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## Submission to the Committee on the Ethics of Gene Therapy

Joint Ethico-Medical Committee of the Catholic Union of Great Britain and the Guild of Catholic Doctors

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# Submission to the Committee on the Ethics of Gene Therapy

by the Joint Ethico-Medical Committee of the  
Catholic Union of Great Britain and the Guild of Catholic Doctors

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The Catholic Union is a non-affiliated lay Organisation under the Presidency of His Grace the Duke of Norfolk and The Guild of Catholic Doctors is an autonomous Body of approximately 1,000 practising British Doctors. This Submission is made by the Joint Ethico-Medical Committee on behalf of the two Bodies.

As Catholics we have a tradition of affirming human dignity under contemporary conditions and we endorse; the generally accepted ethical principles of justice and beneficence, and the autonomy of patients. Although scientific discovery can be a legitimate end in itself where Man is concerned we accept the principles of the Helsinki Declaration which state *inter alia*: — "Concern for the interest of the subject must always prevail over the interests of science and society" (*Principle 1.5*).

## GENE THERAPY

We consider this development to be exceedingly important and follow with interest the decisions taking place between Clinicians and Scientists in this field both in the country and overseas. We hope that new therapeutic possibilities will arise which could benefit patients, but there are dangers.

As a result of the science of molecular biology four thousand single gene disorders have so far been identified. In time a complete decoding of the human genome may reveal the genetic predisposition for other diseases including some which are multi-genetic.

Advances in conventional treatment have become available in recent times, leading to symptomatic relief from some 12% of the inherited diseases (e.g. Phenyl-ketouria) and the partial relief of another 40% (e.g. Cystic Fibrosis). slightly less than half of the known inherited diseases cannot be substantially relieved by conventional medicine.

Tissue and organ transplantation may improve these figures. Examples are successful marrow transplantation for some of the inherited anaemias and, more recently, lung transplantation for end stage sufferers of cystic fibrosis. (Royal College of Physicians Conference on 'Gene Therapy' 1990).

Clinical gene therapy is aimed at the replacement of defective genes and is similar to organ transplantation. This technique can be applied to somatic cells or to germ-line cells. The consequences of germ line cell therapy would be that the alterations would be transmitted to progeny, thus making a profound ethical difference from somatic cell therapy.

## **SINGLE GENE DISORDERS**

For successful gene modification it is necessary that:

1. the gene and its regulatory region has been isolated,
2. the target cell for genetic modification is accessible,
3. a safe transfer system must be found, and
4. there must be a reasonable prospect of the long term survival of the new cell population, with its beneficial expression.

We understand that some of the disorders which might be treated in this way when suitable techniques have been perfected include:

Some congenital immune deficiency disorders  
Thalassaemia  
Phenylketonuria  
Gauchers disease  
Lesch-Nyhan disease.

This is only the beginning of what could prove to be a substantial list.

## **ETHICAL CONSIDERATIONS OF SOMATIC CELL GENE THERAPY**

In general terms, the ethical considerations are similar to those of tissue or organ transplantation. There must be a balance between risks and benefits, and after the techniques have been perfected using animal models, including Public Health aspects, they may become applicable to humans.

We acknowledge that the first disorders to be treated are those which are currently fatal or profoundly crippling but cannot exclude the possibility that, with time, other conditions may legitimately benefit from gene modification. An example of this could be haemophilia which can already be treated successfully. The risk/benefit ratio for gene therapy would have to be better than that of the present treatment.

In this, it is noted that the patients will, for the most part, be in a position to give consent on their own behalf, or, with children, by proxy. In general, it seems to us, the giving of consent on behalf of a minor would require a higher degree of assurance of success and beneficial outcome than that which would justify consent by adults on their own behalf. It is neither ethical nor legal for a parent to give consent on behalf of a child to any procedure which is not in the child's own interest. We consider that this, in practice, excludes the application of gene therapy for reasons (such as cosmetic or aesthetic) other than for the treatment of pathological conditions.

It also seems to us not inconceivable that children could sue parents for any damage done to them, as an individual, as a result of an intervention by the parent.

## **ETHICAL CONSIDERATIONS OF GERM LINE CELL GENE THERAPY**

There are major scientific and ethical differences between somatic (non-reproducible) and germ line (reproducible) therapy. The latter results in a permanent alteration of an individual's genetic composition which would be transmitted by them to future generations. The first and obvious factor is that such a step is irreversible.

A particular problem relating to autonomy arises from the impossibility of obtaining the consent of future or developing affected individuals. Even if an assumption is made that individuals would wish to be spared a disease, there would need to be a wide measure of agreement in Society that only those diseases of the most crippling nature would justify the risks of permanently altering the human genome.

We also consider that alteration of the human genome, which would affect future generations, would be unjust as it denies such generations their autonomy and may not accord with full human dignity. In other words, even if it could be foreseen that germ-line cell therapy might become an acceptable form of treatment for disease, such that the parents might be entitled to consent to it for the child's benefit and to its own good, there remains the impossibility of obtaining the consent of future generations to alterations affecting the human 'genetic library'. We have no right to assume that their wishes necessarily correspond with our own, and it thereby becomes impossible to envisage a situation where we would be entitled to assume their consent.

The long term effects of alterations to the genome cannot be foretold. The removal of defective genes (such as sickle cell anaemia) might lower community protection factors (in this case against malaria).

In addition, whilst some of the common disorders, such as diabetes, atherosclerosis and hypertension, which are known to have genetic predispositions, could arguably be alleviated by gene therapy we consider this to be unjustifiable when alternative therapy or alterations in life style achieve comparable results.

Further difficulties are likely to arise with germ line therapy if, as it seems likely, it would be inevitably linked with screening during antenatal development with a view to terminating those pregnancies in which the genetic transfer appeared imperfect. We think it probable that at the early stages of germ line gene therapy such screening might be a condition of the patient being accepted for treatment. This would, of itself, be incompatible with a woman's autonomy and should not be required, although there is at present no experimental basis for treating polygenetic conditions, there is at least a theoretical possibility that this could be used not only for the

treatment of maladies but for such manipulations as attempts to improve human intelligence, physique or life span. this would be analagous to eugenics which is open to grave abuse and could lead to great human injustice. We doubt if there ever could be agreement in Society on those human characteristics which should be enhanced or those which should be eliminated and attempts to take scientific control of human evolution seem to be little more than scientific hubris. We have already expressed our view that such attempts would be ethically unacceptable.

## **CONTROL OF GENE THERAPY RESEARCH AND APPLICATION**

It is implicit in the establishment of your Committee that Society has an interest in regulating research and treatment by genetic modification. The issue is one of such magnitude and public interest that we would consider it inappropriate that it should be controlled by the existing Ethics Committees of Hospitals, Post Graduate Institutes or Universities. Although National Bodies such as the Royal Colleges clearly make a major contribution, particularly with their appreciation of scientific and medical issues, a more broadly based regulatory Body which fully reflects Society's interests needs to be established.

There is also a need for National Governments to work with others towards international conventions. Work has already begun on this with the European Community. (*Recommendation* No. 934 (1982) on Genetic Engineering from the 33rd ordinary session of the Parliamentary Assembly of the Council of Europe.)

We acknowledge that advances in molecular biology might perhaps lead to more extensive embryo screening in *In Vitro Fertilisation* programmes for an increasing number of inherited disorders. Within our moral tradition, however, there are particular difficulties in the use of *In-Vitro Fertilisation* as a method of reproduction.

*In-Vitro Fertilisation* is not in accord with our view that the gift of life should normally come as a result of mutual self gift of parents. The role of third parties (as technician or as donor) in what can correctly be regarded as asexual reproduction has not been determined and we are concerned at the possibility that new life conceived in this way may be seen as a 'product' under human control. This in our tradition would not do full justice to the standing of the individual. It has always been our view that human life has an inestimable value which is not lost through sickness or aging or inborn imperfection. Furthermore, it has always been the Catholic position that human life demands respect from its first origins to its natural end (*Donum Vitae*, Vatican Polyglot Press, 1988).

There is here, perhaps, a further argument for a national Medical Ethics Committee with wide representation and public accountability. Such a Body should be answerable to Parliament through the Secretary of State and the proposed Licensing Authority for Embryology and Human Fertilisation could, with suitable amendments, be a model for such a

regulatory and licensing body. There is an obvious need for scientists of adequate standing to be advising this Body, but an equal need for advice from other traditions in Society including the main religious denominations and systematic philosophies as well as informed lay opinion. A regulatory Body would enjoy more public confidence if its composition was not predominantly medical and scientific.

Society has a major interest in future developments of the manipulation of the human genome and a Regulatory Body could only properly be seen as accountable to Society if it were established on the authority of Parliament.

*It remains our conviction that whilst scientific advancement is a legitimate objective in its own right, when applied to Man science must always remain at his service and that human dignity remains paramount.* We conclude, that somatic cell therapy will offer substantial benefits, suitably controlled. Germ line cell therapy, however, should not be contemplated until somatic cell therapy has proved successful for a suitable length of time, perhaps one generation. We do not consider germ line cell therapy ethically justifiable at the present time, if ever.

*Signed by*

NORFOLK

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J. C. GALLAGHER

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*Chairman of the Joint Ethico-Medical Committee*

*The Committee wishes to record its appreciation to Dr. Anthony Cole, FRCPE, DCH, who wrote the initial draft of this paper.*

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