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THE RIGHT TO LIFE

ISSUES IN BIOETHICS

A collection of papers presented at the twelfth symposium of the Institute for Theological Research (Unisa) held at the University of South Africa in Pretoria on 7 and 8 September 1988

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Preface

The concept of life has fascinated mankind through the ages. Theories on the origins of the human race, the nature, origin and end of life, whether there is life after death, and how these different aspects interrelate, have been widely discussed over many centuries. In addition to what we learn in the Bible about the views of life of the Jews and early Christians, similar and different ideas about life — all valuable — are found in other religions. Philosophers have grappled with the complexities of the phenomenon and have given many answers to the various questions concerning life. Biologists have come up with the most interesting ideas and theories; so have medical scientists and many others to whom the concept of life presents tantalising secrets. These different views have given rise to a wide range of bioethical issues, which need to be addressed in terms of our current understanding of life.

The emergence of industry and the development of technology have opened up new challenges to humankind, and have changed our concept of life. Because of the discovery of the structure of DNA (deoxyribonucleic acid), modern genetic engineering, for example, has enabled scientists to modify genetic material, which has major implications for humankind and its environment. Developments in reproductive technologies, such as in vitro fertilisation, embryo freezing and oocyte donation, have necessitated serious thought by medical scientists, philosophers, ethicists, theologians, jurists and others. These developments are part of our daily experience. At the same time we are reminded daily of other realities influencing our concept of life and raising questions about the right to life.

Malnutrition, poverty, power struggles, oppression, warfare, terrorism, the emergence of new and horrifying diseases such as AIDS, and many other things we experience, influence the way in which we construct reality and how we conceive of life. It is only by considering the challenging complexity of life that we can really start thinking about the right to life.

The concern of the organising committee of the twelfth annual seminar of

the Institute for Theological Research at Unisa was to offer a forum for those who are interested in the complexities of bioethics from a theological point of view. To this end we invited a number of speakers to prepare papers on a variety of topics about the right to life. To talk meaningfully about bioethics, one has to consider the question 'What is life?'. The answers to this question lead to ideas about the right to life. Being aware of the many possible answers to that question, we decided to invite speakers to tackle the question of the right to life from different angles. This book contains a selection of the papers delivered at the seminar. It addresses a small, but nevertheless important aspect of the problem and clearly indicates the complexity of the right to life and quality of life in our own time. The views expressed are those of the authors of the essays and not necessarily those of the Institute or the University.

I am indebted to many individuals who helped me with the preparation of the seminar and the book. The organising committee, consisting of Jansie Kilian, Hilda Steyn, Klippies Kritzinger and Willie Wessels, was responsible for finding a topical issue, appropriate topics and knowledgeable speakers, and for organising the seminar. In this connection it gives me great pleasure to thank Professor J V van der Merwe, Dean of the Medical Faculty of the University of Pretoria, who has made it possible for us to have Dr Quigley of Cleveland, Ohio in the USA as one of our speakers.

I am also indebted to the authors of the essays contained in the book and to the referees who had to ensure academic quality. Deep appreciation is extended to Jansie Kilian, Hilda Steyn and Beverley van Reenen for their help in editing the book, and to those who assisted in proofreading the manuscript: Almarie Blaauw, Adrian Blom and Ernst Horn. The manuscript was typed by Nonnie Fouché. My sincere thanks to all of you, including my secretary, Linda Bedingfield.

THE EDITOR

A P DU TOIT

What is life?

As a way of presenting possible answers to the question 'What is life?' I shall begin with two parables.

FIRST PARABLE

Scientists first produced life in the laboratory by physico-chemical experimentation in the year 2010. A form of life had spontaneously come about. This breakthrough made it possible for the scientists to produce and cultivate a human being by physico-chemical processes. They made a male human being and, by the time the boy was seven years old, scientific tests had shown that he was in all respects similar to any other human male. During this time scientists had also produced a substance which stopped the ageing process. If humans took it at the age of thirty years, for the sake of argument, they would to all outward appearances stay that age and not show any physical deterioration. Scientists claimed that, by taking the substance regularly, humans could live indefinitely.

Then the philosophers came along and said, 'Look, the boy created by the scientists may have to be distinguished from human beings born in the usual way. We could have a new mutation of the human species which also calls for new descriptions. For the time being we shall label this mutation a Category B human being. The human beings who take the substance that gives everlasting life may also be of a different category. We shall call them Category C humans, and by observation and argumentation we shall decide how to describe them and where they fit in. Clearly our concept of life will also change.' The philosophers went away to work on

new descriptions, new theories and alter their concept of life.

The theologians came along and said, 'Look, the first thing we shall have to decide is whether the human male produced by the scientists has a soul, or not. And what does "soul" mean in this context? We may find that the soul has never existed, and that human beings born in the usual manner do not have souls, after all. It may even be necessary to drop the concept "soul" from the theological vocabulary. On the other hand, perhaps God has had a change of mind and now allows man to produce both life and souls.' The theologians went away to think about these matters and to contemplate the kind of contribution they could make in this changed world.

And the scientists and the philosophers and the theologians all started taking the substance that makes humans live indefinitely.

SECOND PARABLE

In the year 2010 mutations of the AIDS virus had become so prolific and contagious that 95% of the world's human population had been wiped out. Estimates showed that it would take three years for man to become extinct. The latest reports said that scientists were frantically preparing space ships to travel to the earth's moon and other planets, thus hoping to escape the deadly viruses. At that point in time there were no indications that conditions elsewhere in space could sustain human life and thus save the species.

The few remaining philosophers and theologians had become strangely silent. It was rumoured that they now agreed that they may have been mistaken about what life was really all about ....

-oOo-

Why should we interest ourselves in the question 'What is life?' Because we regard life as something vital, deep and of great importance, surely. Theories on how human beings first came into existence, and on the phenomena of birth, life and death, are bound to interest us; they also shape our views of what we are and wish to be, and thus profoundly affect our lives. Through the ages the concept of life has always been a central topic in theoretical contexts and if we go back in history we find numerous great thinkers who had important ideas about life, existence and being.

'Life' is a multifaceted concept. It has various meanings, depending on the context in which it is used. The question 'What is life?' could relate to the origins of cosmic life, to problems concerning the period from birth to death, to the actions or fortunes of individuals, to various forms of life, to the distinction between conscious and unconscious life, transcendental life, to the meaning of our lives, to the survival of the human species, and so forth.

For present purposes I shall investigate some of the more important issues raised by the question, 'What is life?' and the theories which form the basis of the various answers. I shall argue that questions about life posed within the context of empirical science are dependent for their answers on available scientific evidence - that is all we have to go by - and questions on the non-empirical level are by their nature of a different order and thus require different answers.

1 THE QUESTION 'WHAT IS LIFE?' IN A SCIENTIFIC CONTEXT

The world in which we exist gives us the living and the nonliving (Thürkauf 1980:351), and in the course of ordinary daily life we have no difficulty in distinguishing between the living and the nonliving. It is only in very extraordinary circumstances that we would be uncertain as to whether something was alive or dead. We have a 'natural' ability to observe the difference between the living and the nonliving. This ability can also be extended and aided by scientific instruments which make it possible to observe the living and the nonliving on macro and micro levels to which we do not have access through our ordinary senses. Since the advent of the Natural Sciences, every age has had an explanation of the origin of life. These explanations have always carried weight and have usually become the point of departure for reflection on the concept of life. Current scientific progress has heightened expectations of finding answers to important questions on life, its origin, its various forms, evolutionary processes, and so forth.

1.1 The origin of life

Contemporary science generally explains the origin of life as follows:

Living beings are composed largely of molecules, called proteins, the complex organic compounds formed by the combination of amino acids. The amino acids arrange themselves in long chains in different orders, giving rise to an enormous number of proteins

which have functions of support for the organism, as well as controlling and guiding its internal activities. Enzymes are an important class of proteins with catalytic properties that allow the development of the chemical reactions needed within the organism. The cellular construction of living organisms, achieved through the manufacture of proteins, is undertaken by a code - a communication system within the organism - which transmits the messages indicating how to construct amino acids. In the living cell, cytoplasm and the nucleus can be distinguished, the latter containing chromosomes which in turn contain genes - substructures that carry hereditary characteristics. A gene again is composed of a long, linear molecule of deoxyribonucleic acid (DNA), made up of a chain of elementary units. DNA chains, appearing in pairs, form a double helix structure. A unit of the chain contains a character of a code and the characters, composed of the DNA bases, are guanine, adenine, cytosine and thymine and their order in the genetic chain determines genetic information. The mechanism of writing and reading a certain message involves other large molecular structures, known as ribonucleic acid (RNA) of different types. Without getting involved in intricate molecular biology, suffice it to say that the essential problem for those who study the origin of life is that of knowing if these molecular chains and this code have been put together according to a preordained plan, or if the process could have developed by itself under suitable environmental conditions. This is a much debated point, but today a considerable number of scholars are convinced that in a certain environment (like that of the earth billions of years ago), the phenomenon could have started by itself. An essential condition is that processes that free sufficient energy to break molecular bonds should exist in nature (Di Francia 1976:370). How such energy could have been released, and certain processes set in motion, has been explained by simulating earth's primitive atmosphere, thus attempting to show that certain natural processes give rise to complex molecules, among them DNA bases (Di Francia 1976:371). Although the precise, detailed origins of cosmic life are still largely a matter of conjecture, most natural scientists accept the hypothesis that life is nothing more than especially complex physics and chemistry.

Herbert Spencer wrote in 1862:

> Life in its simplest form is the correspondence of certain inner physicochemical actions with certain outer physicochemical actions; each advance to a higher form of life consists in a better preservation of this primary correspondence by the establishment of

> other correspondences. So that, over its nominal nature of which we know nothing, life is definable as the continuous adjustment of internal relations to external relations.
>
> (Spencer 1928:70)

The same sentiment was echoed by Pierre Teilhard de Chardin (1966:39), who claimed that the beginnings of life are lost to us. Life, in scientific experience, is none other than a specific effect of complex matter, 'a property in itself coextensive with the whole stuff of the cosmos, but perceptible to us only where ... complexity exceeds a certain critical value - below that value we cannot perceive it at all' (Teilhard de Chardin 1966:24).

It seems to me that the statements of natural scientists on the origin of life are descriptions of primitive forms of life, or life in action as encountered for example on the microbiological level. These statements should not be taken as explanatory statements of the *origin* of the complex molecules, DNA bases, and so forth.

1.2 Life as a force versus life as physicochemical processes

Another option would, of course, be to conceive of life as a synthetic force of a higher order than that of physicochemical forces, a force which would influence the physicochemical causes without disturbing their functions. Most scientists reject this idea on the grounds that should such an intelligible causality or power bring about life or influence the steps in evolution, then it should be empirically verifiable. If that were possible, this force would be on the same empirical level as the physicochemical forces, which would of course rob it of a higher status:

> Many scientists ... argue as follows: either this intelligible causality to which you appeal has some influence upon each step of evolution, or it does not. If it does, then it should be empirically verifiable. In that case, it is an empirical causality, on the same level as the others. If it does not, how can it have any influence upon life or evolution as a whole?
>
> (Donceel 1967:52)

Those who argue for a higher-level force claim that its working has the character of becoming, being, vanishing and returning. It is difficult to conceive of a force which cannot be identified in the usual manner and the workings of which cannot be checked.

We can legitimately claim that the practice of chemistry and physics is something other than nature itself. Chemistry and physics are the results of our reflection on nature; they embody our thinking on, and our descriptions of, nature. The practice of chemistry and physics, it is argued, is in itself nothing chemical or physical. Rather, chemistry and physics are objects of inquiry; they come about through human thinking on nature according to a very definite hypothesis. Chemistry and physics cannot be understood physicochemically! To understand physics and chemistry one needs to reflect *on* chemistry and physics and this act is more than just a physicochemical process (Thürkauf 1980:352-353).

1.3 Experimentation, mechanism and hypotheses

Clearly, then, natural scientists depend greatly on experimentation and *factual evidence* for their theories about the possible origin of life. The empirical criteria for life would roughly be its cellular constitution, that is, the build-up of cells, metabolism of some kind, unstable equilibrium, some sort of organisation, and eventual death.

Scientists are often accused by philosophers of having a mechanistic world view:

> Mechanism holds that life is some kind of material energy, or the result of a combination of material energies; that it can be explained, or will eventually be explained, by the laws of physics and chemistry; that a living being is only a complicated machine.
>
> (Donceel 1967:44)

There are many variations of the mechanistic model, one such recent attempt to integrate mankind with nature being the so-called Gaia hypothesis put forward by J E Lovelock. The Gaia hypothesis states that life is not governed by physical events, but that life itself is the guiding principle which makes and remakes its own environment.

> Life reacts to global and cosmic crises, such as increasing radiation from the sun or the appearance for the first time of oxygen in the atmosphere, and dynamically responds to insure its own preservation such that the crises are endured or negated.
>
> (Sagan & Margulis 1984:61)

According to this theory no unknown external forces need be invoked to account for the origin or the continuance of life; temperature regulation, for example, becomes a consequence of the well-known properties of life's responsiveness and growth, whereas other theories wrongly state temperature regulation as a prerequisite for life. The Gaia hypothesis thus reverses the whole process - it is not that something invokes life, but rather that life itself invokes; for example, life continually synthesises and removes the gases necessary for its own survival. 'Life controls the composition of the reactive atmospheric gases' (Sagan & Margulis 1984:67). Sagan & Margulis (1984:66) also claim that 'The Gaia hypothesis says in essence that the entire earth functions as a massive machine or responsive organism'.

In science, 'mechanism' covers a great deal. The concept is used to describe almost any system, some of whose elements act upon the others. Mechanism has today more defenders than ever before among physicists, biologists and philosophers - especially in the form of the thesis that man is a computer. Suffice it to say that the doctrine that man is a machine or computer is unsatisfactory, because it regards man and the world as a closed physical system '... whether a strictly deterministic system or a system in which whatever is not strictly determined is simply due to chance: according to such a world view human creativeness and human freedom can only be illusions' (Popper 1972:254). Popper (1972:219) explicitly states:

> By a physically closed system I mean a set or system of physical entities, such as atoms or elementary particles or physical forces or field of forces, which interact with each other - and *only* with each other - in accordance with definite laws of interaction that do not leave any room for interaction with, or interference by, anything outside that closed set or system of physical entities. It is this 'closure' of the system that creates the deterministic nightmare.

It is especially by using certain scientific methods that biology has been able to examine the lower forms of life, working from the higher forms of life to the lower. It is at the level of an

elementary form of life that experimentation often becomes controversial, because much of the work is hypothetical. Hypotheses are proposed and thought experiments become the *modus operandi*. The empirical situation usually forces on us the hypothesis that we eventually accept. How do we choose between hypothesis A and hypothesis B? Both may initially have strong evidence to support them. However, as we gain more knowledge about nature and more and more observations begin to favour hypothesis B, it will become increasingly difficult to maintain hypothesis A and we may reach a stage where we are prepared to abandon it. This is practice, but the problem arises when our experimentation prompts us to hypothesise about the probability of one thing happening rather than the other on the level where we do not (and for a long time yet may not) have sufficient knowledge or adequate grounds for accepting one hypothesis in preference to another. By this I mean that our experimentation on this 'uncertain level' could lead us to the hypothesis that things happened in that particular way, and not in any other, or our reasoning could even lead to a prediction that things are going to happen in a certain way in future, excluding other possibilities. In view of the foregoing I want to claim that although experimentation has shown that physicochemical processes are necessary for *sustaining life*, it does of course not mean that they are *sufficient*, or that there is enough evidence for accepting that life, as we know it, *is* only a physicochemical process.

2 THE QUESTION 'WHAT IS LIFE?' IN A PHILOSOPHICAL CONTEXT

2.1 World-views and empiricism

Science is not so pure or so exclusive that it is practised in complete isolation. Nothing is ever done in isolation. Where science is practised, it is always done within a specific context. 'Facts are not gathered in a vacuum, but to fill gaps in a world-picture which already exists. And the shape of this world-picture depends deeply on the motives for forming it in the first place' (Midgley 1985:2). Personal opinions, distortion of facts, indiscriminately collected information, strong preferences and so forth often distort our theories and lead to unbalanced world-views. Philosophers, scientists and theologians are all to blame, because they do not always have the background, insight or flexibility to detect possible alternatives or errors.

The fear of distortion has compelled certain philosophers to adhere to a strict form of empiricism, even advocating that the place of philosophy is within the realm of the natural sciences. One such philosopher is W van Orman Quine (cf Quine 1984) who

argues that we should accept the external world as it is given. In his philosophy of natural realism Quine is not interested in ontology, but in structure. The truth about nature is to be discovered by looking to the stimulatory input of sense data through the triggering of our nerve endings and our subsequent output - that is, our claims to knowledge - which he labels as the descriptions of faraway things and the theories of the inner workings of nature. All we can really do is analyse the descriptive use of language. He then proceeds to distinguish various types of sentences - observation sentences and standing sentences.

> Science ... is about regular occurrence, or what Quine calls 'standing sentences'. The connection comes in observation categoricals in which one finds a *whenever* or *wherever* construction, as in 'Where there's smoke there's fire'. Here is the beginning of rudimentary science. Scientific theory is the distinction between true and false observation categoricals .... All evidence stems from sensory stimulation and enters language through observation sentences ....
>
> (Rouner 1984:2)

This type of approach is favoured by many contemporary philosophers who prefer to stay away from ontological questions and rather focus on the network of the logical implications of our observation sentences which in turn result from sensory stimulation.

2.2 An existential interpretation

A different philosophical approach is for example that of Hans Jonas (1982) who offers an 'existential' interpretation of biological facts. He claims:

> ... scientific biology, by its rules confined to the physical outward facts, must ignore the dimension of inwardness that belongs to life: in so doing, it submerges the distinction of 'animate' and 'inanimate'. A new reading of the biological record may recover the inner dimension - that which we know best - for the understanding of things organic and so reclaim for the psychophysical unity of life that place in the theoretical scheme which it had lost through the divorce of the material and mental since Descartes.
>
> (Jonas 1966:IX)

Jonas seeks to break through the anthropocentric confines of idealist and existentialist philosophy, as well as through the materialist confines of natural science.

> Although my tools are, for the most part, critical analysis and phenomenological description, I have not shied away, toward the end, from metaphysical speculation where conjecture on ultimate and undemonstrable (but by no means, therefore, meaningless) matters seem called for.
>
> (Jonas 1966:X)

Philosophers such as Jonas vehemently attack dualistic world-views which regard humans as consisting of the interrelation of two different entities, body and soul, thus splitting reality into self and the world, mind and body, inner and outer existence, and so forth. The notion of separate spheres of spirit and matter entrenches on the one hand the view that matter can be without spirit and on the other hand the opposing viewpoint that spirit can be without matter.

Suffice it to say that philosophers who concern themselves with the origin of life and the question of what human life consists of, how it is to be explained, and what comprises man, usually end up in one of the two mainstreams of thought on these matters - psychophysical monism or psychophysical dualism.

2.3 Life, death and the soul

I believe that, in posing the question of what life is, the very fact of death is brought to mind. In the Homeric age it was held that man passes away as leaves fall from a branch, that there is no life to come. The doctrine of the soul had not yet been developed and if some afterlife existed, it was at best shadowy and unconscious. The cycle of the seasons, night following day, and death following life, were all seen as the natural order of things - so we should eat, drink and be merry. The Orphic religion taught that the body is the tomb of the soul (soma-sema), thus offering a dualistic answer to the problem of death. Life (the soul) is alien to the body and needs eventually to be liberated from its tomb. Plato was the first to offer a scientific justification for the belief in the soul. According to Plato, souls - like common-sense people - are substances, and the soul, for various reasons - such as the fact that it is the principle of life - is also immortal. Aristotle, on the other hand, regarded a soul simply as the form of the organisation of

the body and in view of this it would be unacceptable to suggest that it might survive death. The Christian religion extended and entrenched the dualist notion of body and soul, the emphasis on present life (being alive, existing) as such. Although the Christian religion and other religions did have laws against killing, the preservation of life or the extension of life for the sake of life itself, was something of minor importance.

> At the peak of the dualistic movement, in Gnosticism, the *soma-sema* simile, in its origin purely human, had come to extend to the physical universe. The whole world is tomb (prison house, place of exile, etc) to the soul or spirit, that alien injection of what is otherwise unrelated to life. There, one might be tempted to say, the matter rests to this day - with the difference that the tomb has meanwhile become empty.
>
> (Jonas 1966:14)

Dualism was finally elevated to a dogma by Cartesianism. The world was regarded as a vast machine, the Creator being the clockmaker. The universe functioned according to the general laws of mechanics. During the seventeenth and eighteenth century this view was generally accepted and history had to wait for evolutionism to rediscover the concept of life.

> Evolutionism, however, regards this given type of structure, the condition for a specific performance of life, as itself a product of life, the outcome and temporary stopping-place of a continuous dynamism which itself must be termed 'life'. Thus life appears in its very means, that is, in its structural equipment for living, as its own achievement, or at least result, instead of being simply endowed with its means and faculties. This is one of the most far-reaching discoveries ever made with regard to the nature of life.
>
> (Jonas 1966:45)

2.4 Philosophies of life

The deterministic outlook on life prevailing in science before the twentieth century provoked protest from a number of thinkers who, in their writings, propagated the right to life, the worth of the human person, and spiritual values. There were three prominent movements in philosophy which generated new interest in the phenomenon of life and related matters:

(a) *The philosophy of life*

These philosophers were actualists who emphasised movement becoming life. Their conception of reality was an organic one. Biology was given high priority and their method was strictly empirical. Pluralism and personalism were strong trends within the movement. Important exponents of this trend were Henri Bergson, Wilhelm Dilthey and William James.

(b) *The philosophy of existence*

Philosophies of existence also contributed greatly to a renewed interest in the phenomenon of life (Kierkegaard, Heidegger, Jaspers, Marcel, Sartre, etc). Although it is extremely difficult to exactly define philosophies of existence, for present purposes suffice it to say that these philosophers attempted to see man in his totality and they reflected on problems such as the possibility of human life, subjectivity, the meaning of life and death, and other particular human experiences.

The following extracts from José Ortega y Gasset's *Some lessons in metaphysics* captures the mood of the age of the philosophies of existence: 'Life is what we do and what happens to us ...' (Ortega y Gasset 1969:36), 'Our life is what we are doing now ...' (1969:37), 'all living is one's own living ...' (1969:38), '... all living is a living with, a finding oneself, in the midst of a circumstance, a surrounding ...' (1969:40). 'Life is thrown at us, or we are thrown into it - but the life we are given is a problem which we ourselves must resolve' (1969:41). 'To live is to be continually deciding what we are going to do' (1969:43). 'Life is decision' (1969:57). '... our life is most of all a colliding with the future .... Life is an activity pointed toward the future; we find the present as the past afterward, in relation to the future' (1969:45).

(c) *The philosophy of being*

These philosophers confined themselves mostly to the analysis of being. They offered philosophies of nature, a philosophy of man and so forth. Of the more important figures in this movement were Alfred North Whitehead, George Santayana, Nicolai Hartmann and the Thomists.

One should of course also not underrate the influence of new movements in sociology and psychology which overcame mechanistic materialism in favour of a more humanistic approach.

2.5 The ethical life

Clearly, then, there is also the other type of philosopher who does not concern himself with the origins of man, the body-mind problem, the status of the mind, the possibility of introspection and so forth, but is interested in the question of *ends*. The concept of life is studied in its broader context - and themes such as the following come into play: forms of life, living responsibly, interpretations or views of life, the value of life, and the quality of life. The concept of life is studied in its broader application, for example in ethical systems, where the 'value of life' principle is of great importance. A prerequisite for any ethical system is the existence of living human beings. 'It is perhaps the most basic and necessary principle of ethics, since empirically speaking, there can be no ethics whatsoever without living human beings. This principle can be stated in several ways, but I prefer to state it as follows: "Human beings should revere life and accept death"' (Thiroux 1986:124). The principle stated by Thiroux has two components. Firstly, there is the reverence for life. The foregoing analysis - whatever one's point of view about the origin of life and of how different forms of life (including the life of man) are to be explained - clearly shows modern man's concern and interest in the phenomenon of life.

Today most cultures revere life and have strict rules prohibiting killing, although some allow killing under special circumstances. Prohibitions against killing are found in Judaeo-Christian ethics, Buddhism, Hinduism, Islam and in the ethical codes of humanism. Although some systems do allow killing under special circumstances, it can safely be suggested that in contemporary cultures, with the possible exception of a few small primitive groups, preserving and extending human life is a common goal. In most contemporary cultures the preservation and protraction of life are desirable under normal circumstances. It is argued that life is a basic possession, the one thing that all humans have in common, although of course each human life is unique and can never be exactly duplicated. That a living human being has life is an empirical fact which is universally accepted. What is to be done with that life, how it is to be used, whether in certain circumstances it can or should be terminated, are all matters of a different kind. How we argue about these issues would also reflect the worth or value we place on our lives and the lives of others.

The ethical dimensions of our beliefs, attitudes, actions and policies regarding the begetting, sustenance, protection, manipulation and improvement of life are especially the concern of bioethics, which means 'life ethics'. This includes the ethics

of sexuality, population and birth control, fertilisation, abortion, sterilisation, genetics, birth, health care, human experimentation and informed consent, organ transplantation, the treatment of dying patients, mercy killing, truth-telling and confidentiality in medicine, and related matters such as the right to live and the right to die. Ethical problems arising in areas such as medicine, business, law and ecology have caused renewed interest in ethics, not only on the theoretical level, but also as something which should be applied to human affairs in a very practical way. I believe that the ethical issues that have arisen have served as a great stimulus in our time and have generated new interest in the implementation of applied ethics.

3 THE QUESTION 'WHAT IS LIFE?' IN A THEOLOGICAL CONTEXT

3.1 Scientific facts and theological theories

Philosophers and theologians cannot ignore the information which the natural sciences offer regarding the origin of the cosmos, the origin of forms of life and especially that of human beings. Discoveries in the natural sciences and theories put forward by natural scientists have important implications for philosophy and theology alike.

Wolfhart Pannenberg (1981:4) expresses the following opinion:

> If the God of the Bible is creator of the universe, then it is not possible to understand fully or even appropriately the processes of nature without any reference to that God. If, on the contrary, nature can be appropriately understood without reference to the God of the Bible, then that God cannot be the creator of the universe, and consequently he could not be truly God and could not be trusted as a source of moral teaching either.

I do not think that theologians can ignore *indisputable* evidence concerning man and his origin, whatever the content of this evidence may be. It is often argued that scientific evidence which in the past was offered as indisputable has often turned out to be questionable or false. There are writers who warn against accepting everything science offers at face value. Mary Midgley (1985:11) contends that:

> The point I am currently making about the idea of 'the universe' as a whole is that, if one means by it not much more than is already described in scientific books, one is less likely to be deeply impressed with its vastness and mystery than if one regards those books as small mirrors reflecting only parts of its more superficial aspects.

The ideal would, of course, be for scientific, philosophical and theological theories of life to coincide. The fact is that they do often clash, but this is because of the confusion created by each attempting to understand the other from its own point of view. The foregoing analysis has clearly shown that the concept of life is not only to be considered on the factual level, but it also concerns the meaning we attach to these facts. We order our experiences of life in a certain way, and their meanings are consistent with a certain system which we usually describe as our world-view. Facts, our interpretation of them and the meaning we attach to them, all form an interconnected whole. Facts about the origin of human life are at one end of the scale, whereas the meaning we attach to our lives is at the other end, where faith operates - the sense of our life having a plan within a whole greater than ourselves. And these two ends of the scale are on different levels - facts and values are of a different order.

John Hick (1976:46-47) wrote:

> This emphasis upon human potentiality completes an important shift of emphasis in theological anthropology from the question of origins to the question of ends. It is not what man has come from but what he is going to that is important. We must assume that the picture being built up by the natural sciences of the origin of man, both individually and as a species, is basically correct and is progressively becoming more adequate and accurate as research continues. According to this picture, life on this planet began with natural chemical reactions occurring under the influence of radiations falling upon the earth's surface. Thus began the long, slow evolution of the forms of life, a process which has eventually produced man. And each human individual comes about through the partially random selection of a specific genetic code out of the virtually infinite range of possibilities contained even in the portion of genetic material lodged in his parents. This is, in broadest outline, the picture of man's beginning as it emerges from the physicists', chemists' and biologists' researches. And Christianity

> does not offer a different or rival account of our human origins. It says, in its hebraic myth of man's genesis, that he has been created out of the dust of the earth; but the details of the creative process, from dust to the immensely complex religious and valuing human animal, are for the relevant sciences to trace.

3.2 The rediscovery of the present self

Man's quest for meaningfulness is what Hick describes as 'what he is going to'. Philosophies of being, of existence and of life have also influenced theology where the emphasis has shifted away from the preoccupation with man's eternal soul (as life hereafter) to the existing human self, man in his concrete existence here and now.

It has for many years been fashionable amongst theologians, influenced by the life philosophies, to describe life as a mystery. They claimed human life to be totally different from any other form of life. Man was regarded as an exception in the world of living creatures. They argued as follows: Man is aware of and awaits his own death. But no other organism dies as man dies, because in life man is aware of his own approaching death and what he loses by dying. He can understand and explain the death of an organism, the disintegration of living structures or his relations into what remains after death has set in, but man cannot explain what it is for the 'I', the 'person', to die. In this sense death is a mystery. Of one thing we are certain - our own death - but it has been argued that 'personhood' sets humans apart from other living creatures, thus making human life and death unique. Knowing about death is also simultaneously a non-knowing - death, like life, is also a mystery (cf Brunner 1965:107f).

Much of contemporary thinking on life centres on the meaningfulness of man in an everyday context.

> To say that human beings have a soul is to say that they can do various things. ... I [have] enumerated their ability to think, hope, love, speak, perceive, etc. These are all things which human beings do. The category of action is, in this way, internal to that of having a soul. To say that human beings have a soul is to say that they have a capacity or ability to perform actions. The soul simply is this capacity for action which human beings have.
>
> (Cooke 1986:270)

This type of argument leads to the following claim:

> When the human being dies, his body decays and ceases to be the foundation for spatial and temporal predications of the human being. Can the human being still exist and be the subject of activities attributable to him because of the capacity for activity which is the soul? I do not see any metaphysical or logical reason why this should be impossible ....
>
> (Cooke 1986:274)

The emphasis is on the quest for a *meaningful life*. Human life as such has come to be regarded as extremely important; it is to be respected and even prolonged, if possible. The individual and society should both work toward the goal of making every human life a meaningful one. The idea of the life of the eternal soul has now become the idea of the moral life as responsible and meaningful. The life of the self has been rediscovered. Life for the contemporary religious individual means to be the responsible, the understanding self living as a social in-response-relationship-to-other-selves (cf Niebuhr 1963).

Some of the important issues in religious life at this point in time are: In terms of which symbols should we interpret religious life? What is the correct form and character of Christian life? How does it differ from other styles of human existence and action? To what other life styles is it closely related? Which is the best possible way to make sense of life? How can I give meaning to my own life and that of others?

4 THE FUTURE?

Spectacular progress in the natural sciences has confronted philosophers and theologians with new challenges. On the other hand it must be stated that the metaphysical controversies are still very much the same. Although new arguments have been put forward, none of the major metaphysical questions has an answer yet that is agreed upon. Philosophical contributions (other than metaphysical) to the general question 'What is life?' - with all its subsidiary offshoots and problems - lies on the level of the conceptual. Progress in this area means new ways of thinking about perennial problems, new descriptions and the development of alternative philosophical vocabularies. It is especially in this last area where much work needs to be done. The existing vocabularies have become outdated.

And what about the contribution of theology? Recently theologians have been under strong pressure to demonstrate the credibility and contribution of theology to areas of research such as bioethics. The burning question is: Can theology make a significant contribution to bioethics in general? (cf Shelp 1985). The question reaches even further: Can theologians offer a significant contribution towards the question 'What is life?', with its many ramifications? I think that ongoing discoveries in science and the application of new techniques in various fields, together with the development of innovative philosophical theories and vocabularies, will in future generate controversial and radically new thinking in theology as well.

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D I FERREIRA

Genetic engineering in life

The scope of modern genetic engineering is discussed in sufficient detail to allow the reader to gain a perception of the 'creative activities' it entails. Examples of genetic engineering (mainly in agriculture) are presented, as well as the dangers and fears which accompany such activities. Finally, reference is made to the ethical dilemmas relating to genetic engineering in living organisms.

1 INTRODUCTION

Genetic engineering - alteration of the genetic components of organisms - has been practised in an elementary form in agriculture for millennia, as plants and animals are selected to favour desired qualities. The fundamental laws of inheritance formulated by Mendel (1866) form the basis of modern plant and animal breeding. Traditional breeding involves the introduction of desirable traits and the elimination of undesirable genetic traits through natural mating and selection of suitable offspring (Council for Agricultural Science and Technology 1986 = CAST 1986). The new genetic engineering was triggered by Watson and Crick's discovery in 1953 of the double helix structure of deoxyribonucleic acid (DNA).

2 MODERN GENETIC ENGINEERING

Modern genetic engineering allows scientists to make precise changes in genetic material, that is, DNA (deoxyribonucleic acid). Like a magnetic tape, DNA stores information in the cell

which directs each phase of development of the individual. The information in DNA is stored in the form of long strings of sequences of four small molecules, in which the order of occurrence of the basic molecular units may differ from one sequence to the next (CAST 1986). The term 'gene' is given to the region in a DNA molecule that gives rise to a particular genetic character. It is now possible to exploit particular enzymes to cut DNA and isolate genes or other segments of DNA which are of interest; this DNA can then be introduced into another organism or it can be modified before reintroducing it into the same or a different organism (Davies 1987). All this has already been done and a few examples will be given later on. This technology is also called recombinant DNA (rDNA) and, in addition to other advantages, it makes it possible to introduce desired genes from exotic sources which would otherwise be impossible.

Thus genes can be transferred between different plants such as tobacco and maize, or different animals like rats and pigs; genes from microorganisms can also be introduced into plants and animals. It is this fact, especially if the transfer and elimination of human genes, or both are considered, which poses the first ethical question. To answer this question the objectives of genetic engineering will have to be stated and evaluated.

3 THE OBJECTIVES OF GENETIC ENGINEERING

The ultimate aim of scientists employing the technology of genetic engineering is to create a 'product' to improve the quality of life of all people, directly or indirectly. It is, however, debatable whether this statement is always valid. If not, genetic engineering becomes a question of morality.

How can this technology indeed improve the quality of life of all people? The umbrella goals of genetic engineering can be summarised as follows:

* The improvement of crop production.
* The improvement of animal production.
* The improvement of health care for humans.

It may occur to the reader that these goals are defined in very general terms, but each entails a large number of diverse activities and secondary goals. In the African context genetic engineering means increasing food production to feed the starving population through plants and animals that have become better adapted. Between six and seven million children under the age of five probably died in Africa during 1985, many of them in the

areas of greatest food scarcity (Joseph 1985). In any given year, some four to five million children die in Africa from the combination of causes that is responsible for death associated with famine (Joseph 1985). In many cases they die from the synergetic effect of malnutrition and infectious disease, and genetic engineering can therefore make an important contribution to health care.

Genetic engineering can therefore be regarded simply as a 'tool' to achieve specific aims. The moral and ethical dilemmas relate to the means of achieving these aims. A greater understanding of the principles involved in genetic engineering can be reached if specific examples are studied.

4 GENETIC ENGINEERING IN LIVING ORGANISMS

4.1 Genetic engineering in crop improvement

According to Goodman (1985),

> Improvement in world agriculture ultimately depends on a combination of improved farming practices, the availability of supplies to allow farmers to grow their crops, the accessibility of markets and the means to move produce to the market. Plant breeding continues to be the applied scientific discipline that delivers improved genetic traits for use by farmers. Genetic engineering will make its contribution in the near- to medium-term in improvements that will reduce input costs, reduce risks, reduce losses after planting or harvest, increase quality, and increase market value.

The application of genetic engineering to plants is possible because of the ability to regenerate whole plants from plant parts, to use *Agrobacterium*, nature's own genetic engineer, to transfer selected genes into the plant genome (the genetic library of an organism); other techniques are also used for direct gene transfer. With the rapid development of the technology for genetic engineering in plants, it is worthwhile examining some of the possibilities for its implementation.

4.1.1 Herbicide resistance

Weeds cause a serious reduction in the yield of crop plants and herbicides are therefore commonly applied to control weeds. Apart from the high costs involved, some herbicides may damage crops. The first useful gene transferred to plants was a gene

which imparted tolerance to glyphosate (a potent broad-spectrum herbicide which inhibits the growth of both weed and crop species). This gene was isolated from a bacterium *(Salmonella typhimurium)* and transferred to plants such as the petunia, tobacco and the tomato (Shah et al 1986; Fillatti et al 1987). Resistance to Atrazine (another herbicide) has also been incorporated into plants by analogous procedures (Davies 1987). Incorporation of these genes into crop plants therefore allows farmers to use these herbicides in the control of weeds without damaging the plants. Useful genes have thus been transferred from microorganisms to plants!

4.1.2 Disease resistance

Improving plants' resistance to disease is one of the more lucrative areas of genetic engineering. Plant disease is disruptive and, at times, catastrophic. For instance, late blight (a disease resulting from an infection by a fungal pathogen) caused the starvation of one million people and forced the emigration of another two million to North America, owing to its decimation of the potato crop in the Irish potato famine of 1845-1860 (Jaynes, Xanthopoulos, Destefano-Beltran & Dodds 1987). Attempts are being made to isolate genes for coding disease resistance from some plants and transferring them to other crop plants. The most novel approaches, however, are those in which genes for resistance to disease are isolated from insects and transferred to plants.

Certain insects have the ability to produce bactericidal proteins. One of these insects is the silk moth *Hyalophora cecropia)* in which the pupae respond to bacterial infection by the synthesis of from 15-20 antibacterial proteins (Dodds & Jaynes 1987). Some of these proteins like lysozyme, the antibacterial protein also found in egg white and human tears, were purified. Genes which code for the production of these proteins were very recently transferred to potatoes to combat diseases such as *Erwinia* and *Pseudomonas* (Dodds 1987).

4.1.3 Pest resistance

Like diseases, pests can also impair agricultural productivity. Biological control of insects is an increasingly attractive alternative to chemical insecticides which are believed to be extremely hazardous to the environment and humans, owing to their toxicity and even carcinogenicity (Carlton & Gonzales 1986).

The best known example of biological control is the use of a bacterium, *Bacillus thuringiensis*, which has been marketed as a biological insecticide for more than twenty years (National Research Council 1987 = NRC 1987). It produces an endotoxin which is a potent insecticide for certain pests. Initially, the gene which codes for the production of this toxin was transferred to another bacterium *(Pseudomonas fluorescens)* which colonises corn roots. This genetically engineered organism is freeze-dried and coated on seeds before planting, and it is therefore able to kill certain pests including the black cutworm - an important maize pest (NRC 1987). An even more novel approach is to transfer this ability to plants. The gene was successfully transferred to tobacco (Vaeck et al 1987). Larvae that were feeding on the genetically altered plants became paralysed after forty-eight hours and died within three days. The gene has also been transferred to tomatoes (Fischhoff et al 1987) while attempts are being made to transfer it to potatoes.

4.1.4 The use of microorganisms

Microorganisms in the environment affect the growth of plants in a variety of ways and can be either beneficial or harmful. The problem of disease has already been discussed. However, while some microorganisms protect plants from bacterial and fungal infection, others protect them from environmental stresses such as acidity, salinity, or high concentrations of toxic metals. Still others attack weeds that compete with crops. The best known association between microorganisms and plants is the symbiotic relationship between nitrogen-fixing bacteria of the genus *Rhizobium* and members of the legume family, such as soya beans (NRC 1987).

The first development which has progressed to the point of field testing involves genetically altered bacteria designed to prevent frost damage. *Pseudomonas syringae* is a bacterial species with many members that are normally harmless and commonly inhabit the outer surface of plant cells. However, some of these bacteria contain a protein that initiates the formation of ice crystals at temperatures below freezing. The growing ice crystals can rupture and damage plant cells. If the bacteria are not present plants can withstand colder temperatures without damage (NRC 1987). The gene that makes the protein was identified and removed from the organism (Lindow et al 1982). The so-called 'ice-minus' strain was thereby developed. In laboratory and field tests, plants sprayed with this strain could withstand frost conditions. The ice-minus strain replaces the wild strain and provides the crop with some measure of frost protection. Due

to public apprehension, based on a lack of understanding and confusion over the types of precautions needed to regulate its release into the environment, it took approximately five years before approval was granted to conduct field trials. This was the first case in which a genetically engineered microorganism was tested outside the laboratory.

Another novel but quite different approach involves the common firefly *(Photinus pyralis)*. When scientists transfer genes from one organism to another it is very difficult to tell whether the gene is actually transferred. In most cases this can only be tested in the mature plant. Scientists therefore make use of 'marker' genes. These genes code for a product, such as resistance to an antibiotic, and their transfer can be detected at a very early stage if the cells are cultured on a medium containing the antibiotic. These 'marker' genes are transferred together with the other wanted gene. Ow and his co-workers (1986) isolated the luciferase gene in fireflies, which encodes an enzyme that catalyses light-producing luciferin. This gene was transferred to carrots and tobacco and the light emitted by luciferase was detected in the plants!

4.2 Genetic engineering in animals

For centuries, people have sought to improve animal productivity by selecting and breeding only the best animals. Breeders have sought to develop animals that grow bigger, produce more, provide leaner products of a better quality, use resources more efficiently, or show increased fecundity or resistance to disease and stress (NRC 1987). Techniques such as artificial insemination and embryo transfer date back to 1782 and 1890 respectively (Steane 1985). These techniques have revolutionised animal breeding in this century while the next important advance in animal husbandry will result from combining conventional breeding methods with genetic engineering. Although the technology of gene transfer in animals is still in its infancy, a number of notable successes have already been achieved. Some of these achievements will be described briefly.

4.2.1 Animal breeding

Gene transfer between mammalian cells by somatic cell hybridisation was achieved in the 1960s. Owing to the fact that an animal can only result from the development of a fertilised egg, the transfer of genes to single cells is of use only in gene mapping. The transfer of genes to fertilised egg cells has been achieved both in a number of laboratory species and in cattle (NRC 1987).

Rat growth hormone genes were transferred to mice resulting in larger body size and this characteristic was also transmitted to their progeny (Palmitter et al 1982). Hammer and others (1985) reported the production of transgenic rabbits, sheep and pigs. The isolation and transfer of the so-called Booroola gene is being attempted. This gene is found in Australian merino sheep and it boosts the incidence of twinning and triplets, giving an overall 20-40% increase in the number of lambs weaned (NRC 1987). Scientists may attempt to transfer this gene to other valuable livestock species once it can be isolated and transferred.

Although the science of pisciculture (fish farming) is relatively young, genetic engineering has already been applied to fish production. The fertilised eggs can easily be manipulated to change the chromosome numbers, leading to bigger fish. The sex of the fish can also be regulated, which is an advantage because female fish are preferred for commercial markets (NRC 1987). Attempts are being made to isolate an 'antifreeze' gene from Antartic fish and transfer it to other fish species, which will allow more species to tolerate low temperatures.

4.2.2 Vaccines against disease

The development of vaccines through genetic engineering holds great potential. The first of these vaccines was Omnivac, which immunises pigs against pseudorabies. This disease infects about 10% of the four million pigs in the United States and is costing the pork industry in that country as much as $60 million a year (NRC 1987). Another vaccine (for colibacillosis) was approved for use in Europe in 1982 (Marketing International 1984). These vaccines depend on cloned genes of the disease agent which are used to produce large quantities of certain proteins in cell culture. When injected into an animal as a vaccine, these proteins stimulate the animal's own immune system to protect it from infection (NRC 1987). Such vaccines can be effective, safe, easy to manufacture and economical to produce. Genes have been cloned for the surface proteins of viruses that cause fowl plague, influenza, vesicular stomatitis, herpes simplex, foot-and-mouth disease, feline leukaemia, rinderpest and rabies; vaccines have either been developed or experiments are leading to their development against these animal diseases (Van Brunt 1987).

4.2.3 Microorganisms in animal husbandry

The production of growth hormones and the modification of intestinal organisms are the two fields of interest which will be briefly presented.

The low cost production of large quantities of animal growth hormones is an exciting prospect. Bovine growth hormone (BGH) is a naturally occurring hormone that increases milk production in cows (Gagliardi 1985). Bacteria have been genetically engineered to produce the hormone, which when administered to lactating cows daily, can increase milk production by up to 40%. The animal's milk composition does not change, although it does require greater amounts of, and more nutritious, feed (NRC 1987). Studies are being conducted to transfer the BGH gene to animals. Another example is that of porcine growth hormone (PGH). This hormone greatly stimulates pigs' growth, elevates the growth rate, feed efficiency, and ratio of muscle to fat (NRC 1987). The PGH gene has also been cloned into bacteria, purified and administered to pigs by injection.

A more speculative area of interst to genetic engineers lies within the agricultural animals themselves. Attempts are being made to improve the microorganisms inside an animal to create a more effective, natural bioprocessing system. This research is still in its infancy but provides a glimpse of the far-reaching possibilities that lie ahead for agriculture.

4.3 Genetic engineering in humans

Genetic engineering in humans is the most controversial field of genetic engineering, or it has at least the potential to become controversial. Reports of such results as the fusion of cells from mouse and man (Harris & Watkins 1965) create public unease. The major application of genetic engineering in humans lies in the field of health care and this will be outlined in the following sections.

4.3.1 Genetic engineering as a tool in diagnostics

The diagnosis of diseases is an important aspect of human health care. New approaches have been developed through genetic engineering using DNA probe technology. A DNA probe is basically a piece of DNA which complements the DNA or RNA of the disease-causing organism. In the case of Legionnaire's disease, for instance, the DNA probe test can be performed on a patient's serum, blood, sputum, faeces or liver cells (Van Brunt 1985). The complementary DNA probe hybridises to a complementary nucleic acid sequence in the sample, which confirms the presence of the disease. This technology holds great potential for the rapid and precise diagnosis of diseases, including cancer.

4.3.2 Genetic engineering as a tool in therapeutics

Developments in this field are finally aimed at the treatment of serious diseases by physicians in a hospital environment. Several products have already been developed and are being marketed. These include the human growth hormone, interferons, human insulin (the first genetically engineered therapeutic, which has been on the market since 1982) and tissue plasminogen activator (t-PA) (Klausner 1985; Ratafia 1987).

The genes that code for the various therapeutics were cloned into bacteria *(Escherichia coli)*, or mammalian cell cultures. Large amounts of the product can then be produced in these cultures. Genetically engineered *E. coli* is for instance used to produce interferons (used in cancer therapy and several other diseases), tumour necrosis factor (TNF, which kills some tumour cells), human growth hormone (for treatment of hypopituitary dwarfism) and interleukin-2 (IL-2, used in the treatment of cancer and possibly AIDS) (Klausner 1985). Mammalian cell cultures can also be used to produce hormones, enzymes and proteins. The best example is the production of t-PA, which is a revolutionary blood-clot dissolver used for treating heart attacks. It has been tested successfully and one company is working on a system of automatic injectors, whereby a person with a heart condition might be able to self-inject t-PA (Klausner 1985). Many more examples can be added but these should suffice to explain the therapeutic principles involved.

4.3.3 Gene therapy

Gene therapy which transforms human cells to treat genetical defects is a high-risk field of research, and strict control measures therefore exist (Beers & Bassett 1977). The ultimate goal of gene therapy is to prevent disease, not just to cure it. Research is still, however, focused on the genetic manipulation of the germ line to produce heritable changes (McCormick 1985a). Marrow culture and transplantation have proved successful in the more conventional (not genetically engineered) treatments of some diseases such as adenosine deaminiase (ADA) deficiency, a disease that produces a severe combined immune deficiency syndrome. Scientists are therefore attempting genetic manipulation of bone marrow cells. According to McCormick (1985a) '... researchers won't yet inject foreign DNA into a human subject. Far better to transfer genetic material in culture and reimplant it.'

There are certain preconditions to experimentation in human gene therapy (McCormick 1985a), all of which ensure the safety of the patient and others. The more controversial possibilities still

lie in the future. These include germ-line modifications, where defective genes - in dominant diseases - are replaced, or in which parents homozygous for a recessive trait are determined to have children free of that trait. The problems associated with system-wide genetic change (i e a change that effects the whole body) are enormous and no reputable researcher is willing to take the responsibility for unknown effects on what might be generations of offspring (McCormick 1985a).

A final possibility of genetic engineering in humans is not to correct defects, but to add desirable characteristics. The debate on this potential has already started and it can only be hoped that it will never be exploited.

5 FEARS AND DANGERS

Public concern about genetic engineering has focused on two nightmarish scenarios. One is of genetically engineered organisms such as bacteria to which we have no resistance, escaping from the laboratory into the environment and causing a new plague. The other features arrogant scientists, always on the look-out for a chance to 'play God', redesigning humans in accordance with their own visions of excellence. None of these are part of the reality of our time, but there are related topics which should be addressed. The fears of genetic engineering in microorganisms, plants, animals and humans and the associated dangers will be dealt with briefly.

5.1 The release of genetically engineered microorganisms

When a 'new organism' is released into the environment the question of safety or possible danger immediately arises. The release of genetically engineered microorganisms into the environment is controlled by statutory bodies in countries all over the world. The current approach to determine if the release of such an organism constitutes a hazard focuses on five questions (Marx 1987):

* Will the released organism survive?
* Will the organism multiply?
* Will it spread beyond its original area of application?
* Can it transfer its genetic material to other organisms?
* Will the original organism or any of those that might pick up its genes prove harmful?

The risk of releasing genetically engineered microorganisms will therefore be assessed, case by case. As a result of uncertainty and the actions of environmental activists it took Steven Lindow and his co-workers five years to obtain approval for the field testing of the 'ice-minus' bacteria (McCormick 1985b; Marx 1987). It may be concluded that the risks involved in the release of genetically engineered microorganisms are minimised by strict control measures.

5.2 Genetically engineered plants

The cultivation of genetically engineered crop plants might pose two environmental risks: the negative environmental effects of a modified genotype (genetic constitution of an individual) itself and the possible movement of that unique DNA to other organisms (Hauptli, Newell & Goodman 1985).

Weedlike tendencies are the only real environmental nuisance posed by a new crop variety. Careful assessment of a new plant in natural and agricultural environments, before introduction is permitted, should reveal the weedlike nature of the plant. The transfer of the transformed DNA from a crop species to a weed species may be at best impossible or, at worst, result in an overly persistent weed (Hauptli, Newell & Goodman 1985), especially if the transferred gene codes for herbicide tolerance. However, the mechanisms involved and the reproductive barriers separating most crop species from weeds, make such an event highly unlikely. These risks must nevertheless be assessed before permission for release is granted.

5.3 Genetically engineered animals

The environmental impact of genetically engineered vaccines is probably the only aspect of such vaccines that needs to be considered. This should not cause any ethical problems, provided that assessment procedures are sound enough. The transfer of a genetic trait from one mammalian species to the germ line of an unrelated mammalian species may, however, raise certain ethical questions. If proper attention is given to animal welfare, modification of the germ line of domestic animals raised for food, with the intention of improving their properties, may become ethically acceptable (Danforth & Roblin 1986).

5.4 Genetically engineered humans

The development of therapeutics and diagnostics for human health care through genetic engineering causes no serious ethical problems, provided that strict testing for unwanted side effects is maintained. Even gene therapy in humans is not a controversial subject if it is done through somatic cells such as bone marrow. The first ethical problem arises when germ line modifications are considered. There can be no objection if this action can lead to the cure or the prevention of the disease. The problem is that the side effects of such an action are unknown. This is of great importance because once the gene is inserted the trait becomes inheritable. The side effects will only become visible once the gene is inserted but the gene cannot be inserted before scientists are sure that it is safe. This is therefore a catch-22 situation.

Another ethical question involves the transfer of genetic traits from human beings into the germ line of another mammalian species or the transfer of a genetic trait from any mammalian species into the germ line of a human being. A lawsuit seeking to prohibit experiments of this type was filed in the USA (Danforth & Roblin 1986). Do these experiments violate ethical and moral standards? The debate will undoubtedly continue for many years. However, the insertion of genes with the aim of adding desirable characteristics (not to correct defects) cannot be defended on any ethical or moral basis.

6 CONCLUSIONS

The ultimate aim of life scientists is to improve the standard of living of all people. Genetic engineering can be regarded as a tool to achieve certain goals which could not be achieved through conventional approaches. The long-term possibilities created by genetic engineering for the production of food and the improvement of human health care, make it a moral imperative that such research should be done, although society must be involved in its demarcation and application. Society's involvement should be based on moral and ethical principles.

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M M QUIGLEY

The right to experiment with human life

This essay is prepared from the viewpoint of a clinician-researcher. I claim no credentials as a moral theologian, philosopher, ethicist or social scientist. My interest in this topic has developed from my clinical practice, which primarily involves the new reproductive technologies, such as in vitro fertilisation, embryo freezing and oocyte donation. In clinical application of these technologies, there is often an unclear separation between clinical experimentation and innovative therapy.

With that caveat however, I will develop this topic by progressing from a brief introduction to the relevant ethical principles, through an overview of the international statements on human experimentation, into a detailed examination of the checks and balances required before human experimentation is permitted in the United States. Finally, I will raise some questions concerning the introduction of innovative therapy, particularly in the area of reproductive technology.

1 ETHICAL PRINCIPLES

The title of this presentation, 'The Right to Experiment with Human Life', frames but one-half of the relevant ethical question. Human experimentation involves two principal parties. First, society, for whose ultimate gain human experimentation should be designed, and second, the individual, who (hopefully) freely consents to participate in the experimentation. A third

party involved is the investigator, who is obliged to conduct the research in accordance with the ethical principles discussed below in order to maximise the benefit to society, while protecting the subject's rights.

As analysed by Hans Jonas, there is a basic conflict between society's *moral claim* to a common good and society's *right* to the attainment of that common good. A *moral claim* necessitates the consent of the participant while a *right* can be required without consent. As an example, society has a *moral claim*, on those of us who are able, to provide the means to feed the hungry. Society has a *right* to collect taxes, part of which may be used to feed the hungry. Even though the end result, that is feeding the hungry, is the same, in the first example an individual can refuse to contribute but in the second, no individual can refuse to pay his taxes without facing penalties.

Society only has a *right* to require human experimentation when there is an extraordinary danger to society as a whole. An obvious example of such a danger is the current AIDS epidemic. Society has an obligation to protect the wellbeing of the greater number, even at the risk to the rights of some individuals. For example, it is entirely appropriate to demand HIV screening of prospective blood donors to protect the supply of safe blood or blood products for transfusions, even at the risk of violating an individual's confidentiality.

Research which is aimed not to remove a clear and present threat to society, but rather to improve the health, wellbeing and/or longevity of individual members of society does not fall under the same umbrella of *right*. As an example, even though improving the longevity and quality of life of individuals with certain types of cancer by developing better treatments may benefit the individual, that in itself does not remove a current threat to society as a whole. In other words, avoiding a disaster, for example by research to limit the spread of HIV infection, always carries greater weight than promoting something beneficial, for example, by developing a more successful treatment for certain types of cancer.

2 DEFINITIONS

As defined by the United States Department of Health and Human Services (see Appendix C), a *human subject* is a living individual about whom an investigator (whether professional or student) conducting research obtains *firstly*, data through intervention or interaction with the individual or *secondly*, identifiable private information. *Research* refers to a class of activities designed

to develop or contribute to generalisable knowledge. By generalisable knowledge is meant theories, principles or relationships (or the accumulation of data upon which they may be based) that can be corroborated by accepted scientific observation and influence.

Thus, strictly speaking, the daily practice of medicine is not research, although it is never exactly known in advance how an individual patient will respond to a given drug. However, if a physician plans to treat half his patients with drug A and half with drug B and compare the results, this is research, even if both drugs are accepted standard treatments for the condition. Likewise, it is research if a physician reviews his files and reports the outcome of a specified therapy in a number of patients.

3 RECENT HISTORICAL BACKGROUND

The modern history of human experimentation dates from the end of World War II. Two different forces have resulted in the current state of the supervision of human experimentation. First was the widespread abhorrence upon discovery of the 'medical' experiments performed on humans by the Nazis before and during World War II. The second is the widespread application of what has been termed the 'randomised clinical trial'.

4 NUREMBERG CODE

The revelations at the Nuremberg War Crimes Trial concerning the Nazi prisoner experimentation led to development of what has come to be called the Nuremberg code (Appendix A). This document states that medical experiments are ethical with the stipulations that the subject voluntarily consents, the experiment is anticipated to yield results beneficial for society and unobtainable by other methods, and that the degree of risk undertaken by the subject should never exceed the potential benefit to be obtained from the study.

5 RANDOMISED CLINICAL TRIALS

The randomised clinical trial is a device used to compare the efficacy and safety of two or more interventions or regimens. Although primarily designed to test new drugs, it has more recently been applied to the study of established drugs, vaccinations, surgical interventions, and even social innovations. Prior to the development and application of the randomised

clinical trial, clinical research had proceeded in a haphazard fashion, generally without vigorous examination of whether or not the new or innovative therapy was superior to the old. An extreme example of this type of reasoning dates back to the ancient Roman physician, Galen, who wrote 'all who drink of this remedy recover in a short time, except those whom it does not help, who all die. Therefore, it is obvious that it fails only in incurable cases'.

The randomised clinical trial allocates experimental subjects to receive either standard or innovative therapy. In the best designed experiments, the specific treatment being given is unknown to the subject (single blind study) or, ideally, to both the subject and experimenter (double blind study). In many randomised clinical trials, particularly ones involving new drugs, a percentage of the study subjects receive an inactive drug (placebo) as an additional check on the efficacy as well as side effects of the drug under investigation.

The natural human bias that 'new is better' is often disproved through the mechanism of the randomised clinical trial.

Table I summarises a study of forty-six trials of innovations in surgery and anaesthesia compiled by John P Gilbert and co-workers. Their study revealed that the innovations subjected to randomised clinical trial were only 'successful' in about half the cases. In their study, success was defined as being equal to or better than the standard therapy. Less than a third of the time was the innovation superior and in only 13% was the innovation much superior to the standard therapy.

TABLE I
ANALYSIS OF RANDOMISED CLINICAL TRIALS

Outcome			
Standard Treatment Better	-	Much Superior:	7%
		Superior:	15%
		Innovation has Undesirable Features:	23%
No Difference	-		5%
Innovative Treatment 'Successful'	-	Approximately Equal:	18%
		Superior:	18%
		Much Superior:	13%

The Declaration of Helsinki (Appendix B), which was adopted by the World Medical Association in 1964 and revised in 1975, refined and expanded the standards of the Nuremberg code. The Declaration specifically required supervision of research involving human subjects by an independent committee. For the first time, the Declaration differentiated between what was termed clinical research (medical research combined with professional care) and nonclinical biomedical research (which was defined as nontherapeutic or pure research conducted on a human subject, without any potential benefit to the individual participant).

6 ETHICAL STANDARDS FOR CLINICAL RESEARCH

Several ethical norms for human experimentation can be summarised from the Nuremberg code and Helsinki Declaration. *First*, there must be good research design. In other words, the research project needs to be organised and conducted in such a way that the conclusions based on the data obtained are likely to result in scientifically valid, meaningful conclusions. *Second*, the investigators conducting the research must be competent. This implies that the physicians who are administering drugs or performing procedures are trained and experienced to not only perform their professional services with the least risk to the subject, but also to be able to recognise and manage any unanticipated or untoward complications. In addition, the investigators need to conduct the research in such a manner as to protect the scientific validity of the observations. *Third*, there must be a favourable balance of harm and benefit. The research must be designed in such a way that the anticipated benefit, both to society and the subject, outweighs the risks. Particularly in the area of research for which there is no direct benefit to the subject, maximum effort must be made to limit the risk to the subject. The experiment must be terminated promptly if it appears that the risks are greater than those anticipated when the study was designed. *Fourth*, that informed consent be obtained from the subject. This informed consent requires that competent or capacitated individuals be provided with all the reasonably available information concerning risks and benefits in order to make a true, knowledgeable, and free choice about their participation in the research. This area will be discussed at length in subsequent sections. *Fifth*, that there be equitable selection of subjects. This is particularly critical when individuals such as prisoners, minors or even captive groups such as employees of the health centre are contemplated as potential research subjects.

7 REGULATION OF HUMAN EXPERIMENTATION IN THE UNITED STATES

On 12 July, 1974 the United States Public Health Service Act was amended. The amendment required that all entities which apply for a grant or contract that involves the conduct of biomedical or behavioural research involving human subjects, nust be subjected to an Institutional Review Board (IRB) to review such research. This requirement was designed to protect the rights of the human subjects of such research. **Appendix** C contains the full text of the most recently enacted revision of those regulations (issued 8 March, 1983).

Strictly speaking, these regulations only apply to research involving human subjects as conducted or funded by the Department of Health and Human Services (basically the National Institutes of Health). However, the Federal Food and Drug Administration has implemented essentially identical regulations covering the conduct of all clinical trials of investigational drugs and medical devices. Virtually all institutions in the United States that conduct research involving human subjects conduct some research which is either funded by the National Institutes of Health or involves drug or medical device clinical trials. Thus, these institutions are required by law to have an IRB that oversees such research. As a practical point, to my knowledge all institutions that have an IRB require *all* human experimentation to be supervised by the institutional IRB, regardless of whether IRB surveillance is required by Federal law or not. Thus, for all practical purposes, virtually all human experimentation in the United States is supervised by an IRB which functions under Federal law.

8 CONSTITUTION OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The IRB is required to have at least five members with varying backgrounds, in order to ensure complete and adequate review of research activities. Generally, IRBs are substantially larger than the minimum required. The IRB is required to have both men and women, is not allowed to have its members entirely from one profession, and must include at least one member whose primary concerns are nonscientific areas (e g lawyers, ethicists, and members of the clergy). The membership of the IRB is required to have diverse backgrounds (including consideration of race and culture) as well as sensitivity in such areas as community attitudes. There must be at least one member of the IRB who is not otherwise affiliated with the institution and who is not a part of the immediate family of a person who is affiliated with the institution.

The IRB reviews and has the authority to approve, require modifications in, or disapprove all research activities. The IRB controls what information must be given to the subjects and the method of documentation of informed consent.

9 CRITERIA FOR IRB APPROVAL OF RESEARCH

Regulations state that, in order to approve research involving human subjects, the IRB should determine that all of the following requirements are satisfied. *First*, risks to subjects are minimised by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and where appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. *Second*, that the risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result. *Third*, that the selection of subjects is equitable, taking into account the purposes of the research and the setting in which the research will be conducted. *Fourth*, informed consent (as discussed below) is obtained from each prospective subject and is documented appropriately. *Fifth*, where appropriate, research plans make adequate provision for monitoring the data collected to ensure the safety of the subjects. *Sixth*, where appropriate, there are adequate provisions to maintain the privacy of the subject and confidentiality of the data. The regulations also require that, where some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged), that appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

10 INFORMED CONSENT

Investigators are prevented from involving humans as subject of research unless the investigator has obtained the legally binding, ethical, informed consent of the subject or the subject's legally authorised representative. The investigator is required to seek the consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether to participate and to minimise the possibility of coercion or undue influence. The information that is given to the subject must be in a language understandable to the subject or the representative.

The subject or representative is required to be given the following information:

1. A clear statement that the study involves research. This must include an explanation of the purpose of the research and the expected duration of the subject's participation. It also must include a description of the procedures to be followed and identification of any of these procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of all appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. An explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and experimental subject's rights, and whom to contact in the event of a research related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

In addition, where appropriate, one or more of the following items of information shall be provided to the subject:

1. A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable.
2. Anticipated circumstances under which a subject's participation may be terminated by the investigator without regard to the patient's consent.
3. Any additional cost to the subject that may result from participation in the research.
4. The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
6. The approximate number of subjects involved in the study.

A copy of the generic informed consent document currently used at the Cleveland Clinic Foundation is given in Appendix D. In addition to this, the subject is provided with a written summary of the information presented orally. This includes the specifics concerning the research plan, procedures, risks, discomforts, alternatives and benefits.

In addition to preapproving the proposed research and the elements of informed consent, the IRB is further given the authority to review and supervise the conduct of research. Reports on the progress of the research must be made by the investigator to the IRB at intervals not to exceed twelve months and any unanticipated or untoward events must be reported promptly to the IRB. The IRB has the authority to monitor the informed consent process, review the research records, and to suspend or terminate research not being conducted in accordance with the guidelines, or research in which it appears there is unreasonable risk to the subjects.

11 INNOVATIVE THERAPY VERSUS HUMAN EXPERIMENTATION

All innovative medical therapy by its very nature is 'experimental'. Obviously, even 'successful' innovative therapy is far less likely to be successful in its initial application when compared to the ultimate success rate obtainable after years of refinement and experience. Modern medicine is full of examples, many of which, such as heart transplantation and the artificial heart, have received worldwide publicity soon after the initial application of the new therapy.

As an example of innovative therapy, let us review the early experience with human in vitro fertilisation. Infertility therapy presents several unique ethical concerns. First, the patients are not suffering from a classical disease which represents a threat to their physical health or life. In fact, in the United States at the present time, many insurance companies refuse to provide payment for diagnosis and treatment of infertility by simply stating that infertility is not a disease. As the social conditions, at least in the United States, have changed, adoption is no longer a viable option for most couples.

These desperate individuals, who are unable to be helped by conventional infertility therapy, have been forced to pursue innovative therapy as their only realistic hope of having a family.

Table II summarises the clinical results obtained by the British pioneers, Steptoe and Edwards, during five years of attempts at producing pregnancies by means of human in vitro fertilisation and embryo placement. From 1972 to 1977 they reported on seventy-seven patients who underwent embryo placement (undoubtedly many other patients had attempts made at treatment that terminated without having any embryos available for placement). Of these seventy-seven patients treated over five years, only three became pregnant and none of the three pregnancies resulted in a live birth.

TABLE II

EARLY RESULTS OF HUMAN EMBRYO PLACEMENTS
FOLLOWING IN VITRO FERTILISATION (1972-1977)

Follicular Stimulation	Luteal Support	Patients	Pregnancies
hMG/hCG	None	13	0
hMG/Clomiphene/hCG	None	2	0
hCG	hCG, progesterone	7	0
hMG/hCG	hCG, bromocriptine, clomiphene, progesterone and/or 17-OH progesterone	55	3*
	TOTALS	77	3

* 2 biochemical, 1 ectopic

Table III summarises Steptoe and Edwards's two years of research from 1977 through 1978. In these experiments they attempted oocyte recovery during the natural menstrual cycle.

TABLE III

HUMAN IN VITRO FERTILISATION RESULTS, 1977-1978

Patients Admitted		79
No laparoscopy	11	
Patients with Attempted Oocyte Recovery		68
No Oocyte Recovered	23	
Patients with Oocyte Inseminated		45
No Fertilisation	10	
No Cleavage	3	
Patients with Embryo Placed in Uterus		32
No Pregnancy	28	
Patients Pregnant		4
Spontaneous Abortion	2	
Children Born		2

During these experiments, seventy-nine patients were treated and ultimately two children were born. Overall, these pioneering experiments culminated in a success rate, after seven years of experimentation, that did not exceed 1%.

In the United States today there are approximately 150 centres providing in vitro fertilisation treatments. It is shocking that fewer than sixty centres have satisfied the minimum criteria (including three live births) for membership in the Society for Assisted Reproduction of the American Fertility Society. Indeed, it has been estimated that there are over fifty centres that have collectively treated thousands of patients without the result of a single live birth.

This example is not meant to condemn medical innovation, but rather to serve as a cautionary note that innovative therapy is unlikely to be dramatically successful when first applied. Patients who participate in innovative medical therapy should receive the same protection given to experimental subjects, in as far as the requirements for obtaining valid informed consent are concerned. Patients who are desperate are naturally inclined to take any risks and chances with the hope of achieving their goal, in this example, having a child. However, before these patients can validly agree to accept innovative therapy, they must be provided with the same type of information required for subjects participating in human research projects. This would include information such as the risks, discomforts, and costs involved with the treatment, the likelihood of success (taking into account the previous success of the *specific centre* applying the treatment), as well as disclosure of alternative treatments and their anticipated likelihood of success.

12 SUMMARY AND CONCLUSIONS

The use of humans as experimental subjects is an integral part of the medical research necessary to continue making improvements in available therapies. However, with the exception of conditions that represent a real and current risk to society as a whole (such as infectious disease), society has no *right* to require any individual to participate in human experimentation. Violation of subjects' rights, particularly by the Nazis before and during World War II, has led to the development of codified rules to protect the rights and minimise the risks of humans who participate as research subjects. Strict adherence to these rules, with consideration of the ethical guidelines concerning the design, goal and conduct of research, will allow the greatest likelihood of obtaining meaningful results from the research, with minimal risks to the participants.

Innovative clinical therapy, defined as therapy which is untried or so new that the likelihood of success is small, should be treated in the same manner as research. In other words, patients for whom innovative therapy is recommended also need to have the same degree of protection of their rights by being provided with all reasonably available information concerning risks, predictable outcomes and alternatives in order to make a truly informed decision to participate in a trial of the innovative therapy.

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APPENDIX A

THE NUREMBERG CODE

Permissible Medical Experiments

The great weight of evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject ...

[Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2 (Washington, D.C.: U.S. Government Printing Office, 1949), pp. 181-182.]

APPENDIX B

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: RECOMMENDATIONS GUIDING MEDICAL DOCTORS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

INTRODUCTION

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the world, 'The health of my patient will be my first consideration,' and the International Code of Medical Ethics declares that, 'Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest.'

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies a fortiori to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every doctor

in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the law of their own countries.

I BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (CLINICAL RESEARCH)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope for saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III NONTHERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (NONCLINICAL BIOMEDICAL RESEARCH)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator of the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

[Adopted by the 18th world Medical Assembly, Helsinki, Finland, 1964, and as revised by the 29th World Medical Assembly, Tokyo, Japan, 1975.]

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D—Additional Protections for Children Involved as Subjects in Research

Authority: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 289i-3(a)).

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Source: 46 FR 8386, January 26, 1981, 48 FR 9269, March 4, 1983.

§ 46.101 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.

(1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or funded by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of this section waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if

information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(c) The Secretary has final authority to determine whether a particular activity is covered by these regulations.

(d) The Secretary may require that specific research activities or classes of research activities conducted or funded by the Department, but not otherwise covered by these regulations, comply with some or all of these regulations.

(e) The Secretary may also waive applicability of these regulations to specific research activities or classes of research activities, otherwise covered by these regulations. Notices of these actions will be published in the *Federal Register* as they occur.

(f) No individual may receive Department funding for research covered by these regulations unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under an assurance satisfying the requirements of this part, or the individual makes other arrangements with the Department.

(g) Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

(h) Each subpart of these regulations contains a separate section describing to what the subpart applies. Research which is covered by more than one subpart shall comply with all applicable subparts.

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

§ 46.102 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Department" or "HHS" means the Department of Health and Human Services.

(c) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(d) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(e) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(h) "Certification" means the official notification by the institution to the Department in accordance with the requirements of this part that a research project or activity involving human subjects has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the approved assurance on file at HHS. (Certification is required when the research is funded by the Department and not otherwise exempt in accordance with § 46.101(b)).

§ 46.103 Assurances.

(a) Each institution engaged in research covered by these regulations shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in these regulations.

(b) The Department will conduct or fund research covered by these regulations only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Secretary that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. This assurance shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of these regulations applicable to Department-funded research and is not applicable to any research in an exempt category listed in § 46.101.

(2) Designation of one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Secretary.[1]

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv) for insuring prompt reporting to the IRB and to the Secretary[1] of unanticipated problems involving risks to subjects or others.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by these regulations, and shall be filed in such form and manner as the Secretary may prescribe.

(d) The Secretary will evaluate all assurances submitted in accordance with these regulations through such officers and employees of the Department and such experts or consultants engaged for this purpose as the Secretary determines to be appropriate. The Secretary's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Secretary may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Secretary may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Within 60 days after the date of submission to HHS of an application or proposal, an institution with an approved assurance covering the proposed research shall certify that the application or proposal has been reviewed and approved by the IRB. Other institutions shall certify that the application or proposal has been approved by the IRB within 30 days after receipt of a request for such a certification from the Department. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

§ 46.104 [Reserved]

§ 46.105 [Reserved]

§ 46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of these regulations each IRB shall:

(a) Follow written procedures as provided in § 46.103(b)(4).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Secretary[1] any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary has established, and published in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the *Federal Register*.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Secretary may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary.[1]

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

§ 46.114 Cooperative research.

Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible to the Department for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly from the Department, except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 46.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members as required by § 46.103(b)(3).

(6) Written procedures for the IRB as required by § 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to the Department with the knowledge that subjects may be involved within the

period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research described in § 46.101(b), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in these regulations, and certification submitted to the Department.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research (conducted or funded by the Department) is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in these regulations, a certification submitted to the Department, and final approval given to the proposed change by the Department.

§ 46.120 Evaluation and disposition of applications and proposals.

(a) The Secretary will evaluate all applications and proposals involving human subjects submitted to the Department through such officers and employees of the Department and such experts and consultants as the Secretary determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

(b) On the basis of this evaluation, the Secretary may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 Investigational new drug or device 30-day delay requirement.

When an institution is required to prepare or to submit a certification with an application or proposal under these regulations, and the application or proposal involves an investigational new drug (within the meaning of 21 U.S.C. 355(i) or 357(d)) or a significant risk device (as defined in 21 CFR 812.3(m)), the institution shall identify the drug or device in the certification. The institution shall also state whether the 30-day interval required for investigational new drugs by 21 CFR 312.1(a) and for significant risk devices by 21 CFR 812.30 has elapsed, or whether the Food and Drug Administration has waived that requirement. If the 30-day interval has expired, the institution shall state whether the Food and Drug Administration has requested that the sponsor continue to withhold or restrict the use of the drug or device in human subjects. If the 30-day interval has not expired, and a waiver has not been received, the institution shall send a statement to the Department upon expiration of the interval. The Department will not consider a certification acceptable until the institution has submitted a statement that the 30-day interval has elapsed, and the Food and Drug Administration has not requested it to limit the use of the drug or device, or that the Food and Drug Administration has waived the 30-day interval.

§ 46.122 Use of Federal funds.

Federal funds administered by the Department may not be expended for research involving human subjects unless the requirement of these regulations, including all subparts of these regulations, have been satisfied.

§ 46.123 Early termination of research funding; evaluation of subsequent applications and proposals.

(a) The Secretary may require that Department funding for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Secretary finds an institution has materially failed to comply with the terms of these regulations.

(b) In making decisions about funding applications or proposals covered by these regulations the Secretary may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not Department funds were involved).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Secretary may impose additional conditions prior to or at the time of funding when in the Secretary's judgment additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in Vitro Fertilization

SOURCE: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978, 43 FR 51559, November 3, 1978

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare

grants and contract supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following explusion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health, Education, and Welfare.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or

verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is

not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov 16, 1978

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health, Education, and Welfare involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "DHEW" means the Department of Health, Education, and Welfare.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to

all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHEW may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(A) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHEW shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions (1), (2), (5) and (6) as listed in Subpart A at §46.101(b) are applicable to this subpart. Exemption (4), research involving the observation of public behavior, listed at §46.101(b), is applicable to this subpart where the investigator(s) does not participate in the activities being observed. Exemption (3), research involving survey or interview procedures, listed at §46.101(b) does not apply to research covered by this subpart.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

§46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §§ 46.404, 46.405, or 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of §§ 46.404, 46.405, or 46.406, as applicable, or (2) the following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment

may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §§ 46.404 or 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal,state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §§ 46.406 or 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

APPENDIX D

CLEVELAND CLINIC FOUNDATION
SUBJECT AUTHORIZATION FOR INVESTIGATIONAL STUDIES

NAME: _____

CCF#: _____

It is a principle of medical practice that a subject who is to participate in the research investigation of a new medical treatment, device or procedure must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the treatment, device or procedure. It is the responsibility of the physician to provide a subject with the information necessary to this understanding. This information includes.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomfort to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Note the possibility, if appropriate, that the Food and Drug Administration and sponsoring organizations may inspect the records.
6. An explanation to the patient that, in the event physical injury occurs as a result of participating in this investigational study, medical treatment for such injury is available but the cost of such treatment shall be borne by the subject. Moreover, compensation for such items as loss wages and other direct and indirect losses is not available. The subject is also to be advised that further information with respect to this subject is available from the Office of Professional Affairs.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights and whom to contact in the event of a research-related injury to the subject. Provide name(s) and telephone number(s).
8. A statement that participation is voluntary, that refusal to participate or to discontinue participation at any time will not involve penalty or loss of benefits to which the subject is otherwise entitled.
9. An explanation as to who is paying for the test material. If additional cost is to be borne to the patient, these costs have been reasonably itemized and estimated.

NAME OF TREATMENT OR PROCEDURE _____

_____

_____

Your signature will indicate that your physician has given you the information described above and that you agree and consent to participate in this study.

_____ _____

(Date) Signature of Subject or Legal Representative

The above described information has been provided to the subject and it appears to me that the subject understands it.

_____ _____

(Date) Signature of Investigator

I certify that I was present and heard the presentation of the above described information to the subject, a summary of which has been filed with the Research Program Committee and Institutional Review Board and which I have reviewed, that it appears to me that the subject understands it, and that I witnessed the subject's signature of this authorization.

_____ _____

(Date) Signature of Auditor Witness

R PRETORIUS

The right to live: Legal aspects

INTRODUCTION

The law has the function of regulating society. It is also expected of the law to define exact moments in time, such as the beginning and end of human life. The precise moment of birth and death may have important consequences, not only for a lawyer giving effect to a will or a surgeon performing an organ transplant, but also for family members and friends.

Whilst the philosopher is concerned with the question of when life begins, it is more important for the lawyer to determine the stage at which the law commences, or should commence, to protect the human foetus or embryo, or even to regulate the use of sperm and oocytes which have the potential of becoming human beings.

The abortion debate, which has raged in many countries and reached its peak in South Africa in the late sixties and early seventies sparked renewed interest in the moment human life is initiated. (For a discussion of the common law position, and case law prior to the *Abortion and Sterilisation Act* 2 of 1975, see Strauss 1984:207-245). As much has been said on the topic of abortion and the sanctity of human life, it is not my intention to repeat all the arguments which have been feverishly debated over the years. Instead, a few specific cases of childbirth, involving moral, legal, ethical and religious dilemmas are examined. Advances in medicine and modern birth technology have created problems which have caught legal systems unawares, have initiated large-scale debates and have promoted many dissenting

arguments - not only amongst those directly involved, such as doctors, lawyers, and ethicists, but also amongst church groups, women's organisations, policy makers and the public in general.

1 CLAIMS OF 'WRONGFUL LIFE'

In a recent article (Schedler 1986:357-358), a professor in philosophy at the Southern Illinois University, U S A discussed the following incident:

Mrs A contracted rubella (German measles) in the first trimester of her pregnancy. A child with severe abnormalities was born. She alleged that her doctor had failed to inform her of the potential effect of the disease on an embryo, in which case she would have preferred to have had an abortion. She instituted a malpractice action against the doctor for compensation for pain and suffering, as well as for the recovery of general expenses. The attorney, acting on behalf of the child, also instituted an action against the doctor for so-called 'wrongful life' claiming medical expenses as well as damages for pain and suffering as a result of the child's defective existence.

I do not intend dealing with the question of informed consent and the general requirements for delictual liability of doctors, as much has been said and written on the subject. The wrongful life claim should, however, be considered in more depth. The term 'wrongful life', which is the subject of the present discussion, refers to the claim of a child - generally instituted by the parents - against a doctor or genetic counsellor for failing in his/her duty to inform the patient adequately of the possibility that the child may be born with abnormalities. It is averred that, had the mother known about such a possibility, she would have elected to have had an abortion, which is available in some countries on request, and in others if continuation of the pregnancy poses a serious threat to the health of the child or mother. (In terms of S 8 of the *Abortion and Sterilisation Act*, abortion is permissible if a serious risk exists that the child to be born will suffer from a physical or mental defect of such a nature that he will be irreparably seriously handicapped). The doctor is considered to have breached his duty towards the child, whose birth (and in some instances even conception) he should have prevented. It is therefore alleged that there was an omission or failure to act on the part of the doctor who, according to the plaintiff, was responsible for placing the child in a worse position than if he/she had not been born at all.

What we are dealing with here is the question of whether one has a right to be born as *'a whole and functional human being'* (as mentioned in the Appellate Division of the Supreme Court of New York in the case of *Park v Chessin* 60 A D 2d 80.400 N Y S 2d 110 [1977] discussed by Schedler 1986:361) and whether nonexistence is, in certain instances, preferable to an impaired existence.

The first wrongful life claim of the kind discussed here, was heard and rejected by the New Jersey court in *Gleitman v Cosgrove* (49 N J 20 227 A.2d 689 [1976]). A decade later, a wrongful life claim was awarded by the New York supreme court in *Park v Chessin* (referred to above) in which the court recognised the right to be born whole and functional. This decision was, however, later rejected by the New York Court of Appeals in *Becker v Schwartz* (46 N Y 2d 401 413 N Y S 2d 895.386 N E 2d 807, 812 [1978]) on the ground that there was no precedent for the recognition of such a right. Cases followed in California,[1] Washington,[2] Illinois[3] and New Jersey,[4] where wrongful life actions were allowed, but in most cases, only extraordinary medical expenses were recovered and compensation for pain and suffering for a life burdened by birth defects was not allowed.[5] In most instances the courts have avoided awarding compensation in the form of general damages, as they would then have had to compare an impaired childhood with a state of nonexistence - a comparison involving philosophical considerations which most courts would rather avoid.

In Britain embryos in utero are protected under the *Congenital Disability (Civil Liability)* Act of 1976. Section 4 of this Act provides that a child who has survived for 48 hours after birth has the right, under certain circumstances, to be awarded damages for injury done to it in utero. Wrongful life actions are not permitted under the Act (Puxton 1986:191). A wrongful life action was, nevertheless, instituted in the 1982 case of *Mc Kay v Essex Health Authority*. (1982 2 WLR 890. For a discussion of the case see Brownlie, S 1985:22; Louw, P F 1987:204-205). The British court rejected the claim and stated that the child has an action only if he/she would have been born normal but for the action of a third party and not if he/she would have preferred nonexistence to a handicapped life. Two of the judges also touched on the 'sanctity of life' argument. Stephenson J stated: 'It could not be suggested that the quality of her life is such that she is certainly better dead, or would herself wish that she had not been born ...' and Griffiths J stated: '... there should be rejoicing that the hospital's mistake bestowed a gift of life upon the child.'

In South African law the general rule is that legal subjectivity commences when a child is born alive. At that moment the child attains the capacity and status of a person and becomes the bearer of juridical competencies, rights and legal obligations (Boberg 1977:8-9; Van der Vyver 1980:92-93). There is, however, one exception to this rule by virtue of the so-called *nasciturus* fiction (*Nasciturus pro iam nato habetur quotiens de commodo eius agitur* - Digesta 1.5.7: Digesta 1.5.26), in terms of which legal protection can be backdated to conception when to do so would be to the benefit of the child, on the condition that the child is born alive (Barnard, Cronje & Olivier 1986:13). In terms of the *nasciturus* fiction, the court will allow a child who suffered injuries in utero, and is born handicapped as a result of the negligence of a third party, the right to sue for damages, provided negligence and causality can be proved (*Pinchin NO v Santam Insurance Co Ltd* 1963 [2] SA 254 [W]).

The South African courts have so far not had the opportunity to consider a wrongful life claim, although several South African writers have speculated on the possibility of success should one be instituted (Brownlie 1985:33; Louw 1987:202; Lupton 1982: 149-157; Strauss 1980:67-68; 1984:199; 1987:5). In the light of the manifest reluctance of our courts to encourage and broaden the liability of doctors, it seems unlikely that such an action will be successful in South Africa. Apart from the difficulty of establishing causality, failure to inform a patient adequately does not *per se* constitute negligence (Strauss 1984:324-325). Above all, sensitive policy issues are involved in calculating damages, for example, the comparison of a handicapped life with nonexistence. Our courts would most likely favour the attitude of the English court in denying that an unborn child has the *right to be born whole and functional*, and in refraining from burdening a doctor with the duty of preventing the birth of a handicapped child or compelling him/her to make a decision on the 'worth' of a human life.

Viewing wrongful life actions from a different perspective, the question may rightly be asked whether the human race, in striving for excellence, has become so consumer-orientated that it is applying to pregnancies standards similar to those it applies to consumer goods - accepting only the best and having little tolerance for any defects (Schaeffer & Koop 1980:55).

2 POSTHUMOUS ARTIFICIAL INSEMINATION

In the second example, the case of the Parpalaix couple, (discussed by Atherton 1986:380-383; Deutsch 1985:299; Current Topics 1984:627-628) dealing with posthumous artificial insemi-

nation or insemination after the death of the donor, a young French couple fell in love, only to discover soon afterwards that the male partner had cancer of the testicles. He was warned that the prescribed chemotherapy could result in his sterility. To ensure that they would still be able to have children, Mr P deposited sperm in a Government-run sperm bank. Soon after the treatment his health deteriorated rapidly and three days before his death the couple were married in a bedside ceremony in hospital. When Mrs P claimed the frozen sperm for artificial insemination, the sperm bank refused, on the grounds that sperm should not be considered an object returnable under a normal deposit arrangement to the next of kin of a dead depositor. Mrs P sued the sperm bank for the release of the sperm, but her claim was denied in the district court as the frozen sperm had not been specifically mentioned by the husband in his will. This decision was later overruled by three judges in a suburban court in Creteil, (Tribunal de Grande Instance de Creteil, Aug 1 1984 225/84) which ordered the release of the sperm. Mrs P was subsequently inseminated but apparently failed to conceive.

In 1984 there were no clear laws in France governing the legal and ethical problems raised by the case. Under Napoleonic law, however, a child born to a woman more than 300 days after her husband's death is considered illegitimate.

The most important questions raised by the case are the following:

* Can one claim ownership to sperm and ova?
* Should posthumous fertilisation (fertilisation after the death of a donor) be allowed?
* Should there be a time limit on the freezing of genetic material?
* Is a posthumously conceived child legitimate?

Although there have been no reported cases of posthumous artificial insemination in South Africa, such a case was reported in England in 1977[6] and it would be interesting to consider the possible approach of South African law to the problems mentioned.

Gametes differ from other human tissue which may be donated or transplanted in the important respect that they contain readily utilisable genetic information - a gamete has the potential of becoming a human being (Jansen 1985:123-126). Although South African law does not recognise proprietary rights in a human body as such (Van der Merwe 1982:20; Strauss 1984:163-166), a person has the right to decide what to do with his/her body, tissues, organs or gametes after death, or once they have been removed from the body as long as it is not against public policy or

contra bonos mores and not in conflict with the provisions of the *Human Tissue Act* (No 65 of 1983). The donor's consent remains an absolute prerequisite for utilisation of human tissue or gametes (Strauss 1984:180). Utilising the frozen sperm of a man without his consent, either for the creation of an embryo or the fertilisation of a woman other than his wife - when that was the purpose of the storage - is reprehensible and should not be even contemplated by a responsible institution.

Artificial insemination and in vitro fertilisation are lawful procedures in South African law, provided they are performed in compliance with the *Human Tissue Act* (No 65 of 1983) as amended and the Supplementary Regulations (R 1182 GG 10283 20-06-86). The Regulations do not, however, address storage of sperm or embryos at present. Artificial insemination may only be performed by a medical doctor or someone acting under his/her supervision at approved premises and the recipient must be a married woman, whose husband has consented to the procedure (Reg 8[1]). If the husband dies before the artificial insemination, it is submitted that the widow is not a *married woman* in terms of the Act, as marriage is dissolved by the death of one of the spouses.

Another aspect which has to be taken into account is that the *Human Tissue Act* permits artificial insemination for *medical purposes* (S 19) only. Can artificial insemination, performed for sentimental reasons on a widow who is otherwise perfectly healthy and capable of producing children, be considered as insemination for medical purposes? The act itself provides no clear indication in this regard. Schutte (1986:76-77) believes that such insemination is not permitted by the Act, as the inability to procreate in the normal way is terminated by the death of an infertile husband. There is therefore no medical purpose in performing the artificial insemination. A doctor doing so can - theoretically, at least - incur criminal liability under the Act and the Regulations (S 34 and Reg 14).

A third aspect which must be taken into account is that the South African Medical Research Council (1987:32) has stated that the long-term freezing of gametes and embryos is not recommended - in any event for not longer than the expected reproductive life of the donors.

Although posthumous artificial insemination is not addressed directly in our law, it seems clear that the performance of artificial insemination is limited to *married women* and for *medical purposes* only. As a widow is not a married person in terms of the Act, she is precluded from being artificially inseminated with the frozen sperm of her deceased husband. For the same reason, artificial insemination of one partner in a

lesbian relationship is also prohibited. Furthermore, children born as a result of posthumous artificial insemination are illegitimate in our law, as the child's natural parents were not married to one another at the time of the child's conception or birth, or at any time between conception and birth (Van der Vyver 1980:102; Van der Vyver & Joubert 1985:203). The recently adopted *Children's Status Act*, No 82 of 1987, (GG 10974 published on October 14 1987) aimed at improving the status of illegitimate children in general - does not address the legitimacy of posthumous artificially created children and they are therefore still illegitimate. Section 5 of the Act provides for the legitimacy of children born by artificial insemination with donor sperm if the husband of the woman giving birth has consented to the procedure.

The present position of our law may adversely affect a woman requesting to be inseminated with her deceased husband's sperm. Society in general, however, is concerned that children should not be born long after the death of one of the spouses. Such births are as a rule actively discouraged, primarily as they may create immense problems in the field of inheritance and succession, as pointed out by the Warnock Commission (1984:par 10.9) in England, which investigated the social, legal and ethical implications of Human Fertilisation and Embryology.[7] With the advances in modern birth technology and the possibility of freezing not only sperm and ova, but also embryos, new solutions must be found. In the rare cases of posthumous artificial insemination, a possible solution would be to permit it *only* if a specific request for the release of the frozen genetic material is made by the deceased in a valid will, and only within a limited time after the death of the spouse.

3 SURROGATE MOTHERHOOD

Since the birth of South Africa's first known surrogate babies - the Ferreira-Jorge triplets - in October 1987, surrogacy has become an increasingly controversial issue debated on moral, legal, ethical and religious grounds.

Surrogate motherhood as a new reproductive method - used in conjunction with artificial insemination or in vitro fertilisation - is utilised to alleviate the problem of infertility - a problem as old as civilisation itself. The despair often associated with infertility is captured in the desperate plea of Rachel to Jacob in the Old Testament of the Bible: 'Give me sons or I shall die!' (Gn 30:1). In our society children are often seen as a gift from God and it is therefore not surprising that the inability to have children is sometimes experienced as

punishment. Confirmation of infertility can be emotionally devastating for a couple and responses may vary from denial, isolation, anger, guilt and feelings of unworthiness, depression and grief, to acceptance (De Jongh van Arkel 1982:25-26; Wood & Westmore 1983:35-38).

The biotechnological revolution and the discovery of new and improved techniques for artificial reproduction have created hope for childless couples who, previously, could consider adoption as the only alternative method of obtaining a baby. In recent years, however, there has been a vast increase in the number of childless couples. According to a recent estimate, approximately 15% of all married couples experience infertility in some form (Andrews 1984:2; Cappucio 1985:93). A marriage is normally classified as infertile if pregnancy does not occur within a year of persistent trying. Infertility can be attributed to various factors such as genetic, physical or psychological defects, certain diseases, or as a result of surgery or environmental factors. Some forms of infertility can be cured, but unfortunately there are some couples for whom no cure exists.

With extremely long waiting periods for adoption and too few babies available, it is not surprising that alternative methods of conception are continuously being explored. Technological advances in reproductive techniques have contributed to making artificial insemination and in vitro fertilisation household words. Although the first artificial insemination was successfully performed as long ago as 1799 in England by John Hunter, and in 1866 by Marion Sims in the United States (Smith & Iraola 1984:263), in vitro fertilisation and paid surrogate motherhood are less than a decade old. The birth of Louise Brown in 1978 in England - the world's first test-tube baby - sparked renewed interest in modern reproductive technology. In vitro fertilisation and embryo transfer are increasingly performed in South African infertility clinics (Kruger 1986:593; Van der Merwe et al 1984:641), and in October 1987 the first known surrogate babies - the Ferreira-Jorge triplets - were born by utilising in vitro fertilisation and embryo transfer.

In a standard surrogacy agreement the surrogate mother agrees to be inseminated with the semen of the 'commissioning' or genetic father and undertakes to carry the baby to term and hand it over to the 'commissioning' couple at birth. This is sometimes referred to as partial surrogacy or surrogacy in its original form, which must be distinguished from complete or gestational surrogacy, where fertilisation takes place in vitro when oocytes (egg cells) of the 'commissioning' mother are fertilised with

semen of her husband or a donor in a glass dish in a laboratory. The fertilised egg is then transferred to the surrogate or host mother who undertakes to carry the baby to term and hand it over to the 'commissioning' couple at birth.

With all these modern technological advances, it is now possible for a child to have as many as five 'parents': the egg donor, the sperm donor, the surrogate who bears the child and the couple who raise it (Dalgety & Pryor 1986:25). It is even possible for a grandmother to bear a child for her daughter, as in the Ferreira-Jorge/Anthony case. In a recent American article by Lori Andrews (1985:29-31), a well-known Chicago attorney, journalist and author of a book on modern birth technology (Andrews 1984), the case of a 46-year-old divorced woman who married a 49-year-old childless widower was discussed. The couple wanted a family of their own and approached a University in vitro fertilisation programme with the suggestion that the divorced woman's 25-year-old daughter donate oocytes to be utilised in vitro with the sperm of her stepfather (the widower). As she herself was not prepared to act as a surrogate mother, the suggestion was that the embryo be implanted in a surrogate mother who would carry the baby to term. In this way it is possible for the child to be approximately 25% genetically related to the mother, although she herself was no longer fertile. She would then be both 'mother' and 'grandmother' to the child and her daughter would be both its 'mother' and 'sister'.

These examples merely illustrate that we have reached a stage where the traditional definitions of 'mother' and 'father', whether in the legal, medical, or sociological context, are no longer accurate (Wadlington 1983:465-514; Stumpf 1986:187-207).

The advantage of surrogate motherhood is that the waiting period is a normal pregnancy term - approximately nine months - as opposed to the long waiting period for adoption. The child is also genetically related to at least one of the 'commissioning' parents. Surrogacy may also be the only alternative for women who are completely sterile and who may be emotionally devastated by the discovery of their infertility. Many childless couples may have also completed a series of exhaustive infertility tests over a long period of time and request surrogacy as a final alternative to adoption.

It is difficult to ascertain the number of children born by utilising surrogate motherhood, but according to a recent estimate, the number is put at approximately 500 (Katz 1986:1). (Statistics obtained from Gelman & Shapiro, Infertility: Babies by contract. *Newsweek* 04-11-1985.) As with most technological advances, the law lags behind and at present we face the situa-

tion where surrogate babies may be born in a legal vacuum. Legislation directly addressing surrogacy exists in only a few countries and is in most cases unsatisfactory (Pretorius 1987b: 275-293 for an evaluation of British and Australian legislation). An example is the *British Surrogacy Arrangements Act* of 1985, aimed at prohibiting commercial surrogacy and the Australian *Infertility (Medical Procedures) Act* 1984 in Victoria which prohibits all forms of surrogacy. Since the much publicised 'Baby M' case in New Jersey, USA, approximately 26 American states have proposed legislation for the regulation of surrogacy (Andrews 1987:31-40; Donovan 1986:57-61; Katz 1986:41-53). These proposed bills range from a blank authorisation of the procedure to careful regulation or, in some instances, prohibition.

Common law principles do not provide sufficient answers to the problems surrounding surrogate motherhood and doctors, lawyers, theologians and other professionals, faced with queries regarding surrogacy, find it increasingly difficult to provide satisfactory answers to desperate childless couples. There is certainly no unanimity in professional circles about the future of surrogate motherhood and whether it should be considered a viable option to adoption.

Amongst the most important questions lawyers are asked are whether such contracts are legal and enforceable. What about the legitimacy of the child? What happens if the surrogate mother changes her mind and refuses to hand over the baby at birth? Can the 'commissioning'/biological father be held liable for child support? What happens if the baby is born with an abnormality? What happens if any of the parties dies or gets divorced before completion of the contract, and should the surrogate mother be compensated for her services? These are only a few of the many questions surrounding surrogacy.

Because of the limited scope of the paper, only the most important problems will be addressed.

First and foremost, it is important to alert the parties to the difficulties which may be encountered when entering into a surrogacy agreement. At this stage there is no guarantee that a surrogacy agreement will be enforceable in a court of law. Although the agreement may not in itself be regarded as 'unlawful' in the sense that it does not violate any existing legislative provision, it could, depending on its content, be regarded as conflicting with morality and be unenforceable, either in its entirety or in part (Tager 1986:395). Breach of contract may occur in various ways. The most probable form is refusal by the surrogate mother to deliver the child to the commissioning couple

at birth. The bitter custody battle in the much-publicised 'Baby M' case, when the surrogate mother refused to hand over the child, is adequate proof of the bitterness and heartache which both the surrogate and the 'commissioning' couple may experience if things go awry. A court faced with such a situation relies primarily on the criterion of the *best interest of the child* in deciding who should have custody. (In Re a Baby ['Baby Cotton' case] in England 1985 NLR Rep 106; Baby M case in the United States of America.) Breach by the commissioning couple will be relatively rare, particularly when one considers the risks for such a couple attendant upon the agreement. This view is strengthened by the fact that the child is genetically related to at least one of the parents. Such cases are, however, conceivable where the child is born with an abnormality. This is what happened in the contentious, and as far as could be determined, unreported American case of Mahlahoff/Streiver in 1983, where the child was born microcephalic. In this case neither of the contractual parties was prepared to have the child. Blood tests determined that the child was that of the surrogate mother and her husband. (For a discussion see Mandler 1985:1286-1287; Cappucio: 1985:104-105).

For a contract to be enforceable it should not contravene public policy or the so-called *boni mores*. Public policy is a difficult concept to define accurately. It denotes the ethical, social and moral convictions of a society. It may therefore have different meanings at different times and in different places. What was considered science fiction only a few years ago has now, through technological advancement, become part of our everyday reality. As a general rule, an agreement to transfer or delegate parental power permanently, such as an agreement to hand over a child at birth, is considered contrary to public policy in South Africa (Spiro 1985:43-45) and may therefore be invalid and unenforceable. Under certain circumstances, such as divorce or adoption, a court may grant an order for the transfer of all or some aspects of parental power (Spiro 1985:265; *Ex Parte Van Dam* 1973(2) SA 182 W; *Baseti v Louw* 1979(4) 225). This common law rule that one may not agree to relinquish parental power voluntarily - without interference by a court - became part of our law long before anyone could have anticipated that procreation technology would become so advanced that as many as five people could claim parental rights to one child. It is consequently submitted that, in the light of the tremendous advances recent years have seen in this field, this rule should no longer automatically be accepted as valid. An agreement to transfer parental powers in cases of surrogate motherhood should be statutorily recognised, and be enforceable.

One of the most controversial aspects is compensation of the surrogate for her services as this may be considered 'baby bartering' and exploitation of a human being. In Britain, the *Surrogacy Arrangement Act* 1985, prohibits commercial surrogacy. This followed the recommendations of the Warnock Commission. In the United States of America, however, many commercial agencies are flourishing. Generally it seems that altruistic surrogacy, where no compensation is involved and the profit motive is wholly lacking, is more acceptable in South African society than commercial surrogacy (Strauss 1983:22; Lupton 1982:354; Tager 1986: 400-404; Pretorius 1987a:273). It is, however, submitted that the surrogate should be compensated for her basic expenses such as maternity wear, transport and medical expenses, as it cannot be expected of a woman to face the risks inherent in pregnancy without at least covering her basic expenses. Furthermore, donors of semen may be compensated for reasonable expenses in terms of the *Human Tissue Act Regulations* (Reg 7).

It is the contention of the author that, in the absence of a profit motive, surrogate motherhood should not be branded as immoral, provided it is fully controlled and regulated. It is therefore submitted that the entire process of surrogacy be carefully regulated in a manner analogous to adoption. The parties to such an agreement should be carefully screened and it should only be made available to those couples for whom no other alternative exists. Merely to prohibit all forms of surrogate motherhood will drive it underground and couples will be denied the help of professionals in the medical, legal and related fields. Criminal sanctions are also inadvisable, as they would make criminals of desperate childless couples, and indirectly punish the child for the acts of the parents. Furthermore, no law could prevent a couple from travelling to a country where surrogacy was legal and bringing the baby back to South Africa, a situation which would be totally unacceptable and which would not solve the problem.

ENDNOTES

1 *Curlender v Bio-Science Laboratories* 106 Cal App 3d 811, 165 Cal Rptr 477 (1980), where both special damages and medical expenses were allowed and later in *Turpin v Sortini* 31 Cal 3d 220, 643 P 2d 954, 182 Cal Rptr 337 (1982), where general damages were denied but extraordinary expenses allowed. Wrongful life suits were barred by the California Legislature in 1982 Cal Civ Code 43.6(a) (West 1982).

2 *Harbeson v Parke-Davis* 98 Wash. 2d 460 656 P.2d 483 (1983)

3 *Siemieniec v Lutheran Gen. Hosp.*, 134 Ill, App. 3d 823, 480 N.E. 2d 1227 (1985).

4 *Procanik v Cillo* 97 N.J. 339, 478 A.2d 755 (1984).

5 *Turpin v Sortini* n 7 supra; *Siemieniec v Lutheran Gen Hosp* n 9 supra; *Harbeson v Parke-Davis* n 2 supra and *Procanik v Cillo* n 4 supra.

6 Kim Casali who is best known for the creation of the 'love is...' drawings had a child 17 months after her husband died from a terminal disease. In this case frozen semen was also kept in storage for her subsequent use. This case is discussed by Van der Vyver 1980:88.

7 Cmnd 9314. The Committee consisted of sixteen appointed members under the leadership of Dame Mary Warnock and their task was: '...to consider recent and potential developments in medicine and science relating to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.'

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L D HULLEY

The right to end life

1 INTRODUCTION

When an ethicist is asked to discuss an issue like 'the right to end life', it immediately tends to become a normative question. I succumbed to that temptation and the statement began to function as a question 'is it right that we have a right to end life?', and I shall respond to the issue in that form. I shall therefore discuss moral questions which seem to me to be related to the issue of whether you have the right to end life, your own - with or without assistance - or someone else's. Merely stating the matter in this way has no doubt already raised many moral questions. Indeed the topic simply bristles with ethical problems; each move you make creates a host of side issues - each important in their own right. It is impossible to give each of them the attention they deserve. You are therefore faced with the unsatisfactory position of having loose ends as you pursue the main argument. I shall therefore soldier on fully aware that I will be raising many questions which perforce must be left unanswered. In any discussion I shall, however, try to consistently use clearly identifiable principles.

2 NARROWING THE PARAMETERS

It is necessary to reduce the area of discussion by excluding certain aspects of the topic. Friedrich Nietzsche argues that: 'freedom to live is identical with freedom to die when I choose, so that death does not just happen to me, thus bringing life into bondage to it. I commend my death as a free death that comes when *I* choose' (Thielicke 1983:69).

Jean Améry takes this argument further and sees suicide as that act which belongs to the 'original core of what is human' (Thielicke 1983:73), and distinguishes human beings from animals. According to these two thinkers the right to take your life is inherent. I shall return to that question in a moment. What concerns me for the moment is how a person goes about exercising this 'right'. In February 1988 a vagrant testified in a court of law that he had been paid a sum of money by a businessman to shoot him. Initially I was not concerned here with the reportedly related financial matters, or are they indeed relevant? Can financial straits be regarded as sufficient cause for one to exercise the 'right' to die? Are such problems to be regarded as the moral equivalent of a terminal illness, accompanied by severe discomfort, which is held by some as a good enough reason for a person's life to be ended? Intuitively most people would feel that the two cases cannot be equated, and I believe that intuition to be correct. I will not take this point much further other than to say that I reject Nietzsche's point of view primarily because of my view of what human life is, more about which presently. A second reason for my rejection of Nietzsche and Améry's approach is that it is dependent on the idea that human beings as individuals are responsible to themselves and for themselves only. In his *The Responsible Self* H Richard Niebuhr has argued cogently that at least part of the idea of responsibility is that it has an element of social interaction. As human beings we are not merely responsible to and for ourselves but need also to take other people into account. We are accountable to them, especially to those for whom we are responsible. This is quite apart from the question of whether we are accountable to God for our present behaviour. I find the extreme individualism implied in Nietzsche and Améry's position unacceptable. In the light of these considerations I shall therefore confine myself to discussing the right to die of those suffering from terminal illness.

3 TERMINAL ILLNESS A GROWING PROBLEM

At this point I want to return to something just mentioned previously, the question of the right to end life where you are faced with terminal illness, your own or another person's. I understand terminal illness to mean:

> ... a state of disease characterised by progressive, irreversible deterioration, with impairment of function and survival limited in time.
>
> (Crispell and Gomez 1987:74)

Such a state could be brought about by a variety of causes, both in the young and in geriatric cases. A British doctor foresees that the extent of the problem as regards geriatric cases will increase markedly. Writing about his own country he says:

> Between now and the year 2000, although the total number of people over the age of 65 will decline, it is predicted that there will be an increase of over 50 per cent in the number of people over the age of 85 and a substantial increase in those aged 75-84.
>
> (Robertson 1982:173)

It must be acknowledged that this forecast refers to a highly developed country with a sophisticated medical care system but you can expect the same tendency to present itself in this country. The growing need for old age homes in all sections of our heterogeneous population is evidence of this. The increase in the number of people of advanced age means the number of geriatric patients who may be faced with terminal illness is likely to increase. Medical science has also developed tremendously in recent years, both in respect of surgical intervention and other forms of treatment. The equipment for monitoring the condition of a patient has reached high levels of sophistication. The sight of intravenous and nasogastric tubes providing hydration and nutrition is not all that uncommon a sight in most hospitals. It is therefore possible to hydrate and feed a patient who is not able to take in liquids and food in the normal way. Conditions which would have ended in death, and still do where only less sophisticated medical facilities are available, no longer do so. In terms of the utilitarian, or consequentialist, theory of ethics the positive effect of modern medicine in society must be approved. One can only applaud these advances in medicine; the good which society derives from them is wellnigh incalculable. It is now possible to keep people alive, and hopefully help them to recover, in many cases in which the prognosis would previously have been very poor. But here lies the crux of the problem. Are there not also cases where people should not be kept alive? It is in this context that the question of the right to end life is forcefully raised. Should everybody be kept alive at all costs? Should people's lives be prolonged as long as humanly possible?

4 THE SIGNIFICANCE OF HUMAN LIFE

These questions penetrate to the heart of the matter, from the other end as it were. Why are these questions regarded as significant by many people? Behind the discussion is the ques-

tion of the meaning and significance of human life. Unless we have a sneaking suspicion, or may be strongly convinced, that human life is significant the question of death or the right to die would hardly warrant a second thought in circles such as this conference. We are not prepared to regard human life and death as matters of purely biological interest thereby removing the discussion from the moral realm. This is generally an intuition for most people, but once again an important intuition for it touches on the value of human life, sometimes discussed in terms of the concept, the sanctity of life. Jacques Thiroux, a philosopher, makes this point as follows:

> [The Value of Life Principle] ... is empirically prior to any other because without human life there can be no goodness or badness, justice or injustice, honesty or dishonesty, freedom or lack of it. Life is a basic possession, the main possession of each individual human being. It is the one thing that all human beings have in common, yet each individual experiences life uniquely - no one else can truly share or live another's life. Therefore individuals (as Kant correctly maintained) should never be treated merely as means, but rather as unique and individual ends in themselves.
>
> (Thiroux 1986:131f)

Human life is the precondition for all human goods, any questions of value or ethical considerations. Depriving someone of life means depriving them of that without which all other issues are meaningless. Small wonder then that human life has been regarded as sui generis, accorded a unique status and valued for its own sake. It is appropriate therefore that at this point I note some other theological and philosophical views on the value of human life, a fortiori because the theological views in particular play an important role in this discussion.

In Judaeo-Christian thought there is a strong tradition regarding the sanctity and inviolability of human life. In most cases the foundation of the conviction is traced back to the concept of the *imago Dei* contained in the creation story.

> God created man in his own image, in the image of God he created him; male and female he created them. And God blessed them, and God said to them, Be fruitful and multiply, and fill the earth and subdue it; and have dominion over the fish of the sea and over the birds of the air and over every living thing that moves upon the earth.
>
> (Gn 1:27-28)

The special status accorded humankind as creatures created in the divine image has prompted Thielicke to speak of an *alien dignity* with which human beings are endowed. Any activity which threatens that dignity must be called into question. I have quoted both verses from Scripture because in the passage it is clear that human life is not equated with other forms of biological life. Human beings are directed to have dominion over other forms of life. The implications of being created in the divine image and the injunctions regarding the rest of creation is that human life is a special case with a special worth. Taken together with the prohibition against killing in the decalogue, it has prompted some ethicists so to exhalt the idea of the sanctity of life that life should be saved at all costs. I shall return to that below. Just in passing we should note that in the early medieval period when the influence of Augustine's dualism was at its height, the *imago Dei* was believed to be in the human soul, the body being of lesser value. In the early Renaissance the idea that the human species was somehow unique began to develop. With the Reformation came another important change. The concept of dignity was not attached merely to the human species, but to each individual member of the species. Our sense of individualism has developed to such an extent that we find it hard to conceptualise anything other than the dignity of individuals.

Both Greek and Latin philosophers touched on the special status of the human species but did not influence modern thought to any marked degree. Among the philosophers, Immanuel Kant's ideas had the greatest influence on modern thinking about human beings. Kant argued for an ideal society which he called the kingdom of ends. He insisted that human beings should never be treated merely as means to an end but always be regarded as ends in themselves at the same time. In *The doctrine of virtue* he argues as follows:

> Man in the system of nature is a being of slight importance. Although man has, in his reason, something more than they (other animals) and can set his own ends, even this gives him only an *extrinsic* value in terms of his usefulness.
>
> But man regarded as a person - that is, the subject of morally practical reason - is exalted above any price; for as such he is not to be valued as a mere means to the end of others or even to his own ends, but as an end in himself. He possesses in other words, *a dignity* (an absolute inner worth) by which he exacts *respect* for himself from all other rational beings in the world: He

> can measure himself with every other being of this kind and value himself on a footing of equality with them .... Autonomy is the basis of dignity of human and of every rational creature.
>
> (Gaylin 1984:18f)

It is easy to see how Kant's views found ready acceptance in this debate. The concept of dignity found a ready resonance in the long held Christian understanding of dignity, derived from the *imago Dei*. This combination may well have contributed to Thielicke's concept of alien dignity which belongs to human beings. The growing western individualism could happily embrace the idea that autonomy, which embodies the power to reason and make moral decisions, is the foundation upon which human dignity is built. The idea of autonomy also found ready acceptance among the growing band of theologians who argued that individuals had a freedom of choice in religious and moral matters. This set of interrelated ideas - human beings as ends in themselves, human dignity and autonomy - is often used in the debate on the right to die. I too find them important. They reflect a deep conviction that human life is of great value, and that it is an indispensable precondition for any valuing whatever, as Thiroux argues. The question arises whether you are to regard human life to be an absolute value, one which must be preserved at all costs.

In his book *A Christian method of moral judgement* Philip Wogaman (1976) argues for what he calls methodological presumptions. These presumptions are regarded as primary values which you assume to be valid in your ethical decision-making; any deviations from the primary values have to be justified. From the foregoing argument you can readily conclude that human life is to be regarded as a primary value and the burden of proof is on those who choose to end it. Gustafson argues in similar vein, but he qualifies the value placed on human life.

> Human physical life is not of absolute value. But it is the indispensable condition for human values and valuing, and for its own sake it is to be valued. Thus the burden of proof is always on those who would take it. The delicacy of discerning what value is to be given to human physical life under particular circumstances when it is not valued absolutely presents one of the principal practical moral problems men have to face.
>
> (Gustafson 1971:140)

Before commencing the discussion on the last point made by Gustafson, I want to mention one other argument sometimes used in this debate in addition to the theological and philosophical arguments already noted. It is sometimes referred to as the pragmatic argument for the preservation of human life, at other times spoken of as the slippery slope argument. Trianosky (1978:414) summarises it as follows:

> It is sometimes said that permitting some form of euthanasia would gradually erode moral motivations and behavioral inhibitions that support a moral code. It is said, for instance, that permitting voluntary euthanasia would lead to erosion of inhibitions on killing in general to the point where we would wink at euthanasia for those who are a nuisance to society: idiots, recidivist criminals, defective newborns, and the insane for example.

An implication of this argument is that once you have allowed the sanctity of life principle to be disregarded in respect of one identifiable group it would be easier to do the same for others. Herein lies a great danger. For us the implication is that the putative advantages of allowing voluntary euthanasia would be more than wiped out by a growing disregard for the related moral values. What happened in Germany under Hitler, when first one category of people then another was exterminated is usually cited as an example of the slippery slope.

Holding human life to be a relative rather than an absolute value requires some justification. On the theological level I hold that God alone is absolute or ultimate, all human ideas - even truths held to be revealed - are at best penultimate. This includes such things as the prohibitions in the commandments. This does not mean that they can lightly be disregarded, but it means that circumstances may arise in which the strict application of the concept of the sanctity of life does not seem appropriate. One would then have to justify departure from the norm. For example, many people regard war, or a threat to national security, as sufficient reason for departing from the prohibition on killing or from regarding human life as sacrosanct.

5 WHEN DYING BEGINS

Having reduced the area of discussion to persons suffering from terminal illness one is faced with a situation where the condition of the person is inexorably getting progressively worse, resulting in the deterioration of functions and a limited lifespan. In the terms used above one could speak of limitations in respect of both the quality and quantity of life.

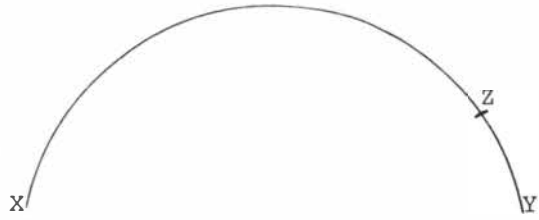
At this point Young's distinction between prolonging life and prolonging death is relevant. Young holds that some people would regard life as depicted in the following diagram.

Figure 1

In figure 1 birth is represented by X and death by Y. Medical treatment and nursing care would be aimed at postponing Y at all costs. Those who hold the extreme view of the sanctity of life would fall in this category. They would regard it as necessary to continue with the aggressive medical treatment of a person irrespective of the effects the treatment may have on the quality of life of the person, or whether such treatment denies the person any vestige of human dignity or may even be against the wishes of the person.

Young introduces another diagram into the discussion.

Figure 2



In figure 2 X and Y represent respectively birth and death as they do in figure 1. Point Z represents the point at which physicians notice discernable evidence that the dying process has begun. Even for highly skilled medical people this point is often an educated guess. Nevertheless, you may then be faced with a situation where both the quality and quantity of life are limited. Those who are most closely related to the person by kinship ties would sense a progressive loss of dignity and even perhaps such a loss of personal human attributes that to speak of

personhood becomes a distortion. Towards the end there is little or no response, no self-awareness. Autonomy - which Kant regarded as the foundation of dignity - has all but disappeared or even disappeared completely, the person having little or no control of either voluntary or involuntary movement. It is in the ZY phase of life that the problem of the right to die becomes most acute. This is highlighted in an investigation carried out in New York into suicides in 1985. The suicide rates of men in the age group 20-59 diagnosed as having AIDS was more than 73 times as high as that of the general population and more than 36 times as high as men in that age group in general. It is clearly evident that these men exercised their right to die.

Two questions arise here: in what sense have we a right to die and, if it is a qualified right, in what circumstances may it be exercised?

5.1 A right to die?

Rights have been defined as moral entitlements. In this sense they give the holders moral claims upon society, both upon individuals and institutions, to assist them to receive that to which they are entitled, or at least to do nothing which will prevent them from receiving their due. In this discussion it would mean so structuring the availability of medical resources and expertise that people's wishes are fulfilled, assuming for the moment that they are rights, or that people are not prevented from carrying out their wishes.

Rights are generally of two classes, those regarded as inherent rights or those which are created by negotiation and societal agreement. In the writings of some ethicists inherent rights are regarded as divinely ordained or natural rights, whereas the second is seen as part of the social contract theory. An example of the former is the statement in the American Declaration of Independence that '... all men are endowed by their Creator with certain unalienable rights; that among these are life, liberty, and the pursuit of happiness' (Borchert and Stewart 1986:336). The acceptance that people have a right to life is well-nigh universally accepted. It is held by some that individuals may forfeit that right by for instance committing murder. Somewhat hesitantly I wish to add here another group, badly deformed infants. In some circles it is held that they have no right to life, or this is the implication of the decision to let them die. This is a highly emotive issue and I do not wish to take it further, although I shall touch on it again below.

There is much less acceptance of the idea that we have a right to die. If it indeed is a right, is it to be regarded as an inherent right, in the manner of Nietzsche and Améry, or a negotiated right? The widespread discussion surrounding the issue suggests that at present, at any rate, the matter is being negotiated. We should note, however, that in certain American states persons may express a desire, either in writing or verbally, not to be kept alive should they find themselves in the last stages of a terminal illness for example. Here we are faced with persons in the ZY stage of life and this I have already suggested differs materially from persons faced with a different set of problems.

5.2 Active and passive treatment

In this discussion of the right to die I have tried to limit it to a discussion in which both the quantity and quality of life are significant factors. Even within this limited discussion there remain at least two variables, these are the physician's intention and the person's will. In the first instance one may speak of the direct treatment by the physician or nontreatment by the physician. These are sometimes referred to as active intervention and passive behaviour. In the case of active intervention the physician may engage in aggressive treatment of the disease; administer palliative treatment with drugs which may have the indirect result of shortening the person's life; engage in activity which is designed to put an end to life such as administering a drug intended to be lethal. In the case of passive behaviour, treatment is withheld so that the disease may take its course. Here one has to add the possibility that treatment previously commenced is stopped with the purpose that the person should die sooner rather than later. In each of these possible courses of action the person may be a willing or unwilling party to the course of action taken. In some cases such as comatose accident victims who have not previously expressed a preference, the family in consultation with the physicians may make a decision based on what they think the person would have decided had the opportunity been available. I once again wish to mention the case of badly malformed infants; they are sometimes placed in this category.

At the outset I must exclude the possibility of acting directly to end an unwilling person's life; that would be murder. It would also be regarded as the blatant disregarding of the right to life which is well-nigh universally regarded as inherent. Disregarding this right places all other human rights and values in jeopardy as I noted above.

I do not intend going into arguments surrounding the question of whether there is any moral difference between the active and passive approaches to this issue in any depth. Some philosophers would argue like Landman that there is no inherent or intrinsic moral difference between acts of active euthanasia and omissions of passive euthanasia (Landman 1982:5). To this point I have deliberately refrained from using the term euthanasia in favour of the more neutral phrase the right to die because euthanasia evokes in many minds a set of presumptions which I have been trying to avoid. In this essay I shall regard them as equivalents.

I shall attempt a short explanation of why I do not regard active and passive euthanasia as morally equivalent. Some years ago there was the notorious incident in New York where a young woman, Kitty Genovese, was stabbed to death while a number of apartment dwellers watched. Both the assailant's action and the lack of action by those watching were necessary conditions for her death. You cannot, however, argue that both the attacker and the onlookers were equally culpable. Had the latter not been there to witness the event it would still have happened, whereas had the attacker been elsewhere she would not have been killed. You may argue that the cases are not quite similar and propose a different scenario. Say someone was drowning in a pool and two people were watching, the one an onlooker not able to swim and the other the lifesaver on duty. The former would not be regarded as having an obligation to save the swimmer's life while the latter would have. It is then argued that the lack of intervention by the lifesaver could be regarded as the moral equivalent of deliberately drowning the swimmer. While the lifesaver was not the cause of the swimmer's drowning, you may nonetheless hold such a person to be responsible for the other's death. Here the crux of the matter is whether the person who refrains from action may be regarded as having an obligation to prevent the death of the other. In the case of the lifesaver, you would answer in the affirmative.

In terms of the above argument one would have to hold that the physician likewise always has the obligation to prevent the death of the person being attended to. This assertion, however remains part of the debate. I have consciously used the phrase prevent the death rather than save the life of the person being attended to because this raises another important aspect of the discussion. Is the physician merely preventing the person from reaching point Y on the ZY segment of the line or are we talking of further human activity on the XZ segment? People who advocate continuing aggressive medical intervention to sustain life, even when a person is in the ZY phase, usually function with an extreme view of the sanctity of life. The question must now be

asked whether conditions may arise in which the physician may depart from the prima facie obligation to prevent death, or - to use Wogaman's concepts - to depart from the presumption that life ought to be sustained.

5.3 The quality and quantity of life

At this point in the discussion I want to introduce two concepts which have a significant bearing on the debate, that is the quality and quantity of life. If you accept their relevance, as I do, it raises questions such as the following: Will any proposed treatment not only provide an extension of life, but will that life be of such a quality that the person can exercise such human behaviour as: engaging in interpersonal relationships; communicating with other people; be consciously able to take decisions about the future? Will the continued treatment be of such a nature that the negative side-effects outweigh any hoped for advantages in either the short or the long term? A closely related question is whether the nature of the treatment itself will be so uncomfortable that the person being treated would find the discomfort from the disease easier to bear. Another important consideration is whether treatment would be manifestly futile (Callaghan 1982:397). Behind all these questions there is the following basic consideration: Would the advantages that could reasonably be expected, either in the short or longer term, outweigh the disadvantages of the treatment? An example of short-term advantage would be double effect drugs administered to a terminal cancer sufferer to control pain and allow the person to communicate at the interpersonal level, although these drugs may shorten the person's lifespan. An example of long-term advantage would be where the treatment may entail even severe discomfort in the short-term but promises a significant extension of the quantity of life with a concomitant reasonable quality of life.

Should you grant that the foregoing are significant considerations in the decision-making process you have agreed in principal that consequentialist arguments are a valid contribution to the debate. Unhappily the sanctity of life principle, which is seen as deontological, or a legalist approach is often regarded as the alternative to the consequentialist, or situational approach. Wogaman's methodological presumptions combine aspects of the two approaches. I also want to argue that if one regards human life as sacred, that which is holy is more than mere biological existence but includes that which we regard as human life. Human life seems to imply a level of personhood in which people are able to perform certain functions which reflect their personalities. In other words they ought to be able to engage in

significant relationships involving their emotions, among other things. I am aware that I have used various 'definitions' of what constitutes being human but basic to them all are the ideas that human beings are sentient beings who can enter into significant relationships with other human beings.

5.4 Expressing human care

I now wish to explain why I have pedantically continued to use the term person rather than patient. It seems to me that if we are engaged in a holistic approach to life, and the nature of this seminar suggests that at least the organisers and perhaps the speakers regard it as a multifaceted affair, then the idea of personhood must be regarded as important. In the context of this discussion the following statement by James B Nelson, an American ethicist, is apposite.

> Our first responsibility is not to save a physical life and then only later to worry about the whole person. Our first responsibility is to take into consideration the person's wholeness - involving emotions and significant relationships - at each step of the way. Our first responsibility is to care. This is even more basic than curing, and acts of care will center principally upon the person rather than principally upon the disease.
>
> (quoted in Young 1977:53)

5.4.1 Switching off the machine

In this quotation Nelson makes the very important claim that our first responsibility is to care. Most people would grant that whereas medical treatment may be seen as evidence of care, for the ordinary person it is shown principally in providing nutrition and hydration, or, to put it plainly, giving food and drink. Before discussing nutrition and hydration I want to discuss the discontinuing of medical treatment. To stop treatment once it has started seems to be more difficult than not to start treatment at all. It seems to suggest a callous and deliberate attempt to end another's life. Under treatment I would here include both life-support systems and the use of drugs and other medical procedures. Furthermore to switch off a life-support system seems to engender a great deal more conflict than a team of surgeons deciding that further surgical intervention in the case of widespread cancer would be futile. In both cases there is a decision to stop treatment because it no longer serves any useful purpose. It is reasoned that the person

being treated could not expect any benefit from continued treatment. Although these two situations seem very similar there seem to be important differences. In the case of the operation neither the person nor any family members are likely to be consulted prior to the decision being taken, yet strangely this is accepted without question. In contrast to this there is usually wide consultation with family members, also taking into account any preferences the person may have previously expressed, before the decision is taken to switch off life-support systems. As I noted above the incidence of geriatric cases in this category is likely to increase, apart from the growing number of other people who may be treated in this way merely because these facilities are becoming more readily available. This can lead to problems. In America for example a prominent physician who was taken to court in a malpractice suit for switching off a life-support system won the case but appeared thereafter to be reluctant to connect people to such a system. Should such an attitude become common many people who may benefit from the treatment may be denied the opportunity. Where the concept of the sanctity of life is taken to such extreme positions that the machine may never be switched off physicians would likewise become reluctant to use them. Not only would physicians be reluctant to employ life-support systems, but you can envisage that where they are used and the decision to switch them off is excluded in principle you would eventually have whole hospital wards full of people connected to life-support systems. I submit that far from this being a recognition of the sanctity of life, it is in fact a denial of it. I have already made it clear that the mere continuation of biological life cannot be considered to be a human life; dignity, autonomy and personhood are absent. To speak of the dignity and quality of life of such people is to do violence to those concepts, they can only be referred to in terms of their negation. In this situation one can argue that such a person has probably entered the ZY segment of life and should be allowed to die. One could even argue that such a person has the right to be allowed to die. Far from playing God by allowing the person to die, as is sometimes suggested, it seems to me that Fletcher is right when he argues that those who prevent death in such circumstances are guilty of playing God (Gill 1985:483) By arguing in this way, that is, considering the results of a course of action, I have once again used consequentialist reasoning.

5.4.2 Suspending nutrition and hydration

I now wish to raise perhaps one of the most difficult aspects of this debate: the continued provision of nutrition and hydration to patients in the ZY phase of life. Surprisingly enough this is

not a new problem. Already in 1587 the Dominican theologian Francisco de Vitoria argued that 'if death is immiment, the relative benefit of sustaining nutrition may objectively be outweighed by the burden of force-feeding a dying patient' (Sparks 1987:173). In this respect we are faced with the problem that on occasions people themselves have requested that naso-gastric tubes be removed in the knowledge that they would die slowly of starvation. (See *Hastings Center Report* 1987:23; Lynn & Childress 1983:17). In the case study contained in the Special Supplement to the Hastings Center Report the views of the commentators from the Federal Republic of Germany and the People's Republic of China substantially agreed with that of the English commentator R H Nicholson, who commented on the legal and medical aspects as follows:

> If a court were ever to decide, it would do so under English common law according to whatever practice a responsible body of medical opinion felt to be appropriate. In other words, if Mrs Randall refused the tube, the court would uphold that decision, since the majority of experienced doctors in this field would not wish to feed her.
>
> (*Hastings Center Report* 1987:24)

The German commentator added that even if the request was acceded to, other medical and nursing care should be continued. This is a generally held position. The Chinese commentator holds that acceding to the person's request would reflect a further humanisation of medicine, and that no one has the right to reject the person's wishes. Rather than an easier death, suspension of nutrition and hydration could lead to an agonising end. It remains perhaps the most difficult facet of this debate, one which has no simple solution. The decision is usually made on the basis that to continue life on the level being experienced is not worth while.

Having considered the person's wishes we turn to the medical point of view. In Nicholson's statement above reference was made to treatment which medical opinion held to be appropriate in the circumstances. This is a most significant concept. The issue is not whether one should treat, refrain from or suspend treatment but to decide what in the circumstances of each individual would be the most appropriate treatment. What may be appropriate in the case of an acutely ill person where there are hopes of recovery may not be appropriate for one who is terminally ill.

> Cardiac resuscitation, artificial respiration, intravenous infusions, nasogastric tubes, and antibiotics are all primary supportive measures for use in acute or acute-on-chronic illnesses to assist a patient through the initial period towards recovery of health. To use such measures in the terminally ill, with no expectancy of a return to health, is generally inappropriate and is therefore, by definition bad medicine.
>
> (Twycross 1982:87)

What Twycross is arguing for is that the course of treatment should be decided upon after considering the advantages and disadvantages which might accrue to the person being treated. The treatment which offers the greatest balance of advantages over disadvantages is deemed to be the most appropriate. This is in line with the consequentialist argument used above. Where there is a reasonable expectation of advantage on the level of both the quality and quantity of life the measures mentioned above, cardiac resuscitation and others appear to be appropriate. Where there is little to be gained from such procedures in terms of the quality and quantity of life of the person being treated one may regard the treatment as serving little or no purpose. It is at this point that the person being treated and the physician may find common ground. Both may regard further curative medical treatment to be futile - this holds true whether the person is able to express an opinion, or earlier expressed the wish to be allowed to die rather than to be subjected to such treatment; in the case of a comatose person the family considers that the person would have so wished had the opportunity been there.

5.5 The quality of dying

I shall now introduce a concept which I believe is given too little attention in this debate. In my argument I raised the issue of the dignity belonging to human beings as human beings; I spoke of the quality of life as being an important corollary of the idea of dignity. I now wish to introduce what to me is an equally important corollary, that of the quality of dying. The way we treat people during the ZY period of life largely determines how they die.

In Tolstoy's novel *Anna Karenina* Levin and his wife Kitty go to visit his brother Nicholas who is dying from tuberculosis and is living in rather sorry circumstances. Levin is horrified by the plight of his brother and is powerless to do anything. Kitty immediately takes in the situation, rolls up her sleeves and washes the dying man, dresses him in fresh clothes, makes him

comfortable and feeds him. Her actions will not cure but they bring a measure of dignity to Nicholas's last moments and, most importantly, are an expression of love and care. I quoted earlier from Nelson's statement in which he held that caring is more basic than curing. The widespread acceptance of this maxim would explain the veneration accorded Mother Theresa of Calcutta by people of all faiths and none. She enables people to experience some dignity and loving care in their last moments thereby enhancing the quality of dying. The hospice movement functions in a similar way. There is no question of providing curative treatment, people are merely treated with the love and respect proper to those who have an inherent dignity. People are not prevented from dying, other than by the sort of care provided, but the quality of their dying is improved a great deal.

Inherent in the concept 'quality of dying' is an acceptance of human finitude, an acceptance that death is part of life - if I may be allowed to coin a phrase. But, having accepted death it attempts to humanise it. In this context I believe one can say that people have a right to die, but it is necessary to add that the quality of that dying should be such as befits a respect for life. Allowing someone to die when the quality of life is very poor is as much a respect for life as the aggressive treatment of an illness when there is hope for an improved quality of life and an increased quantity of that life. Whereas when aggressive treatment is maintained even when the prognosis is poor and there is little or no prospect of a return to a reasonable quality of life it reflects a disrespect for human life or at least a distorted view thereof. One would enhance the quality of dying by: providing such treatment and nursing care as would make the person comfortable; enabling the family and friends of the person who is ill to show loving care and concern. Such humane treatment, rather than treating people by using the technological extensions of human skill and ingenuity is more likely to have what I consider to be the desired result.

6 CONCLUDING REMARKS

In my concluding remarks I shall summarise the ethical arguments which I have employed in my discussion. Human life is not to be equated with mere biological life, it implies a certain measure of dignity as well as the ability to relate to other human beings. Human life is also to be regarded as having an attribute usually spoken of as the sanctity of life. These attributes when taken together explain in some measure why human life is regarded

as a primary value, indeed that the right to life may be regarded as inherent. The life to which we have a right must also be enjoyed at an acceptable level, there must be a good quality of life.

In the previous paragraph both deontological and value statements are included. The value statements are given substance in the goods which persons experience, they are in other words, judged in consequentialist terms. I believe that Wogaman's methodological presumptions enable us most adequately to combine these two aspects of ethical decision-making. In terms of this discussion, because of the implications of the concept of the sanctity of life, we are prima facie obligated to save life and not take it. Circumstances may however arise which negate the dignity and sanctity of life. Such circumstances do not justify the direct taking of life but rather mean that accepting death is the proper means of showing respect for life. Persons should then be assisted to die in a manner proper to those who carry the divine image. What I have therefore done is to combine the deontological sanctity of life principle with consequentialist arguments such as the quality and quantity of life as well as the quality of death.

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