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Ethical Considerations In Human Experimentation

Charles E. Curran*

Americans have always been fascinated by progress. Medical science and medical practice have progressed greatly in the present century and especially in the last few years. Consider, for example, the phenomenal progress in drug therapy. Three of what are now the eight major classes of prescribed therapeutic drugs were unknown thirty years ago—the antibiotics, the antihistamines and the psychoactive drugs. Two other major classes of drugs, the sulfas and the vitamins, were introduced between the two world wars. Barbiturates and hormones were discovered somewhat earlier in the century. Before this century only narcotic drugs were known; but today's representatives of this class, with the exception of morphine and codeine, are recently developed drugs.1 The average American can readily recall the medical progress marked by heart transplants, kidney transplants and birth control pills. Life expectancy has grown because of the immunization through vaccines against diseases such as poliomyelitis, rubella, rubeola, tetanus and diphtheria. Today we frequently hear about attempts to cure and prevent cancer.

Such progress could never have been attained without experimentation. Science must discover and then test every drug or experimental procedure. Despite all precautions and all prior testing on animals, there will often be elements of risk as newer developments are tried on human beings. The progress in medical science practiced today comes from such experimentation. Moreover, experimentation in many ways is a common phenomenon in our life. We experiment with our dieting, our reading and our work.

However, in the last decade or so there has been a growing realization of some ethical problems connected with medical progress through experimentation. As an aftermath of the Nazi experience, the Nuremberg code dealt with the question of medical experimentation in ten principles. There was a general feeling that concentration camp atrocities were intimately connected with the Nazi phi-

* Professor of Moral Theology, Catholic University of America.

1. See generally B. Barber, J. Lally, J. Makarushka & D. Sullivan, Research on Human Subjects (1973) [hereinafter cited as Barber].

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losophy and mentality and would not exist in our civilized society; but there has been a dawning recognition that there are ethical problems and difficulties with the medical experimentation that does take place in the Western world.2

Perhaps the first symposium on human experimentation, specifically human pharmacological experiments, was held at the meeting of the Federation of American Societies for Experimental Biology in 1948. Legal interests were sparked by an edited volume published by Ladimer and Newman in 1963 under the auspices of the Law Medicine Institute of Boston University, then under the directorship of William J. Curran.3 Governmental action occurred in the Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act4 and in the institutional guidelines of the Department of Health, Education and Welfare published in 1966 requiring that all applications for grants be examined by a committee in the originating institution, in order to insure an independent determination of: 1) the rights and welfare of the individual involved; 2) the appropriateness of the methods used to secure informed consent; 3) the risks and potential medical benefits of the investigation.5

Voices were also raised within the medical community itself about the ethical appropriateness of some human experimentation. In 1966, Dr. Henry K. Beecher, a professor of anesthesiology at Harvard University and himself a medical researcher, published a very influential article in the New England Journal of Medicine which gave summaries of twenty-two different experiments which, in the author’s view, were unethical or at least questionably ethical.6 In England in 1967, Dr. M.H. Pappworth wrote Human Guinea Pigs “to show that the ethical problems arising from human experimentation have become one of the cardinal issues of our time.”7

2. For the most complete work on the subject of human experimentation, including the various codes that have been proposed and excerpts of the most significant cases and articles see J. Katz, Experimentation with Human Beings (1972) [hereinafter cited as Katz].
5. H. Beecher, Research and the Individual 293 (1970) [hereinafter cited as Beecher]. Beecher’s book is a thorough treatment of all aspects of the question and has a helpful appendix containing in chronological order the various codes referring to human experimentation.
The general public has become more aware of the problems and difficulties connected with experimental medicine through widespread publicity given various problems: the disastrous effects of thalidomide on babies in Europe; experiments in the United States in which cancer cells were injected into older patients without their consent; the experiments conducted at the Willowbrook State School in New York in which mentally retarded children were admitted to the institution at that particular time only if their parents would consent to an experimentation in which the children were infected with hepatitis (the normal units of the institute were filled at that time, but parents of prospective patients received a letter saying there were openings in this experimental unit); the experiments at Tuskegee in which black male volunteers were not given the proper penicillin treatment for venereal disease long after it had become recognized as the standard and efficacious treatment.

The realization of ethical problems involved in human experimentations has become more widespread. In July of 1974 the Congress of the United States passed a law setting up a commission of members to be known as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission, with a two year term, has the mandate to identify basic ethical principles involved in biomedical research on human subjects, develop guidelines for such research and make recommendations to the Secretary of Health, Education and Welfare in these matters. The National Institute of Health has been issuing proposed policy directives on the protection of human subjects and soliciting feedback from interested persons and the community at large. This paper will now develop the ethical considerations of human experimentation from a number of different perspectives.

I. IN THE LIGHT OF TECHNOLOGICAL PROGRESS

Medical experimentation and consequent medical progress depend heavily on science and technology, but today in our society there is no longer a naive assumption about the inevitable progress of technology. Horrendous uses of nuclear power, the recognition of the limits and finitude of human existence and the discussions of

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pollution and of limited resources on the earth all have contributed to a more critical approach to questions of science and technology. In reaction to an earlier naive view of human progress through technological advances, some people in our society now seem to be totally negative toward technology and its usage. Among ethicists, philosophers and theologians there are also different views about technology.

From both theological and philosophical perspectives I cannot accept the extreme positions of either uncritical acceptance of all the possibilities that technology can accomplish or a condemnation of technology as being ultimately antihuman. Human beings are called by God to strive for a better human existence. Technology can and should help to develop and enhance the human, but it is never totally identical with the human. Briefly, technology is a limited good that must be guided and directed by the truly human perspective. Technology like any other human reality can also be abused by sinful and evil human beings. This in no way condemns technological progress in itself but rather reminds us of the dangers that might arise and also calls for a vigilance lest technological progress be put to such usage as illustrated in the medical experiments on prisoners in Nazi concentration camps. Technological progress at times seduces people into believing that human progress is always of an ongoing, forward developing type. Today in society we realize that technological progress has not been unambiguous, but is often accompanied by increased human problems as illustrated in the questions of pollution and of ecology.¹⁰

Thus, in the area of medical experimentation one notes the positive aspects of medical science and technology in terms of the great advances that have been made but also recognizes the dangers and limitations which are present. These limitations ultimately center on the fact that human beings are unable to overcome the finitude and mortality which characterize our human existence. One does not have to be a religious believer or a philosopher to recognize that science and technology will never overcome these basic limiting conditions of human existence, but this should in no way be interpreted in a defeatist way as if technology and medical experimentation have nothing positive to contribute to human development.

¹⁰ For a generally convincing exposition which occasionally might be too optimistic see V. Ferkiss, Technological Man (1969).
Medical technology must be employed in the service of the human and in terms of truly human progress in overcoming disease and improving the longevity and quality of human life, even though it can never overcome the basic creatureliness of human existence.

Human experimentation must be seen in the perspective of a proper human approach to technological progress in general, but there is one very important added factor. Human experimentation involves what properly may be called anthropo-technology, for here we are dealing with human beings.\(^{11}\) There is a great difference if technology tries to improve and change what is inanimate or nonliving; but in dealing with human beings one is not working merely with an object. In all other forms of technological experimentation there is much less worry about the mistakes or mishaps which accompany any technological progress. Even here it seems that in the past we might not have given enough attention to the wastage involved, but the problem is qualitatively and significantly different when the mistakes and mishaps involve human beings. One cannot and should not take the same risk with human beings that one can take with nonliving reality. The human factor places another very significant limit on human medical experimentation. In practice there will be times when one must be willing to say "no" to medical progress in the name of the truly human. How, why, when and where this "no" should be said is a question which demands further consideration.

**II. IN THE LIGHT OF MEDICAL ETHICS**

What are the more specific issues involved in human experimentation? A tremendous interest has been shown in medical ethics in the last few years. Before that time medical ethics was mostly the preserve of Roman Catholic theologians.\(^{12}\) There are many reasons explaining the contemporary interest in bio-medical ethics, but perhaps the most significant is that in the contemporary situation a quite different ethical problem has emerged in medical ethics. Medicine, as we have traditionally known it in the past, has been interested in the health of the individual patient. Good medicine in many ways could be the same thing as good morality because they

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both agreed that the good was determined by what was for the good of the individual patient. The first basic rule of medical morality was often formulated in these terms: no harm to the patient. The international code of medical ethics drawn up by the General Assembly of the World Medical Association in London in 1949 states categorically: "under no circumstances is a doctor permitted to do anything that would weaken the physical or mental resistance of a human being except from strictly therapeutic or prophylactic indications imposed in the interest of his patient."

Even a cursory review of the older Roman Catholic manuals of medical ethics supports this understanding of a basic convergence between good medicine and good ethics. The major problem areas highlighted in the medical moral literature in Roman Catholic ethics concern especially abortion and sexuality. In abortion there was another important consideration in addition to the good of the individual patient—the fetus, which for practical purposes Catholic moral theology considered to be a human being from the moment of conception. Questions of contraception and sterilization were very prominent in these Roman Catholic discussions, and here there was often a conflict between Catholic ethical teaching and medical practice (as well as the medical ethics proposed by many or most non-Roman Catholics). If it is for the good of the person, then many doctors see no ethical problems with contraception or sterilization. Roman Catholic ethics, however, asserted that the generative organs do not exist only for the good of the individual but also for the good of the species. Insofar as such organs and functions exist for the good of the species they cannot be subordinated to the good of the individual. The conflict arose in this literature because the controlling norm was no longer what was for the good of the individual. Today many Roman Catholic theologians, including myself, disagree with such approaches to the question of contraception and

14. Representative of this type of literature are the following: E. Healy, Medical Ethics (1956); G. Kelly, Medico-Moral Problems (1958); C. McFadden, Medical Ethics (6th ed. 1967); T. O'Donnell, Morals in Medicine (2d rev. ed. 1959). For recent books by Protestant ethicists on medical ethics which include sections on experimentation see J. Nelson, Human Medicine (1973); P. Ramsey, The Patient As Person (1970); H. Smith, Ethics and the New Medicine (1970).
sterilization. These considerations, however, show that even in Catholic medical ethics problems arose primarily in those instances in which there was some conflict between what seems to be for the good of the individual and a consideration other than the good of the individual.

Human experimentation may be understood in two different senses. In the broader sense in which the primary finality looks to the good of the individual patient, the ethical question does not involve any specifically or qualitatively new dimension, although there will always be the difficulty in making proportionate judgments between the risk involved and the good of the patient. In such cases the doctor works primarily for the good of the individual patient. Since medicine is not an exact science, experimentation is often involved, especially in the employment of any new procedure. The doctor should explain the option with its risks to the patient and obtain the patient's consent. The criterion of informed consent has been discussed at great lengths in the literature. Problems arise in making sure that the patient comprehends enough to give truly informed consent. At the same time one must recognize the bias and prejudice which the doctor, like any human being, brings to the understanding of the facts involved and to the decision. When the patient is unable to give consent for some reason or another, then vicarious consent may be given by the closest relative or guardian. In this case the vicarious consent is based on the fact that the person who is acting for the patient does so on the basis of what is for the ultimate good of the patient involved. For the same reason consent can be presumed if the patient or a relative are not able to give consent.17

A newer and qualitatively different ethical dilemma arises in the case of human experimentation in which there is no direct benefit for the individual or in which the primary benefit is for medical knowledge, other human beings, or the good of the human species in general. This is experimentation in the strict sense of the term as distinguished from therapy which is primarily for the good of the individual concerned.

III. THE INDIVIDUAL AND SOCIETY

Can harm be done to a person or can a person be exposed to the

risk of harm for the good of others? What is the proper understanding of the relationship between the individual and society? There are two extremes which it seems all would agree in avoiding. The first extreme subordinates the individual to the good of society to the extent that the good of society can justify medical experimentation on individual people who are exposed without their consent to great risks as illustrated in the Nazi experiments. Such an ethical theory would propose that morality is determined by the greatest good of the greatest number, and the individual counts just for one. Thus, if there were a greater good or a greater number of people to share in the good, then the rights of the individual could be overridden.

On the opposite extreme is the position which asserts an absolute individualism which sees no morally significant relationship of the individual to others or to society and calls for no infringement on the individual's freedom in the name of society or the human species. Most ethical theoreticians acknowledge that at times the individual is limited by the needs of society, and society also in some ways does expose individuals to risks involving life and limb. Individual people for many different motives voluntarily undertake jobs or professions which expose them to the risk of life and limb more so than if they were in other professions—astronauts, circus performers, steeplejacks. In our own society, we allow people to drive automobiles at certain speeds even though we recognize that more lives would be saved if people were not allowed to drive faster than fifteen miles per hour. Ethical arguments for capital punishment, with which I disagree, acknowledge that the state can take the life of the malefactor. In our society, although I again disagree with the policy, the state has the power to force people to go to war if they are not conscientiously opposed to all wars. The individual soldier in war is thus exposed to a great risk of life and health.

Within these two extremes it is not enough merely to state that one has to balance off the rights of individuals and the rights of society. It is very important for one to recognize precisely how this balance should take place. Guido Calabresi argues that in reality we as a society do not live up to our cherished commitment to the

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dignity of individual human life. Accident law indicates that our commitment to life-destroying material progress and comfort is greater than our commitment to life. Why don't we make safer cars? Why don't we do away with all railroad grade crossings on our highways which take many lives each year and could be replaced but at great expense? It is really a market device of economic values and not a belief in the dignity of human life which controls our attitudes toward automobiles and grade crossings. This market device sees to it that no one seems to be taking human lives and thus we can live with our "cherished" principle of the dignity of individual human life. There is the need for a quite complex structuring to enable us sometimes to sacrifice lives, but hardly ever to do it blatantly and as a society, and above all to allow this sacrifice only under quite rigorous controls.20

Despite some differences, Calabresi sees a usefulness in the analogy between medical experiments and the automobile. There is a genuine difference between a positive choice to subject someone to risk or to take a life and passive acquiescence in a system that results in lives being taken when they could be saved at ascertainable costs, but Calabresi sees the difference between the two as only a psychological difference. Calabresi, on the basis of this analogy, acknowledges that the question remains of trying to find the control system in the medical experimentation field that affords an adequate balancing of present against future lives and is still efficient, indirect and self-enforcing so as to avoid clear and purposive choices to kill individuals for the collective good.21

I have grave difficulties with some aspects of such a presentation. The analogy with deaths caused by accidents through imperfect or faulty cars and accidents at railroad grade crossings is not appropriate. A person drives a car for reasons of one's own personal good and expediency. In the process the individual who is doing this for one's own good does expose oneself to certain risks. Railroad grade crossings are usually clearly marked so that the motorist is warned of their presence. Unfortunately human error is such that a motorist occasionally fails to drive safely and accidents happen at such crossings—unfortunately often fatal accidents. But in medical experimentation the question is quite different. The individual is directly

21. Id. at 183-84.
exposed to risk for the good of the human species and not for one's own good. The harm is done to the individual and in and through this harm which is done a good is expected for others. In the case of automobile accidents, the good does not come about precisely because of the harm which is done to individuals. There is a very significant moral distinction in the way in which the risk or evil is present.

Another important ethical distinction underscores the difference between a positive and a negative obligation. Negative obligations are said to oblige always and everywhere, but positive obligations do not always require that we do everything possible for the good involved.\(^2\) For example, the ethical understanding that lying is always wrong means that one can never tell a lie, but it does not infer that one must always tell everything that one knows. One can never commit murder, but one does not have to do everything possible to make sure that human lives are not in any way lost. In the light of this distinction, traditional natural law theory declared that the individual does not have to use extraordinary means to preserve human life, and thus recognized a right to die.\(^2\) The acknowledgment of this difference between negative and positive obligations indicates the analogy with the grade crossings and automobiles does not seem all that applicable in the present case. One can still maintain the principle of the dignity of human life and yet realize that in some circumstances human lives will be lost. Many ethicists have described this by saying that one can never directly take innocent human life although indirectly life may be taken or life which is existing in an actual conflict with another life might be taken.\(^2\) There are some difficulties with the way in which these terms have been understood, but nonetheless the general thrust of this distinction is very significant, if not always determinative.\(^2\)

There is again a difference between what society asks of other people and what individuals can volunteer to do. There are many times when individuals can and should take risks to their own life

\(^{22}\) H. Noldin, Summa Theologiae Moralis: De Principii 166-69 (33d ed. 1960).


\(^{24}\) E.g., Ramsey, Abortion: A Review Article, 37 Thomist 174, 221 (1973).

\(^{25}\) For recent surveys and evaluations of a growing literature on this subject see R. McCormick, Ambiguity in Moral Choice (1973); Rossi, Il Limite del Principio del Duplice Effetto, 13 Rivista di Teologia Morale 11-37 (1972).
and limb in order to be of help and service to other people. Christian ethics has always recognized the important place of charity although debate continues to exist about the exact meaning of Christian love. In this connection it is also helpful to recognize two levels of moral obligations. There are certain obligations which are incumbent upon all human beings, but above and beyond this there are certain heroic actions which we could not require of all human beings but which some would be willing to do for the sake of the neighbor in need. In these particular questions it is necessary to evaluate the proportion existing between the risks assumed and the good to be attained.

There is more and more concern expressed today about the need to protect the individual against possible invasions of dignity, privacy and freedom by society. In this context it is also frequently said about human experimentation that human beings must be treated as ends and not as means. In general I accept such a formulation, but it is also necessary to nuance it. One can maintain the dignity of the individual and still recognize the complex relationships in which human beings exist with different types of coordination and subordination. Also in human society there are human beings who perform useful functions and to that extent are, in a certain sense, providing means for others. The professor has a useful function for the student. The mail carrier provides a useful function for other people in society. Obviously these people are not mere objects and must always be treated as persons, but the human relationship I have with them is not necessarily an I-thou relationship. In fact my primary concern is that such persons fulfill well their functions in society—be a good professor or a good mail carrier. However, even these "menial" or service type functions do not take away from the person of the individual who is performing them, and that person can never be treated as a mere object. In conclusion it seems necessary to uphold the dignity of the individual human person in society. This does not mean that there are not some societal values and constraints and that some human lives will not be lost, but it calls for a proper ethical understanding lest the individual be unduly subordinated to the needs of the society.

IV. PRIMARY ETHICAL CONSIDERATIONS

The existing literature on the subject of human experimentation frequently describes the primary ethical issue in terms of the need for informed consent. Informed consent implies that the individual has the competency and the autonomy to make a responsible and free decision to agree to medical experimentation. The comprehension of the risks involved and of the good to be obtained serves as the basis for a competent and responsible moral decision by the individual. Questions arise especially for those who are so situated that they do not have the competency or the autonomy to make such decisions—children, prisoners, the dying, the fetus, etc. Such discussions often center on the exact meaning of informed consent and what this concept implies in practice. In theory informed consent means that the subject knows the risks involved and can make a responsible decision to accept these risks for a proportionate good, even though the good is not directly for the subject. There have been many enlightening discussions in the literature about the meaning of informed consent both in theory and practice which it is not necessary to review here.28

It is interesting to note that much of the discussion about human experimentation has come from doctors and lawyers and not from ethicists as such. The legal and ethical perspectives are not, however, necessarily identical. Recently attention has focused on the need for guidelines or a code of ethics to be followed by researchers in such situations.29 This raises the whole problem of what can be expected from an ethical code or guidelines. I believe that such guidelines are absolutely essential and important and reject the opinion of those who say that it is sufficient to rely on the conscience of the researchers. However, there is a certain sense in which there is truth in the statement that ultimately we must rely on the conscience of the investigator. If this is required in addition to guidelines, then it can be properly understood.

Why are the legal and ethical perspectives not absolutely identical? One important difference is that ethics is not only concerned

28. The most significant books are Beecher, supra note 5; Experimentation, supra note 20; Katz, supra note 2.

with the minimal but also continues to urge an even more perfect and more human life. Some ethical traditions acknowledge two types of ethical response—one which demands the minimum requirement of human action and one which calls for a greater degree of heroism and perfection. Law by its very nature tends to settle for the minimum since it exists for the generality of persons. Also ethics involves not merely laws and norms but should include such other considerations as the moral self with the dispositions, attitudes and virtues that should characterize the agent as well as the goals and ideals that should influence human life. There is also another limitation inherent in the very meaning of law or of guidelines. Guidelines have to be proposed in such a way that they can be understood and applied in an even-handed way in practice. Thus guidelines must be specific enough and capable of being verified in practice. For this reason, for example, it is very difficult for law to speak about such things as motives and intentions or even ethical concepts such as kindness or consideration which tend to be somewhat vague.

This difference between the ethical perspective and the perspective of guidelines or laws has ramifications in the question of human experimentation. The various guidelines and much of the writing in the field insist on the primary category of informed consent to guarantee that the individual who is experimented upon for the good of others is truly treated as a person and not as an object. However, from the ethical perspective I would not propose informed consent as the primary ethical consideration.

The active human participation of the experimental subject with the researcher in the enterprise of increasing medical knowledge and making available improved medical service to other human beings is a better description of what is taking place. The subject of experimentation is not merely an object of experimentation who has to give consent. Rather there should be involved here a truly joint venture between two human beings working together for the increase of human knowledge and the ability of human beings to serve one another. From this perspective the subject is a co-participant in the human quest for progress. This calls for a more active role of the subject who then truly collaborates in a human way with the researcher. The subject should be treated as a participant and not merely as a quarry supplying the material necessary for the research. The concept of informed consent, in my judgment, is the minimal legal instrumentality to insure the possibility of human
participation and collaboration in research. To fall short of this involves a failure to respect the humanity of the individual subject, but this remains only the floor and the minimum for that type of human collaboration which should occur.

The difference between an ethical perspective and a legal perspective can be illustrated by the writings of the philosopher Hans Jonas. Jonas points out that one should look for subjects of medical experimentation where a maximum of identification, understanding and spontaneity can be expected—that is among the most highly motivated, the most highly educated and the least "captive" members of our communities. The principle of identification by which the subject is joined most closely with the researcher in the human quest for medical progress results in a rule of descending order of permissibility with a counter-utility sense so that the poorer in knowledge, motivation and freedom of decision (that means the more readily available in terms of numbers and possible manipulation), the more sparingly and indeed reluctantly should the reservoir be used and the more compelling must therefore become the countervailing justification. Jonas argues against a social utility standard based on availability and expendability and is particularly insistent on the fundamental privilege of the sick and the danger of exploiting them.30

In my judgment there is something of the ideal in Jonas' proposals which cannot always be required in practice. Also a danger of elitism lurks in some of his remarks about the more intelligent and seeming identification of them with the more highly motivated. There are many reasons that might motivate one to participate in medical research. It is not necessarily the more intelligent or the more successful people in society who are the best motivated. One who has suffered from a disease or is suffering now might be much more highly motivated than one who has never suffered to that extent. In addition one cannot require the highest motivation of all people. Likewise the sick person has both the time and availability which the well person (even the same person when well) might not have. I reject the requirement that a more countervailing justification would be always necessary to insure against the dangers of taking advantage of certain people, especially the sick. I propose an

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ombudsman to protect the rights of the vulnerable. If a disproportionate number of those involved in research come from hospital ward patients, then there at least arises doubts about taking advantage of the vulnerability of certain people in society.

The relationship between the ethical and the legal perspectives also comes to the fore in any consideration of the legal or administrative guidelines on human experimentation. The proposed policy of the Department of Health, Education and Welfare on the protection of human subjects illustrates this problem. These guidelines frequently recognize the need for ethical considerations and explicitly call for ethical competence and for ethicists to serve on boards and committees. What do these guidelines mean by ethics?

Is ethics a normative discipline or is it just descriptive? Most ethicists would argue for the normative nature of the discipline and insist that morality cannot be reduced to consensus or the will of the majority. Ethicists, however, disagree among themselves both on methodology and on substantive questions. Whoever chooses a panel of ethicists could very well manipulate the desired final outcome by choosing certain ethicists and not others to serve on the committee. As a result it becomes almost impossible for any legal guidelines to incorporate any normative ethical methodology. In many ways the proposed guidelines of the Department of Health, Education and Welfare do not regard ethics as a normative discipline. The proposals often eliminate extreme solutions and then propose committees (a protection committee, later called a consent committee, in the institution of the applicant and an ethical review board in the HEW agency with representative members of the public including clergy or ethicists and only a limited number of scientists) to make the ultimate judgments. Problems are thus solved in a formal way through a somewhat representative committee.

This is probably the only way in which such guidelines can function in our pluralistic society. Even in ethical theory there is a validity to the disinterested person making judgments and using as a criterion whether or not one would subject one's own children to such experiments. However, I would urge that the people who serve

on these boards and the researchers themselves should acquaint themselves with the various ethical considerations and their implications for these questions of experimentation.

Informed consent is a very essential aspect of the participation of the subject in experimental research, but consent alone is not the only important ethical aspect. Even the usual treatments of informed consent recognize that this is a means by which the individual can make the judgment about the proportionality between the risks and the good to be obtained. The researcher before proposing research must also make such judgments. What this indicates is that from the ethical viewpoint the freedom of the subject is not the only question involved. According to my understanding of ethical theory, freedom cannot be the only ethical consideration. There are certain things which are ethically wrong (e.g., sadistic relationships), and free consent does not make them ethically right. In this case at the very least there must be a reasonable proportionality between the risks involved and the goal to be sought. There is much need to discuss this question of proportionate reason in justifying the risks involved in human experimentation, for it concerns both the researcher in proposing the research and also the subject in consenting to it.

V. PRACTICAL OBSTACLES

It is now necessary to consider the practical obstacles or conflicts which in reality may inhibit the subject from fully participating and collaborating in a human way in the experimentation. The ultimate source of conflict comes from the fact that the researcher is interested primarily in the knowledge to be obtained from the experiment and not in the good of the individual. This basic source of conflict is accentuated by the fact that in the eyes of most people there is no distinction between the physician and the researcher.

First of all, it is necessary for the patient to recognize the distinction between the researcher and the physician even if it might happen to be one and the same person who exercises both functions. Traditionally, the doctor has enjoyed a very high position of trust in our society. The patient generally looks upon the physician as the one who is able to cure and help when one is sick and ailing. The

average patient tends to think that all people in white coats are doctors and is predisposed to agree with everything that is asked of him by the "doctor."  

Obviously education of all types is necessary to enable the general society to distinguish the two roles involved. However, an ability to intellectually distinguish the two roles is not sufficient. Many other subtle forms of pressure and coercion exist. To alleviate some of these forms of pressure, especially as they exist in hospital situations, different suggestions have been made. Otto Guttentag concludes his study of human experimentation by making the practical recommendation that experiments done not for the immediate good of the individual subject but for the welfare of others should be performed by experimentors who are not simultaneously responsible for the clinical care of the individual. Such a system of checks and balances exists in practice today in the question of heart transplants with the death of the donor certified by doctors who are not involved with the intended recipient of the heart.

John Fletcher, a Christian ethicist who has devoted much study to the practical aspects of informed consent, wants research institutions to act on Guttentag's suggestion. Fletcher mentions three factors which can affect and limit the autonomy of patients—the very fact of being ill, the circumstances surrounding the institution itself, and the desire to please the investigator. All medical institutions engaging in human experimentation should designate one or more persons as an advocate or ombudsman for the patient. I agree that the work of an ombudsman safeguards in practice the individual when there are forms of pressure which can affect the autonomy and competency to give informed consent.

Practical ethical analysis has the task to discern the pressures which are involved in situations and to act against them. Agere contra has been a traditionally accepted norm in ethics and in spiritual theology. Another form of pressure comes from the competition existing within the field of research—something which is not necessarily bad in itself. As awards and recognition often go to the first one to make a medical breakthrough, the desire to be first might

36. Fletcher, Realities of Patient Consent to Medical Research, 1 HASTINGS CENTER STUDIES 39-49 (1973).
tempt one to act hastily and disregard certain ethical aspects of a situation. This type of competition causes problems on all levels of medical research. Two empirical studies done by Barber and associates point up the problem of competition of researchers for academic rank or prominence on a local level within a given institution. Their data show that

those who have been less rewarded by local rank than peers for whatever they have performed in the area they have emphasized, are more likely to be led to take advantage of human subjects in order to increase their chances of promotion by publishing significant scientific work.\textsuperscript{37}

As mentioned earlier, ethical guidelines alone are not enough and it is necessary to rely on the conscientious convictions of researchers themselves. However, the studies by Barber \textit{et al.} indicate that researchers themselves do not give a very high priority to emphasis on ethical concerns. Much medical experimentation is done in collaboration, but how well developed is the characteristic of ethical sensitivity of a fellow collaborator? The studies by Barber \textit{et al.} indicate that the climate of bio-medical research groups is more favorable to the position designated as "value of research" than it is to the "humane therapy" position. Their data indicate that while characteristics of researchers such as "scientific ability" and "motivation to work hard" are highly desirable in choosing collaborators, "ethical concerns for research subjects" is at the other extreme of salience.\textsuperscript{38} Notwithstanding the limited studies involved, it seems that there is a great need to change the climate in which human experimentation takes place. Responsibility here seems to fall primarily on medical schools and on the medical community itself.\textsuperscript{39} It is necessary to acquaint researchers from the very beginning with the ethical problems which can and often do arise.

Other forms of pressure would include those existing when medical professors ask their students to participate in medical experimentation. Likewise, in university hospitals the residents are under pressure to cooperate with senior professors who want to use the residents' patients for research because the residents are dependent

\textsuperscript{37} Barber, supra note 1, at 91.
\textsuperscript{38} Id. at 192.
\textsuperscript{39} Makarushka & Lally, Medical Schools, Clinical Research And Ethical Leadership, 49 J. MED. ED. 411 (1974).
upon the senior staff in many ways for help and advice.

This section has not attempted an exhaustive discernment of all the pressures which can exist, but merely indicates some of these pressures to highlight the need to be continually vigilant against the different types of pressures existing and to realize the need to act against them in an attempt to neutralize them.

VI. EXPERIMENTATION INVOLVING CHILDREN

As a final section it will be helpful to discuss in more detail a significant and prismatic case—the use of children in nontherapeutic experimentation. Again the discussion will not descend to the level of proposing guidelines. So, for example, it will not even discuss the exact age of what is meant by children who are unable to give consent.

There has been a great divergence in the literature and proposed guidelines about the ethics of using children in medical experimentation understood in the strict sense. Many researchers have proposed the need to use children but have also recognized the role of proper safeguards. Louis Lasagna, a professor of medicine and experimental therapeutics, accepts the use of children and even justifies the famous experiment of the Willowbrook School in New York. 40 Franz J. Ingelfinger, an editor of the New England Journal of Medicine, argues against the absolute position of the World Medical Association statement that does not allow experimentation on children under any circumstances. 41 Charles Lowe, M.D., and associates point out all the advantages that have accrued through experimentation on children and conclude to its necessity but recognize the need for some ethical restrictions which very well might prevent our obtaining some of the knowledge and technological progress which we did obtain in the past. 42 The proposed HEW guidelines also begin with the assumption that experimentation on children is necessary for medical advances for the good of other children. These guidelines conclude that substantial risk with children is never acceptable but that some risk is justified with the ultimate determina-

40. Lasagna, Special Subjects in Human Experimentation, in EXPERIMENTATION, supra note 20, at 271.
tion to be made by review committees.\textsuperscript{43}

Not all researchers have proposed that the parents be allowed to consent to research on their children. Henry K. Beecher and William J. Curran conclude that children under 14 may be involved in medical experimentation only when there is no discernible risk.\textsuperscript{44} As might be expected some philosophical and religious ethicists tend to be more reluctant or even opposed to the use of children in medical experimentation, but again this does not hold true of all ethicists. Paul Ramsey, based on the canon of loyalty by which the parent is related to the child, opposes any medical experimentation with children because the primary ethical consideration is not the risk or degree of risk but the offense of touching which would be involved in any experimentation.\textsuperscript{45} William E. May supports the same conclusion, since proxy consent by the parents in such cases involves a contradiction—it necessarily requires one to treat a child or other incompetent individual as a moral agent, something that a child or other incompetent actually is not.\textsuperscript{46}

Richard A. McCormick has disagreed with Ramsey and comes to a conclusion similar to Beecher’s in allowing experimentation where there is no discernible risk (although he at times speaks of no notable disadvantages and accepts the concept of low risk if it means no realistic risk), undue discomfort or inconvenience.\textsuperscript{47} McCormick bases his conclusion on the fact that such an act is something that one ought to do for other members of the human community and is not merely a work of charity or of supererogation which would never be justified by proxy consent. Elsewhere McCormick rightly points out that his conclusion is quite similar to the one I have proposed on this question.\textsuperscript{48}

In the light of further considerations, I have changed my earlier position, which, in reaction to Paul Ramsey’s approach, proposed that experimentation on children is acceptable when there is no discernible risk.\textsuperscript{49} Now I am willing to accept some risk, discomfort

\textsuperscript{46} May, Experimenting on Human Subjects, 41 LINACRE Q. 238, 250 (1974).
\textsuperscript{47} McCormick, Proxy Consent in the Experimentation Situation, in Love and Society 221-24 (J. Johnson & D. Smith eds. 1974) [hereinafter cited as McCormick].
Ethical Considerations

or inconvenience. Theology and ethicists have always had a difficulty in dealing with children primarily because of their inability to consent freely—the hallmark of the adult human. For example, Catholic theology at one time excluded children dying without baptism from the fullness of eternal life because they were unable to have baptism of desire. Recall, however, that in the ethical considerations I insisted that consent was not the only consideration, for consent itself must always be properly ordered.

McCormick and others claim that the HEW guidelines are utilitarian, but I do not think that conclusion is necessarily accurate. Unlike McCormick, I would see the individual human being in more relational terms rather than as an individual with certain basic human tendencies or human goods which are equally basic and self-evidently attractive and against which one must never directly choose. A more relational understanding would not see all these goods as equally basic and of equal value. Likewise without unduly subordinating the individual to society or others this view recognizes that in our relational existence with others we are often exposed to some risk which is not for our benefit—even in the case of children. In a less complex and relational world, a child would be better off growing up in an environment where there is no air pollution, but other values are decisive in the choice of where the family lives even though this redounds only secondarily to the good of the child and definitely causes some harm to the child. One might argue that even here the decision is made for the good of the child, but consider another example. I believe that individual children in some circumstances should undergo the inconvenience of busing in order to achieve racial integration of schools—which is proximately and primarily for the good of others and only very indirectly redounds to the good of the individual child.

A more relational understanding recognizes that often children are exposed by parents and others to some risk or inconvenience which is not primarily and directly for their own benefit. I agree with McCormick and Lowe and associates that it is necessary here to distinguish two kinds of obligations. A person may freely expose

50. McCormick, supra note 47, at 218.
51. McCormick's thesis is that one may give proxy consent where it is a case of what the person ought to do but not if it is a work of charity that one could freely do for others. His explanation of this in terms of the parents deciding to allow the child to die (by withholding extraordinary means) seems weak, for ethicists do not usually claim that the child or person ought to die but that one can decide not to use extraordinary means.
oneself to a greater risk than the parent can take with the child. The parent can, however, expose the child to some risk, low risk or slight risk for the good of others. My primary difficulty with the HEW guidelines is the failure to spell out what is meant by the some risk which is permitted as opposed to the substantial risk which is forbidden. As practical guidelines these would be much more helpful and less open to abuse if they would offer a more explicit understanding of what is meant by some risk and thereby give more detailed guidelines for the final decision to be made by review committees.

Although I would accept the ethical validity of parents giving proxy consent for experimentation which exposes their child to low risk, some risk or slight risk (or discomfort or inconvenience), I still recognize the absolute need for practical vigilance in all areas of such experimentation. Above all, children should never be used in experimentation unless there is no other way to achieve the purpose of the experiment.

VII. Conclusion

This paper has attempted to give an overall perspective of the ethical considerations of human experimentation without descending into the particulars which should characterize guidelines and without an exhaustive discussion of all the possible cases in which competency or autonomy or both are affected. The primary consideration involves the proper relationship of the individual to society. The rights of the individual mean that at times one must say "no" to proposed experimentation. In the case of children, since the child has some ordering to others and to society, I would justify the proxy consent of parents to experiments if the risk for the child is slight or low.