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Karen Lebacqz

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REFLECTIONS ON THE REPORT AND RECOMMENDATIONS OF THE NATIONAL COMMISSION:
RESEARCH ON THE FETUS

KAREN LEBACQZ†

I. INTRODUCTION

FOR MY REFLECTIONS on the Commission's Report and Recommendations: Research on the Fetus (Report), I shall focus on two areas: the Commission's struggle with questions of distributive justice and its definition of research. I believe that in the long run the most significant contribution of this Report may be the attention it focuses upon the requirements of distributive justice as they impact upon research. I also believe that the most potentially damaging aspect of this Report is its adoption of a distinction between "therapeutic research" and "nontherapeutic research." I shall therefore limit my comments to these two issues, one of which advances the discussion of the ethics of research and the other of which has the potential for retarding that discussion.

II. DISTRIBUTIVE JUSTICE AND RESEARCH

The rash of contemporary concern for the ethics of research using human subjects dates from the exposure, during the Nuremberg trials, of atrocities committed in Nazi Germany under the name of "scientific experimentation." The Nazi experiments shocked the world not simply because they were often unnecessary and poorly designed scientifically, but more importantly, because they flagrantly abused human subjects by using them against their will. Hence the Nuremberg Code, drafted during the time of the trials as a standard for the conduct of research, begins with the principle: "The voluntary consent of the human subject is absolutely essential."¹ Since that time, most discussions of the ethics

† Associate Professor of Christian Ethics, Pacific School of Religion (currently on leave of absence to serve as Consultant in Bioethics to the Director of Health for the State of California); Member, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; Co-founder and Co-director, Joint Program in Bioethics, Pacific School of Religion and University of California in San Francisco; B.A., Wellesley College, 1966; M.A., Harvard University, 1969; Ph.D., Harvard University, 1974.

1. Nuremberg Code, reprinted in NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *Appendix* to REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS 17-1, 17-2 (DHEW Pub. No. (OS) 76-128, 1975) [hereinafter cited as *Appendix*].

of research have focused upon the requirements for voluntary consent, or "informed consent," as it tends to be called today.

The consent requirement derives from the ethical principle of "respect for persons."² This principle requires that persons be treated as ends in themselves, never merely as a means to the ends of another. When persons are to be treated as means to an end — as happens when human subjects are used in research — such treatment is justified only if the individuals are also respected as persons with their own ends. Requiring researchers to obtain consent from a prospective subject is one way of ensuring that the ends of the person are respected and that the person is not simply used as means to another's ends. The person's expression of will — voluntary consent — justifies the use of that person as a means to the ends of the research project. Arguments about what is required for consent to be fully "voluntary" (for example, whether prisoners or students can give voluntary consent) or fully "informed" (for example, whether incomplete disclosure is ever permissible) are largely attempts to refine the meaning of the principle "respect for persons" as it applies to the research setting. It is here that most arguments about the ethics of research have focused. To date, the ethics of research have been largely an ethics of respect for persons.

Fundamental though this principle is, it does not stand alone as a basic principle against which human activity must be judged or by which such activity must be justified. Respect for persons spells out the requirements for ethical conduct toward each person. In the research setting, the principle of respect for persons requires that the researcher seek the knowing and voluntary consent of the subject before proceeding with the research; but it does not tell the researcher who among available potential subjects should be approached with the invitation to participate. The principle that deals with the comparative treatment of persons is the principle of "distributive justice."³ This principle requires that persons be treated fairly, that is, that they neither receive more benefits nor bear more burdens than they deserve.

While no less important than the principle of respect for persons, the principle of distributive justice has been largely ignored in discussions of the ethics of research. This may be due to the common assumption that the *risks* from research are borne by individual subjects, while the *benefits* go to society at large. Thus, concern about the distribution of burdens and benefits has appeared to be almost superfluous, and the focus has been on how to protect those who are the subjects

2. See J. KATZ & A. CAPRON, CATASTROPHIC DISEASES: WHO DECIDES WHAT? 82 (1975).

3. See W. K. FRANKENA, ETHICS 49 (1973).

bearing the burdens.⁴ This assumption is questionable, because not all research involves risk for the subject. Furthermore, much research involves only very small risks.⁵ It is also possible that participation in certain research is not a burden but a benefit. If so, then questions are rightly asked about who should receive that benefit by being asked to participate. Even if participating in research is the burden it is often thought to be, there is still the question of who should bear the burden in order that others may benefit. The Commission's recent report on the use of prisoners as research subjects⁶ amply demonstrates that concerns about justice should be raised any time one segment of the population bears burdens in order that others may benefit — as an example, when black prisoners risk skin infections in order to participate in research on the development of sun tan lotions which will be used primarily by whites.

In the area of fetal research, the Commission encountered questions of distributive justice at several points. The one that generated the most controversy and is most memorable had to do with the comparative treatment of fetuses-going-to-term and fetuses-about-to-be-aborted. Is it ever justifiable to use fetuses that are about to be aborted as subjects in research that would not be done on fetuses going to term? Does such a use constitute a fundamental injustice, subjecting one class of fetuses to unequal treatment? As the Report reflects, the Commission spent many hours deliberating this issue and was divided in its final conclusions. Because the comparative treatment of fetuses is an issue that is so easily misunderstood, I shall elaborate upon the requirements of justice with respect to it.

The formal requirements of justice are expressed in the phrase, "treat similar cases similarly." Much depends upon what is understood to constitute "similar cases." Much also depends upon what is taken to constitute "similar treatment." While the Commission agreed on the meaning of "similar cases," its members disagreed upon the meaning of "similar treatment," and thus upon the application of the basic requirements of justice to the case at hand. Specifically, the members agreed that the "case" of the fetus-about-to-be-aborted is similar to the "case" of the fetus-going-to-term in that both fetuses are vulnerable subjects deserving of protection from harm. The fact that one fetus was scheduled to die did not make it less deserving of respect or

4. This would seem to be the view that underlies Hans Jonas' famous treatment of the issue. See Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in *EXPERIMENTATION WITH HUMAN SUBJECTS* 1 (P. Freund ed. 1970).

5. See, e.g., Cardon, Dommel, & Trumble, *Injuries to Research Subjects*, 295 *NEW ENGLAND J. OF MED.* 650, 651-54 (1976).

6. See NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING PRISONERS* (DHEW Pub. No. (OS) 76-131, 1975).

protection. The members of the Commission agreed in principle that the fetus-going-to-term and the fetus-about-to-be-aborted deserve equal protection and respect. The "cases" are similar.

There was disagreement, however, as to what equal treatment or equal protection meant. Some argued that it would require both "cases," i.e., both classes of fetuses, to be subjected to the *same experimental procedures*. For example, Commissioner David Louisell in his dissenting statement charges that the Commission denied equal protection to the fetus-about-to-be-aborted because it declined to require that such a fetus be used as a research subject only in those situations when a fetus-going-to-term could be used as a subject. I believe, however, that this interpretation of what "similar treatment of similar cases" requires is based upon a misapprehension of what "similar treatment" means. I would argue that "similar treatment" does not mean subjecting both "cases" to the same *procedure*, but putting both to equal *risk*. By way of illustration, suppose that a friend of mine and I are invited to participate in an experiment to measure the effects of exercise on body metabolism at high altitudes. We will both run in place, do sit-ups, and so on, at exactly the same altitude. Thus, we will both be subjected to the same *procedures*. Is it fair to ask both of us to participate? On the surface, it seems that it is. But suppose that my friend carries the gene for sickle cell anemia. In that case, doing the same exercises that I do at the same altitude will put her at more *risk* than I. The risks are therefore not equal, and the burdens of participation in research would not be distributed equitably. Justice is ensured not by subjecting us to the same *procedures*, but by providing us equal protection from *risk*.

I would argue that the same holds true for the two classes of fetuses under consideration. If it can be demonstrated that one class of fetuses would be put at more risk than the other by being subjected to the same procedures, then it may not be fair to use that class of fetuses. This is the case with much research on the fetus, where the ingestion of a drug by the woman will take several weeks to affect fetal tissue if it crosses the placenta. If a fetus is aborted within a period of several weeks, no damage will yet have been done to fetal tissue. For the fetus that is brought to term, however, there may be lifelong damage resulting from the ingestion of that drug. The risk differs for the two classes of fetuses, and it is therefore not just to use both of them.

The meaning of this argument is easily misunderstood. It does not justify anything that we do to a fetus that is going to be aborted. Nor does it deprive that fetus of equal protection and respect. It only specifies the meaning of protection and respect with regard to research: equal

protection means equal protection from risk, not necessarily subjection to the same procedures. One must not mistake this as an argument that "since the fetus is going to die anyway, it doesn't matter what is done to it." It does indeed matter. The principle of justice applies to condemned human subjects. But what that principle requires is equal protection, and equal protection is calculated in terms of the risk of harm to the subject. That risk is affected by the subject's condemned state. The fetus-about-to-be-aborted will not be harmed by the research if it is subsequently aborted; its "risk of harm," therefore, is calculated by multiplying the risk of harm were it to be carried to term by the probability that the woman will change her mind about the abortion and carry it to term. Since the chances that a woman will change her mind once she has contacted a clinic about abortion are generally less than one in one hundred,⁷ the risk to the fetus-about-to-be-aborted is about one one-hundredth of the risk to the fetus going to term. It is on that basis that one can say that justice requires that fetuses to be carried to term not be subjected to some experiments which might be done on fetuses scheduled for abortion.

No doubt controversy about the exact meaning of "similar treatment of similar cases" will continue. What is significant is that this area of concern has been opened up for reflection. Research ethics will no longer be simply an ethics of respect for person, but also an ethics of distributive justice.

III. THE DEFINITION OF RESEARCH

While I affirm in general the Commission's recommendations regarding research on the fetus and in particular its treatment of the question of justice, I have come to think that its use of the terms "therapeutic research" and "nontherapeutic research" is most unfortunate. Although these terms are popularly used today, I hope that the Commission's adoption of them has not given them undeserved credibility. As a result of much further reflection, I would now argue that "therapeutic research" is a contradiction in terms. Moreover, the use of this term obscures the nature of research and hence obfuscates moral analysis of research.

Research is a class of activities — usually, the gathering and analyzing of data in accord with scientific principles — designed to produce generalizable knowledge.⁸ As such, it has nothing to do with the treatment or "therapy" of an individual. To be sure, we sometimes

7. Bracken, *The Stability of the Decision to Seek Induced Abortion, Appendix, supra* note 1, at 16-5, 16-6.

8. This definition was tentatively adopted by the Commission in February 1976.

do research concerning the treatment of individuals. For example, we compare two modes of treatment for the same disorder to see which is more efficacious, or we attempt to validate an accepted mode of "therapy" that has been accepted without being validated. Such research has been dubbed "therapeutic," either because one component of our total activity involves the provision of therapy for the individual, or because it is hoped that what we learn about the individual's disorder or our attempted mode of therapy can then be used to facilitate the treatment of that individual. While both of these links between therapy and research are legitimate, they are indeed links *between* therapy and research; the research itself is not "therapeutic."

A rather typical example of research that would be called "therapeutic" by many is the following: It is standard and accepted therapy for certain forms of bone cancer to amputate the limb in which the cancerous tumor is found. However, since such mutilation has life-long deleterious consequences, we would like to find an equally efficacious treatment that is less disfiguring. Suppose a new drug that has been tested in adults but not yet in children offers some promise of retarding the growth of the tumor and hence some promise for an amputation-free therapy. We wish to do research to test this potential new therapy in children as compared to the accepted therapy. Our subjects will be divided into two groups; one will receive the new drug, the other will receive the accepted therapy. The comparative efficacy will be tested by measuring morbidity and mortality over a period of five years. Is this "therapeutic research?"

Some will of course say "yes," because all of the children are receiving therapy during the course of the research. But note, first, that the point of doing the research is to find out whether the drug will work in children. It is not clear then, that the group of children who get the drug are receiving "therapy." Indeed, it is precisely the point of the research to find out whether they are! The research can hardly be called "therapeutic" before one finds out that therapy is indeed being given.

But let us suppose for the moment that the new drug *is* therapeutic. Even so, it is not clear in what way the research by which that drug is compared to another mode of treatment can itself be called "therapeutic." If the children can get either of the therapies (the drug or the amputation) without being involved in a research project designed to compare them, then the research is not integral to their therapy but is incidental to it. The activities which are done for purposes of generalizing our knowledge about the treatment of bone cancer are not themselves "thera-

putic," even though they may be done in the context of providing therapy.

Some will argue that nothing additional need be done to the child over and above what would be done during the course of providing therapy. The drug is given (or the limb is amputated), and the physician follows the progress of the child as would be done normally. No additional interventions into the life of the child need be made; nothing appears to be added to the therapy, and yet "research" is done. Surely then, the research must be "therapeutic," since it involves no additional, nontherapeutic interventions into the life of the child.

The fallacy in this line of argument can be seen quite easily when we recognize that if indeed all that is done is that the drug or amputation is provided and the child followed over time, then the "research" component — the component which allows us to generalize knowledge — has not yet been performed. The "research" here begins at the point where the charts of the children are compared to each other, and where this comparison is used as the basis for an analysis of the comparative efficacy of the two modes of treatment. Research is not done if the only activity is the provision of therapy to the child with attendant follow-up activities for the sake of therapy. Research is done only when data is analyzed so as to generalize knowledge. In this case, that analysis has little to do with the provision of therapy.⁹

Confusion arises because we sometimes label an entire set of activities "research" when they are presented as a package deal in a protocol outlining both the therapeutic intervention and the evaluation procedures to be used. The fact that therapeutic interventions are given as part of a total research protocol does not, in itself, however, justify the labelling of that research as "therapeutic."¹⁰

Nor, in the example given, could the research be called "therapeutic" on grounds that it will influence the *future* therapy of these children, or that their treatment will be changed depending upon the

9. Indeed, once the true nature of research is exposed, we see that much research is noninvasive data gathering and analysis. The actual activities done for *research* purposes (*i.e.*, to enable us to produce generalizable knowledge) often involve no physical risk at all to subjects, as is the case in this example. It is rather the experimental therapies which involve risk — both the risk of foregoing the accepted therapy, and the risk of unforeseen adverse effects.

10. There is one other occasion on which we are tempted to call research "therapeutic": when our access to therapy is conditioned upon our willingness to participate as a subject in a research project. For example, it is my understanding that growth hormone is available only to those persons who are willing to participate in research designed to validate its use. In this case, since "therapy" depends upon participation in research, one is tempted to link the two and call the research itself "therapeutic." Strictly speaking, however, the research is not therapeutic — it is simply the condition to receiving the therapy.

outcome of the comparative study. It is regrettably true that once a child's limb has been amputated, it cannot be restored. It is therefore too late to change the course of therapy for that child. There is one possible exception here: the case where the child later develops another cancerous tumor in another limb. In this case, the child's participation in the earlier research project may indeed influence his or her therapy, and in this sense one might stretch the meaning of "therapeutic" to call the research "therapeutic" for the child. Note, however, if we do so, that almost *all* research will be called "therapeutic," because it will later influence the future treatment of someone. Thus the distinction between "therapeutic research" and "nontherapeutic research" breaks down. Moreover, we have stretched the meaning of "therapeutic" to the point of the absurd. It remains true that "therapeutic research" is a contradiction in terms, and that no stretching of the term "therapeutic" will make it sensible.

No doubt the reason that this term has come into popular usage is not that most people stretch the meaning of "therapeutic," but that they stretch the meaning of "research." At the time when the Commission issued its report on the fetus, I did not understand the difference between "research" and "experimentation," since the two words are used almost interchangeably in much of the literature. Since "experimentation" can indeed be either "therapeutic" or "nontherapeutic," the confusion between experimentation and research is no doubt what leads most often to the classification of research in terms of being either "therapeutic" or "nontherapeutic." Once research is carefully defined, however, the distinction becomes clear.

Moreover, once research is carefully defined, moral analysis of the conduct of research is facilitated, and mistakes in analysis come easily to light. For example, Paul Ramsey argues that parents have the right to give consent on behalf of their children only for interventions designed to improve the well-being of those children; thus he approves what he calls "therapeutic research," but disapproves of the use of children or fetuses in "nontherapeutic research."¹¹ We see now that even in "therapeutic research," *some* activities will be done that are not therapeutic for the children. Do parents have the right to consent to such activities? If so, then they are consenting to nontherapeutic interventions.

Of course, most of these "interventions" will consist of comparisons of data already gathered during the course of providing therapy and

11. P. RAMSEY, *THE PATIENT AS PERSON* 13-19 (1970). See also Ramsey, *The Enforcement of Morals: Nontherapeutic Research on Children*, 6 HASTINGS CENTER REP. 21, 22 (1976).

they are therefore in no way invasive of the child's well-being. It is also possible, however, that in order to gather data by which we can generalize about treatments for a specific disorder, we will have to do additional maneuvers that *are* invasive. These interventions are not "therapeutic" for the child, since they are done solely for the purpose of gathering data and analyzing it in order to generalize our knowledge. Do parents have the right to give consent for such maneuvers? If so, then they are consenting to invasive, nontherapeutic interventions. The fact that these interventions are done in a research protocol which also includes the provision of therapy does not, it seems to me, automatically justify parental consent for them. If Ramsey and others are genuinely concerned about the prevention of nontherapeutic interventions into the life of the child, then much of what has been known as "therapeutic research" will not be permissible.

Alternatively, I would argue that much "nontherapeutic research" is permissible, since, like much "therapeutic research," it involves only observation or minimal risk to the child. Since we do allow parents to make decisions on behalf of their children provided the child will not be subjected to great risk, children should be permitted to participate as research subjects provided there is no great risk involved.

Of course, there may be risks involved in the use of an experimental drug or other procedure. It may not be the *research* that puts the child at risk, but rather the attempt to provide *therapy*. Only when the research component is separated from the therapeutic component do we see how very difficult the providing of therapy itself can be as a moral problem. When there is an accepted therapy, is it *ever* justifiable to withhold it in order to try something new which might or might not prove to be therapeutic? Herein lies one of the thorniest questions about the ethics of *experimentation* on human subjects; however, it is a question that is separable from the ethics of *research*. Fortunately, it is a question that does not arise frequently in the context of fetal research and experimentation, since there are few "therapies" available that can be given *in utero*. Additionally, we are rarely in a position to withhold a known therapy in order to try something new because almost everything we try in order to provide therapy for the fetus is experimental. This makes it very important that we do *research* to test the validity of such experimental interventions. Far from being a questionable activity, therefore, research is a very necessary and very salutary activity. It can prevent much harm from the use of unverified "therapies."

Unfortunately, the Commission's adoption of the terms "therapeutic research" and "nontherapeutic research" tends to perpetuate a language which only serves to obfuscate moral analysis by preventing

close attention to all the components of a research protocol. Moral analysis is better served, and fetuses and other vulnerable subjects are better protected, by dropping the language “therapeutic research” and “nontherapeutic research” and directly analyzing each of the components of a proposed research activity. I hope that future discussions of the ethics of research, including the discussions of the Commission, will adopt this approach.