would profit from the germ-line therapy, because it would be very expensive.²⁵

In the case of germ-line interventions for enhancement purposes, the objections are more fundamental and are based on the idea that we do not have the right to predetermine the characteristics of future generations. The impact of germ-line engineering on future generations raises various concerns regarding the realisation of human rights and the concept of human. At the same time, any discourse on human right should bear in mind that if there is a human right not to be genetically enhanced, then the right must apply to humans generally. It must apply in the present and the future as well as in all cultures.²⁶ Human rights treaties subject to the vicissitudes of advancing science and changing cultural norms cannot effectively apply human rights to future generations. That means that people should be free to develop their potentialities without being biologically conditioned by the particular conceptions of “good” and “bad” human traits that were dominant at the time of those who preceded them. In other words, genetics should not become the instrument for a kind of intergenerational tyranny.²⁷

At the same time, one should bear in mind that any discussion on germ-line engineering should be seen in an objective manner. Any objection

23 Imre Szebik, “Ethical Issues of Human Germ-cell Therapy: A Preparation for Public Discussion” 76 *Academic Medicine* 32-38 (2001).

24 D. Resnik, “Debunking the Slippery Slope Argument Against Human Germ-Line Gene Therapy” 19 *Journal of Medicine and Philosophy* 23-40 (1994).

25 E.M. Berger, G. F. Cahill Jr. *et.al.*, *Morality and the New Genetics: A Guide for Students and Health Care Provider* 32 (1994).

26 Martin Gunderson, “Enhancing Human Rights: How the Use of Human Rights Treaties to Prohibit Genetic Engineering Weakens Human Rights” 18 *Journal of Evolution and Technology* 27-34 (2008).

27 Q. Renzong, “Germ-Line Engineering as the Eugenics of the Future” in *Germ-line Intervention and Our Responsibilities to Future Generations* 105-16 (1998).



against germ-line engineering should bear in mind that the benefits of germ-line engineering outweigh the consequences. Germ-line engineering has potential to get rid of hereditary diseases if perfected, not only in the foetus itself, but the cure will be passed down to future generations of the individual's offspring. It was also questioned whether ethically acceptable clinical research can ever be begun. Further, most of the concerns discussed above are not solely relating to germ-line engineering. Any introduction of medical and scientific technology is associated with certain risks and uncertainties. For instance, Stephen P. Marks notes, when the techniques of in vitro fertilization (IVF) were first developed many felt revulsion and spoke against "test tube babies".²⁸ At the present time, IVF is widely accepted both emotionally and morally.

III Germ-line engineering : Legislative response

"The struggle for human rights is like an overflowing river that floods down across the valley making the fields ever more fertile". The above comment aptly illustrates the expanding force of the human rights movement, which tends to cover all new areas, which are in need of protection. Probably the most recent field that needs to be "fertilized" by the principles of human rights is medicine, especially genetics.²⁹

The concept of human dignity underlies the concern of human rights. Earlier human rights doctrines in general terms tried to protect and regulate activities having an impact on human dignity. Later, the scope of human rights got expanded to include specific human rights such as right to privacy, right against discrimination, right to development etc. At the international level U.N, the primary agency, to protect, promote and preserve the human rights, first paid its attention to the close relationship and impact of science and technology on human rights in the 1968 Tehran Declaration on Human Rights.³⁰ The principle of the declaration observed "[w]hile recent scientific discoveries and technological advances have opened vast prospects for economic, social and cultural progress, such

28 S. P. Marks, "Tying Prometheus Down: The International Law of Human Genetic Manipulation" 3 *Chicago Journal of International Law* 115-136 (2002).

29 Roberto Andorno, "Biomedicine and International Human Rights Law: In Search of a Global Consensus" in *Bulletin of the World Health Organization* 959-963 (2002).

30 Final Act of the International Conference on Human Rights, Teheran, April 22 to May 13, 1968, U.N. Doc. A/CONF.32/41.



developments may nevertheless endanger the rights and freedoms of individuals and will require continuing attention.”³¹

The specific response to germ-line engineering found its place in the 1997 Universal Declaration of Human Genome and Human Rights.³² There are various sections which can be related to germ-line response. For instance, article 2(A) of the Declaration, states in part that “everyone has a right to respect for their dignity...”.³³ Article 12(b) implicitly rules out genetic engineering for purposes of enhancement. The article states that the applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.³⁴ In specific terms, the declaration provides that germ-line interventions “could be contrary to human dignity”.³⁵ This approach is also closely tied to previously accepted human rights. Violations of the prohibitions can be said to be violations of dignity and hence of the human right to respect for dignity.

The clearest prohibitions of germ-line and non-therapeutic genetic engineering are to be found in the Council of Europe’s Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.³⁶ Article 13 of the convention states that “[a]n intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants”.³⁷ Additional protocol to the convention

31 *Ibid.*

32 A. Res. 152, U.N. GAOR, 53d Sess., U.N. Doc. A/53/625/Add.2 (1998) (hereinafter U.N. General Assembly Resolution on the Human Genome Declaration) (adopting Universal Declaration on the Human Genome and Human Rights available at <<http://www.unesco.org/ibc/uk/genome/projet/index.html>> (visited on April 20, 2008).

33 *Id.*, Art. 2(4).

34 *Id.*, Art. 12(b).

35 *Id.*, Art. 24.

36 Council of Europe 1997, Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Available at <http://conventions.coe.int/treaty/en/treaties/html/164.htm> (visited on January 12, 2009).

37 *Id.*, Art 13.



reiterates this stand.³⁸ Following this the European Parliament adopted a resolution providing that people have a human right to their own genetic identity.³⁹

At the national level, some legal provisions and guidelines that ban germ-line interventions have already been adopted by some countries.⁴⁰ In United Kingdom the Clothier Committee, established to look into the ethics of gene therapy reported that, “[w]e share the view of others that there is at present insufficient knowledge to evaluate risks to future generations”. They recommended that germ-line therapy “should not yet be attempted”⁴¹ and this has now become a law in Britain. This is a safe, pragmatic response, but it falls short of a proper ethical evaluation of the issue, since it focusses on the presently insufficient means to evaluate risk to future generations, and does not address the underlying issue of whether or not we have any right to decide for them.⁴²

Besides there are various experts who support a blanket prohibition to germ-line engineering. According to George Annas and Lori Andrews “cloning and inheritable genetic alterations can be seen as crimes against humanity”.⁴³ Annas proposed an international “Convention on the Preservation of the Human Species” that would outlaw germ-line genetic engineering and cloning.⁴⁴ She argues that germ-line engineering may one

38 Council of Europe. 1998. Additional protocol to the convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, on the prohibition of cloning human beings. *Available at* <http://conventions.coe.int/treaty/en/treaties/html/168.htm>. (visited on February 10, 2009)

39 European Parliament, Resolution on the Ethical and Legal Aspects of Genetic Engineering, Doc. A2-327/88 Called for an absolute ban on all experiments designed to reorganize on an arbitrary basis the genetic make-up of humans.

40 Global Lawyers and Physicians. Database of global policies on human cloning and germ-line engineering legislation on cloning and germ-line interventions. *Available at* <http://www.glphr.org/genetic/genetic.htm> (visited on December 11, 2008).

41 Department of Health. *Report of the Committee on the Ethics of Gene Therapy*, London HMSO 1788 (1992).

42 Donald M. Bruce, “Moral and Ethical Issues in Gene Therapy” in Society Religion and Technology Project *Available at* <http://www.srtp.org.uk/genthpy1.htm> (visited on February 12, 2009).

43 G. J. Annas, L. B. Andrews and R. M. Isasi, “Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations” 28 *American Journal of Law and Medicine* 151-178 (2002).

44 *Id.* at 162.



day be able to alter human nature and undermine the common human nature on which the system of human rights depends.⁴⁵ Correction of a specific genetic abnormality in germ cells or early stage embryos (germ-line intervention) has not yet been carried out in medical practices. Because of the many technical problems and uncertainties about possible harmful effects on future generations, germ-line intervention has been strongly discouraged or legally banned.⁴⁶

The emerging global consensus on bioethics and germ-line engineering is clearly minimalist. When addressing these sensitive issues, international instruments do not pretend to provide a precise and definitive answer to the most intricate questions posed by germ-line engineering. On the contrary, international bodies tend to lay down very general principles like the requirement of informed consent, the confidentiality of health information, the principle of non-discrimination for genetic reasons and the promotion.⁴⁷

IV Germ- line engineering: Indian legal framework

India has achieved spectacular progress in science and technology including research in genetics. It claims to be having a huge share of scientific and human resources. But it has till now shied away from directly legislating on the various ethical and legal issues arising out of the research in genetics.

There is no specific legislation in India governing gene therapy. The only regulations are in the form of certain guidelines issued by agencies regulating human research. Indian Council of Medical Research (ICMR) states that gene therapy should be subject to ethical codes that apply to research involving human patients. Therefore, the regulation of gene therapy can be covered by the same regulations that control clinical trials or human experimentation. Clinical trials in India are minimally regulated by the Drugs and Cosmetics Act, 1940.⁴⁸ This must also comply with the Ethical Guidelines for Biomedical Research on Human Subjects

45 *Id.* at 153.

46 Report of the International Bio –Ethics Committee, IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention (2003).

47 *Supra* note 29.

48 Drugs and Cosmetics Act, 1940. This is an Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics.



2000⁴⁹ and the Good Clinical Practices (GCP) 2001 Guidelines.⁵⁰

The most comprehensive guidelines on biomedical research on human patients are published by ICMR and the guidelines state that, as a human genetic research practice, gene therapy would help to alleviate human suffering. According to the council, somatic cell gene therapy is “the only method that may be permissible for the purpose of preventing or treating a serious disease when it is the only therapeutic option.”⁵¹

The council adds that gene therapy trial consists of two parts. The first part is the preparation of the ‘gene construct’ to be administered, and the second part is evaluation of the efficacy and safety of the administered ‘gene (construct)’. As far as the first part is concerned, the guidelines and clearance for it is to be regulated by the National Bioethics Committee under Department of Biotechnology (DBT) and for the second part clearance from the local IEC and Central Ethical Committee (CEC) of the ICMR shall be obtained. Safety should be ensured especially because of the possibility of unpredicted consequences of gene insertion.⁵²

Regarding germ-line therapy the guidelines does not put a blanket prohibition. But, it prohibits germ line therapy in two categories – gene therapy for enhancement and eugenic genetic engineering. In particular, the ICMR states that there is insufficient knowledge at the present time concerning the effects of the attempts to “alter/enhance the genetic machinery of humans,” and that, “the influence of environmental interaction on the expression of genetic characters is poorly understood.” The guidelines come heavily against selection personality, character, formation of body organs, fertility, intelligence and physical, mental and emotional characteristics which is prohibited. Further under the Ethical Policies on the Human Genome, Genetic Research and Services 2001,⁵³

49 Indian Council of Medical Research., “Ethical Guidelines for Biomedical Research on Human Subjects Guidelines 2000” available at <http://www.icmr.nic.in/ethical.pdf> (visited on October 11, 2008).

50 Indian Good Clinical Practices, 2001, Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. (adopted by the Ministry of Health).

51 *Supra* note 49. *Statement on Specific Principles on Human Genetic Research 2000*.

52 Dinesh C Sharma, “India Publishes Comprehensive Ethical Guidelines for Biomedical Research” 356 *The Lancet* 1528 (2000).

53 Ethical Policies on the Human Genome, Genetic Research & Services, Department of Bio Technology (2001).



the Department of Biotechnology, the Ministry of Science and Technology and the Government of India, all agree that somatic cell gene therapy be allowed “with appropriate safety measures” and “when it is the only therapeutic option” or “it is indisputably considered superior to other existing options.” These policies also ban germ-line therapy in humans.⁵⁴

V Conclusion

As of now, the technology for germ-line engineering, either positive or negative, is still a prospect of the future. But history has always shown that whatever is today’s imagination is realized later. This prospect is a welcome aspect for those living with genetically linked disorders as well as for their possible offspring and for future generations. This new technology, however, brings with it awesome power, and with that comes the great responsibility of using the knowledge wisely and handling this information seriously and cautiously. There are countless moral, ethical, religious, philosophical, psychological, societal, scientific and medical issues regarding gene therapy, and specifically germ-line engineering. In this paper authors have examined some of the arguments for and against germ-line gene therapy as found in the mainstream literature and evaluated the arguments to determine if they apply exclusively to germ-line gene therapy. It can be said that most of the arguments cannot be applied uniquely to this intervention. Many of the properties of germ-line gene therapy occur either in other medical interventions or elsewhere. Yet the ability to replace or alter individual genes within the DNA has perhaps a more profound potential when compared to stem cells and cloning to alter one’s view of human life.⁵⁵ In this background it is difficult to provide a clear cut answer regarding the ethical aspect of germ-line engineering. The present scientific and moral knowledge is clearly insufficient to answer this question.

It is certainly true that germ-line genetic engineering, for purposes of enhancement pose dangers that make them unjustified at the present time. On the other hand, the time may come when genetic engineering can safely be used to prevent diseases such as Tay Sachs or Huntington’s. If human rights are used to prohibit germ-line engineering in such cases,

54 *Supra* note 52 at 1502.

55 David A. Prentice, “Brave New World of Genetic Engineering” *The National Catholic Bioethics Quarterly* 529-539 (2001).



serious problems regarding their appropriateness will arise.⁵⁶ It is a beginning of the science of genetic engineering. It is not clear what advances will be made in the science, and it is not clear how the culture will change in light of those advances. The potential for benefit as well as harm, along with our current profound ignorance, counsels in favour of taking small regulatory steps rather than sweeping prohibitions based on human rights.⁵⁷

56 Martin Gunderson, “Enhancing Human Rights: How the Use of Human Rights Treaties to Prohibit Genetic Engineering Weakens Human Rights” 18 *Journal of Evolution and Technology* 27-34 (2008).

57 J. W. Nickel, *Making Sense of Human Rights: Philosophical Reflections on the Universal Declaration of Human Rights* 257 (1987).