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The problems surrounding "free and informed consent" are discussed in this article by Dr. May, who is Professor of Religion in the Department of Religion and Religious Education at the Catholic University of America.

In May, 1973, a special CBS Report entitled "The Ultimate Experimental Animal: Man" was broadcast. One scene from this televised report struck me as particularly illuminating, and it will serve to introduce the question of experimentation on human beings. A black woman who had been a prisoner in a Detroit jail had, while in prison, participated in a program testing a new type of birth control pill. This particular pill was known to the researchers to carry a high risk for causing cancer, but this fact was not made known to the women who had "volunteered" to participate in the program testing its effectiveness as a contraceptive. When the woman learned, after her release from prison, that the pill she and other women had been taking did in fact pose a serious risk of causing cancer, she was outraged at having been "used," declaring to the CBS correspondent that she had been treated like an "animal."

Her reaction, I believe, is quite instructive. In saying that she had been treated like an animal and in being outraged at having been so treated, she voiced a conviction that human beings ought not to be treated like animals. She was not necessarily denying that she — and other human beings also — was an animal (for after all we are); rather she was affirming that a human being is an animal *with a difference*, that a human being is a subject of rights that ought to be respected by the society in which he lives and that demand protection by that society. She was, moreover, affirming that any experiment performed on the "human animal" must, if it is to be rightfully carried out, respect the fact that human beings are beings of moral worth, subjects of rights rooted in their being and not conferred upon them by others. She was affirming, at least implicitly, the conviction that no human being can be regarded simply as a part

subordinated to a greater whole, the society in which he or she lives, but must be considered as a whole that cannot rightfully be subordinated to the interests of others.

This, I believe, is the cardinal point to be kept as we consider the ethics of experimentations involving human subjects. The moral worth of every human being is indeed *the* crucial truth at stake in considering this important topic; it is the reason why there is operative a primary "canon of loyalty," as Paul Ramsey terms it, namely the principle of free and informed consent, in all situations wherein one human being is the experimenter and the other his "co-adventurer" in the experiment.[1]

There are many different kinds of experimental situations, and the meaning of the principle of free and informed consent relates to the type of experimental situation. From our perspective, we can broadly distinguish between experiments that will be or are intended to be of direct medical value or benefit to the subject of the experiment and those that are not so intended. Among the first can be included experimentations whose purpose is to diagnose an illness from which a person is suffering, experimentations whose purpose is to alleviate or cure a malady from which the subject is suffering, and experimentations whose purpose is to prevent a person from becoming afflicted with a specifiable malady. Thus we can include among our first type of experimentations all procedures that are intended to be of benefit to the subject himself, whether these be diagnostic, therapeutic, or preventive. Among the second type of experimentations are those whose purpose is to further human knowledge and to benefit others by reason of the knowledge that is obtained. The second type of experimentations, thus, includes procedures whose purpose is to further biomedical and behavioral research, to advance the frontiers of human knowledge and thus enable men to develop new techniques for coping with the diverse maladies that afflict mankind, and to enhance the human good. Although it is quite true that persons who serve as subjects of such experiments may themselves be benefited in a spiritual or psychological manner, in such experiments the purpose is neither to diagnose an illness (physical or mental) from which they are suffering nor to cure them of such an illness nor to prevent them from being afflicted by a malady to which they are vulnerable as members of a subject population. There are, in addition, experimentations of a "borderline" character, inasmuch as they are intended both to advance knowledge and thereby to benefit persons other than the subject of the experimentation and also to be of benefit to the subject. These experimentations might be termed experimentally therapeutic/diagnostic/

preventive. But from the perspective of the moral issues involved — and these center on the principle of free and informed consent — the experimentally therapeutic/diagnostic/preventive type of experiment is to be considered along with the first broad type of experiment, inasmuch as there is reasonable hope that the experiment will be of direct medical benefit to the subject himself. Thus for our purposes we can distinguish two general types of experimental situations. The first, which for simplicity's sake can be called diagnostic/therapeutic or simply therapeutic, embraces all experiments that are ordered toward the good health and life of the subject, whereas the second embraces all experimentation on a human subject that is carried out, as Henry K. Beecher puts it, "not for his benefit but for that, at least in theory, of patients in general."[2]

The Heart of Medical Ethics

The canon of loyalty that must be observed in *all* experimental situations is, as noted already, the principle of "free and informed consent." This principle is at the heart of all medical ethics. It has been articulated most eloquently in the articles of the Nuremberg Code (1946-1949), and it is instructive to remember that this Code was formulated at a time when the memory of the atrocities carried out by the Third Reich was fresh in the minds of men. According to the first article of the Nuremberg Code,

> 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 the inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiments.[3]

This concern that a human being who is to be the subject of an experiment give his free and informed consent is reflected also in the codes adopted by the World Health Organization in the *Declaration of Helsinki* in 1964,[4] by the American Medical Association in its 1966 convention,[5] and in the "Ethical and Religious Directives for Catholic Hospitals" set forth in 1955 and revised in 1971.[6] It is a principle at the heart of traditional Jewish and Christian medical ethics, a principle reasserted time and time again by the magisterium of the Roman Catholic Church.[7]

Many, among them Henry K. Beecher, one of the leading au-

thorities on the subject of experimentation on human subjects, have noted that it is extremely difficult if not impossible to secure a "fully" free and informed consent.[8] They have observed that frequently it is not possible to explain to the person who will undergo an experiment all of the factors involved. At times the hazards that may be present are unknown; at other times the persons who are to be the experimental subjects may not be capable of grasping all of the pertinent factors; at other times, a disclosure of all possible hazards might so frighten a person that he may not be willing to submit to a procedure that really is not overly fraught with risks and that really does offer very reasonable hopes of being beneficial. It is for these and other reasons that the American Medical Association, in commenting on the need for a free and informed consent, saw fit to add that "in exceptional circumstances and to the extent that disclosure of information concerning the nature of the drug or experimental procedure or risks would be expected to materially affect the health of the patient and would be detrimental to his best interests, such information may be withheld from the patient."[9] What this means is that the requirement or canon of loyalty demanding a free and informed consent must be understood as demanding "reasonably" free and "adequately" informed consent — and the reasonableness and adequacy are to be determined as a prudent person would determine them. As Paul Ramsey puts it, "a choice may be free and responsible despite the fact that it began in an emotional bias one way or another, and consent can be informed without being encyclopedic."[10] Indeed, as Beecher notes repeatedly, the very fact that a person who is sick goes to a physician is itself an indication that he is giving his reasonably free and informed consent to the physician's efforts to discover what is troubling him and to cure or alleviate the pathology from which he is suffering.[11]

The requirement for a reasonably free and adequately informed consent is essential in *all* types of human experimentation. And the reason for this requirement has been simply and eloquently stated by Ramsey: "no man is good enough to experiment upon another without his consent."[12] To experiment on a human being without securing his consent is to make of him a being who is no longer a being of moral worth; it is to *subordinate* him to other humans; it is to repudiate his humanity.

Consent When the Subject Is 'Incapable'

There are instances, however, and these are by no means rare, when it is impossible to obtain an adequately informed and reasonably free consent from the person who is himself to be the subject of the experiment. What can be done, or better, what *ought* to be

done, in such instances, when the subject is incapable, whether by reason of age, mental infirmity, or physical condition, to give consent in his own behalf?

There is no serious debate among authorities, whether medical, legal, or moral, in instances when the experiment in question is designed to secure some benefit for the person who is to be its subject. This is true whether the experiment is diagnostic, therapeutic, or preventive. In cases of this sort consent to the experiment can be given by others (parents, guardians, etc.) in behalf of persons themselves incapable of giving consent for themselves. Writers speak of proxy consent or presumptive or vicarious consent, and there is a unanimity that in such instances proxy consent is morally justifiable. Yet we can, indeed we must, seek to determine *why* consent can reasonably be presumed in such instances.

It is critically important in cases such as these that the presumption of consent in no way ruptures the canon of loyalty that ought to exist between the experimenter and the person who is his co-adventurer in the role of the subject of the experiment — the canon that is articulated in the principle of a reasonably free and adequately informed consent. This is something stressed by Ramsey in his perceptive analysis of the ethics of consent.[13] The subject is not being depersonalized; the experiment does not reduce him to a thing or to what we can call an entity of no moral worth, and it does *not* do so precisely because it is not *using* him to benefit others. He is not being *subordinated* to the interests of others or to the good of society as a whole. The experiment in no way violates his humanity, his worth as a being who must be regarded as a bearer of rights that simply must be recognized and respected by the society in which he lives.

Proxy consent for procedures that will be of benefit to the subject thus seems to be morally justifiable on the grounds that it does not do violence to the subject of the experiment, that it respects his humanity, his worth as a being who differs in kind from other animals. But is there more to the justification of proxy consent than this?

One of the finest ethicists of our day, the eminent Jesuit Richard A. McCormick, has recently argued that there is much more to justifying proxy consent in experiments that will be of benefit to the subject than simply showing that consent does not do violence to the subject as a human being,[14] and it will be to our purpose to examine his position inasmuch as it will lead us to a consideration of the possible justification of proxy consent in purely experimental types of procedures.

According to McCormick, one of the major reasons why proxy consent is morally justifiable in situations wherein the procedures are intended to be of benefit to

the health and life of the subject is that the subject who is incapable of giving consent for himself can reasonably be presumed to be willing to give consent if he were capable. He *would* choose to subject himself to the experiment because he *ought* to choose to do so. And why *ought* he to choose to do so? McCormick, drawing on the writings of moral philosophers and theologians like J. de Finance, G. de Broglie, G. Grisez, and John Finnis,[15] argues that he ought to do so because his own life and health are real human goods, goods that are to be prized and not simply priced, goods that demand our respect and love, goods that we ought to pursue both for ourselves and for others.

The Pluriform Human Good

The matter can be put this way. All men, simply because they are men, have an obligation to pursue the human good, that is, the good that perfects or fulfills or completes them precisely because they are men to begin with. The human good is pluriform, that is, it consists of a set of real goods constitutive of what we can call the whole or total human good, and these goods are real and not merely apparent because they are inherently related to real needs rooted in our being. And among these real goods constitutive of the human goods are life and health. Life and health are not the *summum bonum* or the highest good, but they are real components of the total human good. It really is good for men to be alive and to be healthy, and consequently all men, just because they are men, ought to respect life and health for what they are: real human goods. They ought to pursue these goods and love them, and they ought to do this not because these goods are some kind of abstractions but because they are real perfections of human beings and are incarnated or embodied in real men. To reject them, to despise them, to hate them is to hate one's own humanity.[16] As McCormick puts it,

> a construction of what the child *would* wish (presumed consent) is not an exercise in adult capriciousness and arbitrariness, subject to an equally capricious denial of challenge when the child comes of age. It is based, rather, on two assertions: a) that there are certain values (in this case life itself) definitive of our good and flourishing, hence values that we *ought* to choose and support if we want to become and stay human, and that therefore these are good also for the child; b) that these 'ought' judgments, at least in their more general formulations, are a common patronage available to all men, and hence form the basis on which policies can be built. . . . I would argue that parental consent is morally legitimate where therapy on the child is involved precisely because we know that life and health are goods for the child, that he *would* choose them because he *ought* to choose the good of life, his own self-perservation as long as this life remains, all things considered, a human good.[17]

In other words, McCormick sees the ultimate reason why it is morally justifiable for a parent

or guardian to offer proxy consent for a child or other incompetent subject to undergo therapy (or diagnosis) to lie in the reasonableness of the presumption that the child or other incompetent subject would himself consent to the experiment in question and *would* do so because he *ought* to do so. McCormick then goes on to argue that *in certain very restricted* situations it would be morally permissible, morally justifiable for a parent (or other competent adult) to give proxy consent for a child (or other incompetent subject) to participate in non-therapeutic, non-diagnostic experiments, that is, in experiments intended of themselves not to benefit the subject but rather to benefit others. To support his position McCormick first stresses the social solidarity of our existence as moral beings, the corporate framework of our lives. "To pursue the good that is human life," McCormick writes,

> means not only to choose and support its value in one's own case, but also in the case of others when the opportunity arises. In other words, the individual *ought* also to take into account, realize, make efforts in behalf of the lives of others also. For we are social beings and the goods that define our growth and invite to it are goods that reside also in others. It can be good for one to pursue and support this good in others. Therefore, when it factually is good, we may say that one *ought* to do so (as opposed to not doing so). If this is true of all of us up to a point and within limits, it is no less true of the infant. He would choose to do so because he *ought* to do so. Now, to support and realize the value that is life means to support and realize health, the cure of disease and so on. Therefore, up to a point, this support and realization is good for all of us individually. To share in the general effort and burden of health-maintenance and disease-control is part of our flourishing and growth as humans. To the extent that it is good for all of us to share this burden, we all *ought* to do so. And to the extent that we *ought* to do so, it is a reasonable construction or presumption of our wishes to say that we would do so. The reasonableness of this presumption validates vicarious consent.[18]

McCormick thus considers it at least possible, theoretically, that a certain level of involvement in non-therapeutic experimentation could be good for the child in the sense that there *could*, in a sense, be an obligation for the child to participate in the experiment. He stresses that this obligation is true only up to a point and within limits, for he wants to avoid any kind of position that would do violence to a subject of an experiment, that would deny his moral worth and subordinate him to the interests of others. But he believes that there are some situations in which one could reasonably presume the consent of the child or other incompetent to participate in an experimentation. He recognizes that in most types of non-therapeutic, non-diagnostic experimentations only true consent (that is, consent given by the subject involved in his own behalf) can justify the participation inasmuch as it is such a high-

ly personal affair and the good that can be secured by the subject is the good of expressed charity, a good that requires one's own free choice. Nonetheless he thinks that it is possible that there could be situations where highly personal and individual considerations are not at stake and where presumed consent is reasonable because we could say of *all* individuals that they *ought* to be willing to participate in an experimentation because *not* to do so would mean a failure to appreciate properly the meaning of the human goods of life and health. McCormick believes that if a particular experiment would involve "no discernible risks, no notable pain, no notable inconvenience, and yet hold promise of considerable benefit," then one could justifiably presume the consent of the child (or other incompetent) to participate in the experiment, and one could reasonably presume this because the child (or other incompetent) "*ought* to want this not because it is in any way for his own medical good, but because it is not in any realistic way to his harm and represents a potentially great benefit for others."[19]

The Use of Human Subjects: Some Guidelines

We have been led, in following McCormick's presentation of the ultimate reasons justifying proxy consent in diagnostic/therapeutic experiments, to take up the question of proxy consent in purely experimental procedures. McCormick, in common with most ethicists who have written on the subject and in common with many medical and legal writers as well (e.g., Beecher and Curran),[20] rejects any position that would justify proxy consent in purely experimental situations along a utilitarian or consequentialistic calculus of net benefits to be achieved. He does not want to deny the humanity of the subject, to *subordinate* him to the interests of others. It is, indeed, for this reason that McCormick rejects the guidelines set forth in 1973 by the Department of Health, Education and Welfare[21] regarding the use of human subjects in clinical (i.e., purely experimental) experiments inasmuch as these guidelines justify using children in experimentations of no benefit to themselves even in situations when risks are involved, so long as "the potential benefit is significant and far outweighs that risk."[22] To adopt this position, McCormick believes, is to go beyond the boundary of reasonably presumptive consent. It is in reality to treat a human subject as an experimental animal, to deny his personal inviolability and to use him for the benefit of others. From this we can see that McCormick, in arguing for the moral justification of proxy consent in purely experimental situations under certain very limited conditions, simultaneously opposes any purely utilitarian or consequentialist calculus.

The position developed by McCormick must be taken quite seriously. It is attractive at first reading, and it seems quite reasonable. Nonetheless it can, I believe, be questioned quite strongly, and it is my purpose now to articulate as well as I can my objections to his position. Before setting forth these objections, however, it will be useful first to call attention to the position taken by Ramsey with respect to proxy consent in purely experimental situations. As we proceed it will become clear that I believe that Ramsey's position is the right one to take, although I intend to set forth some reasons that Ramsey does not for adopting this position.

Ramsey, as we have already noted, agrees that proxy consent is morally justifiable in the diagnostic/therapeutic type of experiment. But he strenuously opposes proxy consent in the purely experimental type of situation. He first argues that it is wrong to make a child (or other incompetent) a mere object in medical experimentation for the sake of good to come.[23] He maintains further that "no parent is morally competent to consent that his child shall be submitted to hazardous or other experiments having no diagnostic or therapeutic significance for the child himself,"[24] and that "morally no parent *should* consent — or be asked to consent to any such thing even if he is quite capable of doing so."[25] McCormick, of course, would agree that it would be wrong to make a child a mere object in medical experimentation, and he would also agree that no parent is morally competent to consent that his child be submitted to hazardous experiments having no diagnostic or therapeutic significance for the child himself. But McCormick, as we have seen, argues that in experimentations involving no discernible risks or pains or inconveniences to the child (these would be included under Ramsey's rubric of "or other experiments" in the citation above) the child is *not necessarily* reduced to a mere object and that it would be morally permissible to presume the child's consent and to allow the parent to give proxy consent in his behalf. But Ramsey has more to say about the matter, for he continues:

> To attempt to consent for a child to be made an experimental subject is to treat a child as not a child. It is to treat him as if he were an adult person who has consented to become a joint adventurer in the common cause of medical research. If the grounds for this are alleged to be the presumptive or implied consent of the child, that must simply be characterized as a violent and a false presumption. Nontherapeutic, nondiagnostic experimentation involving human subjects must be based on true consent if it is to proceed as a human enterprise. No child or adult incompetent can choose to become a participating member of medical undertakings, and no one else on earth should decide to subject these people to investigations having no relation to their own treatment. That is a can-

on of loyalty to them. This they claim of us simply by being a human child or incompetent. When he is grown, the child may put away childish things and become a true volunteer. This is the meaning of being a volunteer: that a man enter and establish a consensual relation in some joint venture for medical progress.[26]

A Matter of Justice?

We are now, I believe, getting to the heart of the matter. McCormick, of course, is aware of Ramsey's position here and indeed explicitly refers to this passage in his study. But he argues, as we have seen, that there can be instances when participation in an experimentation is not a matter of charity, something that is simply impossible without a personal and free choice made on one's own behalf, but rather a matter of justice. He argues, in other words, that there are instances when one could reasonably presume that all men would be willing to participate in an experimentation because they would realize that they ought to do so.

It is here that I believe McCormick's analysis must be seriously challenged. And Ramsey, in an illuminating footnote to the passage cited above, gives us the clue that we must follow in challenging McCormick's analysis. In it he writes as follows:

> To base 'Good Samaritan' medical care upon the implied consent of automobile accident victims is quite a different matter. A well child, or a child suffering from an unrelated disease not being investigated, is not to be compared to an unconscious patient needing specific treatment. To imply the latter's 'constructive' consent is not a violent presumption; it is a life-saving presumption, though it is in some degree 'false.'[27]

Note that Ramsey says that the "constructive" consent offered in behalf of an automobile accident victim is to some degree "false." This, I believe, requires reflection, and if we reflect on the matter we can see that in *all* types of situations when "proxy consent" is at stake, that is, when a person other than the subject of the experiment is authorizing that person's participation in it, the presumption or construction of that subject's consent is indeed a false presumption or construction. Consent is a *human* activity; it is an act that requires knowledge and freedom of choice in order to exist. It is, in other words, a *moral* act, and as such it can only issue from a *moral agent*. An infant, a child, a person rendered unconscious in an automobile accident, and all those for whom "proxy consent" is offered have in common two supremely important characteristics or features. These are (1) that they are all *beings of moral worth*, that is entities who are the subjects of rights that transcend the societies in which they live and that must be recognized and respected by their fellow men, and (2) that they are *not moral agents*, that is entities who are the bearers of moral obligations or duties.

What is the significane of this? To me it seems that McCormick in his attempt to provide the ulti-

mate justification for proxy consent in both the therapeutic and the non-therapeutic or purely experimental situation, does so by regarding the subject in whose behalf consent is given by another as a moral agent, as the bearer of moral obligations. An infant or child is *not*, however, a moral agent. To consider him as if he were is to consider him for what he is not.

The ultimate reason justifying "proxy consent" is not to be found in any presumed duties or obligations attributable to the subject in whose behalf consent is given. Rather it is to be sought in the duties or obligations that do, in truth, relate other members of the human community to that subject. A child (or other person who is not in fact a moral agent) standing in need of therapy is a human being who is to be cared for by others, and he is to be cared for by others precisely because he is incapable of caring for himself. His parents (and other members of the human community) are obliged to care for him. They are to see to it that the real human goods of which McCormick speaks are protected in him. He is in peril of losing his life, or he is already suffering from loss of his health. He is, in short, a human being in need. His parents (or others) are human beings who are aware of his need and who are in a position to do something to meet it. Any moral obligation that exists is an obligation incumbent on the child's parents and others, not incumbent on the child.

To put the matter another way, I would say that the justification for "proxy consent" in the diagnostic/therapeutic situation is somewhat analogous to the justification, indeed obligation offered by John G. Simon, Charles W. Powers, and Jon P. Gunnemann for becoming involved in rectifying wrongs done to others by others. These writers develop what they call the "Kew Gardens Principle." If we now describe this principle and relate the reasoning behind it to the issue of proxy consent in the diagonstic/therapeutic situation, we will, I believe, see what is at issue. These writers term their principle the "Kew Gardens Principle" because of a famous incident illustrating the dilemma confronting us when we see people suffering injustices that are not caused by us. The incident to which they refer occurred several years ago in the Kew Gardens section of the borough of Queens in New York City when a young woman named Kitty Genovese was attacked and, after a struggle lasting more than a half hour, was killed within eyeshot and earshot of more than thirty people, none of whom wanted to become "involved." According to these authors the Kew Gardens Principle (which in my judgment is fully in accord with the moral position developed by the authors to whom McCormick appeals) is relevant in determining when our failure to respond

to a social injury done by others to another human being or group of human being becomes morally culpable. This principle includes four elements: need, proximity, capability, and last resort.[28] A comment on each will help us understand what Simon, Powers, and Gunnemann mean by this principle.

Although they note that it is difficult to give a precise definition of need, by this term they mean that some human good (life itself, health, justice) is being destroyed or imperiled in another human being. A person drowning in a swimming pool is obviously a person who is in need — his life is being threatened. Proximity, of course, is a spatial image, and proximity in space is something relevant in determining our responsibilities in answering needs. But for the authors of the Kew Gardens Principle "proximity is largely a function of notice: we hold a person blameworthy if he knows of imperilment and does not do what he reasonably can do to remedy the situation."[29] Proximity, in other words, is primarily a matter of being consciously aware of the need other people have for help; it is a *noetic* proximity. Capability, of course, refers to the ability of an individual or group of individuals to help those who are known to be in need. "Last resort" is perhaps the most difficult element of the Kew Gardens Principle to determine in the type of situations that our authors have in mind, but they contend that if the first three elements of the principle are verified one must presume that one is the last resort.[30]

Justifying Proxy Consent

Apply this principle to those instances when "proxy consent" is involved in the diagnostic/therapeutic situation. Here we obviously have human beings in need — sick children or other incompetents otherwise suffering ill health and/or in danger of death. The parents of the children are obviously aware of their illness, of their needs for help, and they are in a position to do something, along with the medical profession, to meet that need. This, I believe, is the ultimate reason why we can justify proxy consent in diagnostic/therapeutic situations. There is a real moral obligation on the part of parents and members of the medical profession to come to the assistance of sick children and others who cannot care for themselves or even ask for help or understand what is going on. It would be irresponsible, immoral for parents and others *not* to take effective steps; to assist these helpless human beings, and one of the steps, required because we live in a world where legal protections are fortunately available, is for the parents to authorize the therapeutic work of the medical community. Their authorization is what we term "proxy consent," and it is a true consent on the part of the parents, but it is simply erroneous to speak meaningfully at all about

any consent on the part of the child or infant or other human being who simply is not a moral agent.

In the purely experimental type of experimentation, however, the child is *not* in any need. There can be no moral obligation, even presumptive, for him to participate in an experimentation, simply because he is not a moral agent. To think that he is is to do violence to him and to do violence to reality. It is for this reason that I think the position taken by Ramsey with respect to "proxy consent" in the purely experimental situation is the proper one, and not the position developed by McCormick.

Ramsey, however, does maintain that it is morally justifiable to offer proxy consent for children (and other incompetents) in some kinds of situations that are not properly therapeutic or diagnostic. I would include these among the preventive types of experimentation. What is meant by this? As Ramsey notes, it is possible for children to be considered as members of a population that is subjected to specifiable plagues, epidemics, diseases, etc. Thus, in advancing *preventive* medicine, a parent can rightfully give proxy consent for his child to participate in experiments that are primarily experimental and of no *immediate* or *direct* therapeutic benefit to the child insofar as the child is at that time not suffering from any disease. Still this type of experimentation is of possible benefit to him insofar as he is a member of a population that is exposed to a disease that *might* at some time affect him.[31]

The Cardinal Principle

We can summarize by saying that the principle of a reasonably free and adequately informed consent is a cardinal principle in human experimentation of all kinds. This consent can reasonably, i.e., morally, be presumed and given by one person in behalf of another (proxy consent) *if and only if* the experiment is related, either directly or indirectly, to the well-being of the subject himself, and the ultimate reason why this is justifiable lies in the obligations incumbent on parents and others to care for children and other human beings who stand in need of help. Proxy consent is morally unjustifiable in purely experimental situations, and it is unjustifiable in such cases simply because it entails 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 certainly is not.

In purely experimental situations then, what can be called experimentation, the subject must himself give consent; no one else can give it for him. But a reasonably free and adequately informed consent is not itself sufficient grounds to justify experimentation. This consent is a *necessary* condition to justify the experimentation, but it is not a *sufficient* condition. There must also be a proportionate reason for undertaking it. By this I mean that

the possible hazards to which the subject is exposed by volunteering to take part in the experiment must be made reasonable hazards because of the real goods that the experiment may secure. It is somewhat difficult to express properly what is at stake here. Negatively it can be expressed by saying that it is *not* a matter of some kind of utilitarian or consequentialist calculus — a weighing of the net balance of good over evil. Rather it means that the experimentation itself is "targetted" on the good that will ensue or that is reasonably expected to ensue, and the intent of the investigator and his co-adventuring subject is likewise targetted on this good, whereas the possible harm that may befall the subject is only indirectly intended or permitted.[32] The point that I am trying to make may perhaps be seen more clearly if we compare experimentation to organ transplantation and adopt a "rule of thumb," advocated by some doctors who have given serious thought to the latter subject. For instance, Dr. Jean Hamburger in thinking about the morality of transplants insists that one is warranted in exposing the donor to danger only if "the risk to the donor is very much less than the probability of success to the recipient."[33] Put more generally, we could say that the hazards to which a person who freely consents to an experiment primarily designed to be of benefit to persons other than himself must be very much less than the likelihood that the experiment will indeed advance knowledge and thereby benefit mankind.

It is also obvious that the experimentation must be well designed scientifically. Not so obvious is that the experimentation itself ought to involve no moral evil, no exploitation of persons, no destruction of human goods in a direct way. Thus it would be immoral for one to carry out an experiment, even with the consent of the subjects, that would be immoral in itself. Thus, in my judgment, experiments such as those conducted by Johnson and Masters in their endeavors to learn more about human sexuality were morally wrong.

To conclude, we might take as our guiding themes in thinking about human experimentation two thoughts, one from Beecher the medical scientist, the other from Pius XII. For Beecher, an experiment on a human subject does not *become* morally right because it succeeds in its purposes; rather it must be right from the very beginning.[34] For Pius XII, the moral history of mankind is more important than its scientific history. This means that there may be some things that we can come to know and that would be good to know, but that the very endeavor to gain knowledge of them is impossible without doing something that human beings ought not to do, either because they *subordinate* some human beings to the interests of others or

require human beings to do deeds that simply must not be done if they are to be fully human.[35]

REFERENCES

1. Ramsey, Paul, *The Patient as Person*, New Haven: Yale University Press, 1970, chapter 1.

2. Beecher, Henry K., "Ethics and Clinical Research," in *New England Journal of Medicine* 274 (1966), 1354.

3. The Nuremberg Code, article 1. Text is given in Beecher's work, *Research and the Individual* (Boston: Little, Brown, and Co., 1970), p. 227.

4. The Helsinki Declaration, 1964; in Beecher, p. 227.

5. AMA Code, article 1, i.e., in Beecher, p. 221 f.

6. *Ethical and Religious Directives for Catholic Hospitals*. The text of the 1955 statement is found in Beecher, p. 245. The 1971 statement is available from the United States Catholic Conference.

7. See, for instance, the numerous statements of Pius XII on this subject. Of chief importance are his addresses to the *First International Congress on the Histopathology of the Nervous System* (September 14, 1952), to the *Sixteenth International Congress of Military Medicine* (October 19, 1953), and his *Address to the Eighth Congress of the World Medical Association* (September 30, 1954). They are conveniently gathered in *The Pope Speaks*, Vol. 1, nos. 3 and 4 (1954).

8. Beecher, *op.* cit., pp. 18-20, 121 ff, *passim*.

9. AMA Code, article 3, in Beecher, p. 222.

10. Ramsey, *op. cit.*, p. 3.

11. Beecher, *op. cit.*, pp. 18-19, 231 f.

12. Ramsey, *op. cit.*, p. 7.

13. *Ibid.*, pp. 7-11.

14. McCormick, Richard A., "Proxy Consent in the Experimentation Situation," an essay to appear in *Perspectives in Biology and Medicine*. Father McCormick has kindly sent me an advance copy, and my page references will be to the manuscript.

15. McCormick outlines their position on pp. 11-15. Since my own position is within this framework, and since I am particularly indebted to the work of Grisez, readers will find it worthwhile to consult the latest work by Grisez on morality, *Beyond the New Morality* (co-authored by Russell Shaw), (Notre Dame, Ind.: University of Notre Dame Press, 1974.)

16. I have summarized the position of this school in a somewhat different manner than does McCormick, although the general drift of the argument is the same.

17. McCormick, *art. cit.*, pp. 14-15.

18. *Ibid.*, p. 15.

19. *Ibid.*, p. 17.

20. See Curran, William J. and Beecher, Henry K., "Experimentation in Children," *Journal of the American Medical Association* 210 (1969), 77-81.

21. These guidelines are set forth in "Protection of Human Subjects: Policies and Procedures," *Federal Register* 38 (November 16, 1973), 31738-31749.

22. See McCormick, pp. 18-19.

23. Ramsey, *op. cit.*, p. 12.

24. *Ibid.*, p. 13.

25. *Ibid.*, p. 14.

26. *Ibid.*, p. 14.

27. *Ibid.*, p. 14, note 11.

28. Simon, John, Powers, Charles, and Gunneman, Jon, *The Ethical Investor* (New Haven: Yale University Press, 1972), pp. 22-25.

29. *Ibid.*, p. 23.

30. *Ibid.*, p. 25.

31. Ramsey, *op. cit.*, pp. 14-19.

32. For a fuller discussion of this, see chapter four of my *Becoming Human: An Invitation to Christian Ethics*, Dayton: Pflaum/Standard, 1974.

33. Hamburger, Jean, in Wolstenholm, G., and O'Connor, M., *Ethics in Medical Progress*, London: Ciba Foundation, 1966, p. 357.

34. Beecher, *art. cit.*, in note 2, p. 1360.

35. Pius XII, *Address to the First International Congress on the Histopathology of the Nervous System* (September 14, 1952); cf note 7 above.