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Cover Page Footnote

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A SYMPOSIUM: SOME LEGAL PROBLEMS IN MEDICAL TREATMENT AND RESEARCH

A PHYSICIAN'S VIEW OF INFORMED CONSENT IN HUMAN EXPERIMENTATION

*R. E. RITTS, JR., M.D.**

We cannot conceive what the nature of the instrument made use of is: why did Baker put it on, when he said that plaintiff had fallen into good hands, and when plaintiff only sent for him to take off the bandage? It seems as if Mr. Baker wanted to try an experiment with this new instrument.

. . . [I]t appears from the evidence of the surgeons that it was improper to disunite the callous without consent; this is the usage and law of surgeons: then it was ignorance and unskilfulness in that very particular, to do contrary to the rule of the profession, what no surgeon ought to have done; and indeed it is reasonable that a patient should be told what is about to be done to him, that he may take courage and put himself in such a situation as to enable him to undergo the operation. . . . [T]his was the first experiment made with this new instrument; and if it was, it was a rash action, and he who acts rashly acts ignorantly: and although the defendants in general may be as skilful in their respective professions as any two gentlemen in England, yet the Court cannot help saying, that in this particular case they have acted ignorantly and unskilfully, contrary to the known rule and usage of surgeons.

Judgment for the plaintiff per totam Curiam.[1]

"INFORMED consent" by subjects of biomedical investigations poses a more complex matter in practice than in discussions such as this one. Professor Smith elsewhere in this issue has lucidly reviewed the various codes and mechanisms used by investigators in human experimentation.[2] Reference will be made to these codes in this discussion without repeating them in toto.

It is appropriate to address attention to the semantics of the problem, if only to dismiss this parameter. In medical circles there are occasional grumblings that the responsibility to "inform" the subjects is either unreasonable or impossible. If the investigator were able accurately to inform the participant of all the eventualities which might take place during the course of the proposed study, there would be no need for him to conduct an investigation. In fact, even if he did, it would not be

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1. Slater v. Baker, 95 Eng. Rep. 860, 862 (K.B. 1767).
2. See p. 673 infra.

an experiment. Taken to its captious extreme this posture is patently true. As our colleagues in the law are notable for making relevant definitions, let me admit at once that if the investigator could be completely "informed," the reason for experimentation would cease to exist. To insist upon this stance or even to be sympathetic to it is to beg the question and fail to discuss the issues cogently. Some attorneys have preferred the more meaningful ring of "legally effective consent," others opt for "complete disclosure." To avoid this barren approach, it is submitted that "consent" or "informed consent" means the patient-subject has agreed to participate in a biomedical experiment under the direction of a physician responsible for his physical and mental health and that his agreement has been given after he understands what procedures will be performed on him, the possible risks and benefits as far as can be predicted on the basis of available knowledge and that he is always priviledged to withdraw from the study consonant with his own safety. This is, perhaps, a more stylized and rigid consent than many investigators or types of experiment can tolerate. It is apparent that there are degrees of consent ranging from the above to a casual verbal permission to "do whatever you want." One analysis based on the degree of "rights" surrendered by the participant as well as a categorization of the types of research has recently appeared.[3] Other than articulating some of the issues, I am uncertain that the degrees of consent are as meaningful as the possible risks inherent in a given experiment and the need (as opposed to desirability) to perform the specific experiment.

There are two major premises that most physician-investigators embrace in the course of their studies. Indeed, these premises are in the nature of rubrics. The first principle is that science and humanity demand the participation of humans as subjects for medical experimentation.

In the main, there are two areas in which human studies are essential. The first situation occurs where the species differentiation between man and other animals is so pronounced that to study lower animals exclusively is usually fruitless to understand human biology. This is especially so in the manifestations of central nervous system mechanisms, including attitudinal and behavioral characteristics. The second situation in which only man suffices as the subject relates to the cause, natural history, prevention and treatment of human diseases. Because of species specificity, environmental factors and often the uniqueness of the infecting or sensitizing agent in infectious or immunological disease states, the uniqueness of man and the uniqueness of the resulting interaction demand that only man can serve.

The second major premise is that the conditions and circumstance of the particular experiment are merely extensions of the usual patient-physician relationship. However, rather than abrogating the ethical and

3. Wolfensberger, Ethical Issues in Research with Human Subjects, 155 Science 47 (1967).

moral principles implicit in such a relationship, the conditions of the circumstances and motivations of all the participants should enhance these principles, provided the subject has a clear understanding of the experiment and his role in it.

This author is aware that from a legal standpoint there are objections to this statement since there are no specific rules of liability dealing with clinical investigation.[4] Indeed, the body of opinion in the courts is to the effect that a physician is measured judicially by the conduct of his peers and standards of practice in the community in which he practices.[5] Further, as the subject's physician, he is regarded by the courts to be in a special position of trust and confidence.[6] It is incumbent upon him not only to inform his patient of the experimental procedures, but, because of this special relationship, to ensure that the consent is voluntary. Morse has remarked that what is "acceptable persuasion" for medically indicated treatment may be "undue influence" in the experimental phase, but he qualifies this as outside the usual "physician-patient relationship."[7] From the investigator-physician's view this places him in not only a tenuous position but a vulnerable one as well. Morally, ethically and scientifically, he behaves as in the customary physician-patient relationship during the course of the experiment but with the realization that he does so at his own risk. Schreiner has aptly termed this, from "legal limbo" to "out on a legal limb."[8] Most investigators appreciate that the lack of standards or of accepted or customary practices to be used as a benchmark in a novel experiment makes the matter of the informed, voluntary consent by the participant all the more important, since participant's prior understanding of the risks or hazards that could be reasonably foreseen will be significant.[9] Further, the investigator appreciates that his action will be measured against other competent investigators in comparable situations as well as against those legal decisions wherein informed, voluntary consent was not sought.[10] When an individual participates in an experiment as a normal volunteer or when the experiment cannot possibly benefit him, there is more opportunity for misunderstanding and consequent difficulty.

Central to this notion is the fact that some experimentation involving

4. Morse, Legal Implications of Clinical Investigation, 20 Vand. L. Rev. 747 (1967).

5. See Wells v. McGehee, 39 So. 2d 196 (Ct. App. La. 1949); Luka v. Lowrie, 171 Mich. 122, 136 N.W. 1106 (1912). See also Ollet v. Pittsburg, C., C. & St. L. Ry., 201 Pa. 361, 50 A. 1011 (1902).

6. Valentine v. Kaiser Foundation Hosps., 194 Cal. App. 2d 282, 15 Cal. Rptr. 26 (1961); Yeats v. Harns, 193 Kan. 320, 393 P.2d 982 (1964).

7. Morse, supra note 4, at 749.

8. Schreiner, Liability in Use of Investigational Drugs, 185 J.A.M.A. 259, 263 (1963).

9. Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, aff'd on rehearing, 187 Kan. 186, 354 P.2d 670 (1960).

10. See, e.g., Hyman v. Jewish Chronic Disease Hosp., 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (2d Dep't 1964), rev'd, 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965).

humans may not be related to the patient's particular illness; in fact, he may have no possibility of realizing benefits, direct or indirect. Schreiner has discussed and categorized the various possibilites within the larger framework of the evaluation of risk versus benefit for any given study.[11] While there is no minimizing that risk versus benefit in human experimentation is a valid consideration, it is beyond the scope of this communication other than to remark that (1) the risk is largely the subject's but the benefits expected may not necessarily accrue to the particular subject but to "humanity" or the body discipline of science and (2) when the putative benefit is said to be important for these latter reasons, it is essential that both the physician-investigator and the subject have a clear understanding of all phases of the experiment and that the subject recognizes he will not be benefited except by any feelings of altruism he may have.

Regardless of the possibility of benefit to the participant, it is submitted that a valid patient-physician relationship obtains, and thus existing ethical and legal considerations are germane to the situation. This notion of combining clinical research with professional care is implicit in the Declaration of Helsinki and apparently affirmed in litigation.[12] In short, the subject has the apppropriate avenues to seek redress for any real or imagined wrongs suffered during the course of the experimentation.

Being innocent of legal training, yet not inhibited by ignorance (as bespeaks most scientists), I am persuaded that the tidy virtue of insisting upon the patient/subject-physician/investigator roles is that common law and "ethics" are appropriate to any experimental situation wherein the participating party's consent has been obtained. This posture is adopted because both law and science are dynamic bodies. It is obvious that interpretations of law are responsive to current and evolving practices, customs, mores, attitudes and even social expectations. As scientific knowledge advances, it is inevitable that there will be new situations, new facts and new experiments as unheard of as organ transplantations were years ago. It follows that new interpretations will be required and that it is not possible to anticipate many of the realities of tomorrow. To suggest that one could accurately predict the nature of medical research would further suggest the possibility of writing new statutes that by their rigidity could very likely impede scientific advances. Existing codes such as the Nuremburg Code, the various Surgeon General's policies and the Declaration of Helsinki of the World Medical Association, recently endorsed by most of this country's medical and research societies, are useful bench marks that proscribe the ethics of human experimentation and by their very existence can be invoked in litigation.[13]

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11. Schreiner, supra note 8.

12. See Massachusetts Mut. Life Ins. Co. v. Brei, 311 F.2d 463, 469 (2d Cir. 1962).

13. A word of explanation on my own passion for a recognized code of conduct or guidelines is in order at this point. As the former Director of the Institute of Biomedical

Before the investigator even solicits participants for his study, it is necessary that the duly constituted research committee of the involved institution (and frequently the agency financially supporting the project) approves and, in effect, endorses the study not only as to its scientific merits and appropriateness, but as to the foreseeable risks to be borne by the participants.

Where the subject gives consent for his own participation in experimentation, not only is divulgence of more than the risks and benefits known by the investigator mandatory, but also I believe it is essential that the investigator himself, if he is not the patient's own physician, explain in comprehensible language the appropriate information and techniques involved in the proposed experiment. This discussion should be in sufficient detail that the participant has a firm understanding of the likely course of the experiment, possible discomfort, etc., as well as an appreciation that a placebo or sham technique may be employed and is a valid part of a well-designed and properly conducted investigation. Further, the participant must be made aware that he may terminate his participation in the experiment at any time consistent with his own safety. The physician and the research committee of disinterested physicians can make the medical judgements necessary, if the experiments cannot be stopped immediately without endangering the life of the subject. The subject must also understand at the beginning of the study whether the predictable nature of the study might preclude his abrupt withdrawal and how this matter would be handled should the eventuality arise unexpectedly. It seems reasonable for both the participant's and physician's protection that a signed and/or witnessed instrument attest to this sort of a consent in most studies.[14]

From the standpoint of making valid scientific observations it is occasionally stated that complete disclosure of the details of certain experi-

Research of the AMA Education and Research Foundation, I began in 1964 to try to persuade many of the prestigious medical research societies as well as the AMA to formulate or endorse a meaningful set of guidelines. After several formal meetings and many informal ones, in the autumn of 1966, the following statement and endorsement of the Declaration of Helsinki was issued: "We, the undersigned medical organizations, endorse the ethical principles set forth in the Declaration of Helsinki by the World Medical Association concerning human experimentation. These principles supplement the principles of medical ethics to which American physicians already subscribe: American Federation for Clinical Research, American Society for Clinical Investigation, Central Society for Clinical Research, American College of Physicians, American College of Surgeons, Society for Pediatric Research, American Academy of Pediatrics, American Medical Association." I wish to express my deep appreciation and special thanks to all the officers of the societies and in particular to Messrs. Bernard Hirsch and Richard Bergen, of the AMA Legal Division, Edwin J. Holman, Secretary, AMA Judicial Council, Dr. Russell Elkington, Editor of the Annals of Internal Medicine (of the American College of Physicians), Dr. Oscar Ratnoff of Western Reserve University School of Medicine and Dr. Howard Frazier of Harvard Medical School for making this endorsement possible.

14. Written Consent for Clinical Investigation, 276 New Engl. J. Med. 115 (1967) (editorial).

ments would vitiate the experiment's objectives. This factor enters into drug-trials of mood-affecting agents and many psychological studies. If common or suspected attitudinal or behavioral responses to a pharmacologic agent or contrived situations are discussed with the participants and the participants' subjective responses are the prime data to be collected, it is obvious the experiment is not controlled and any results are open to serious doubt. If it is true that some studies demand that the human participant be unaware that they are involved in an experiment, there is a serious problem. Whenever biological variability is probed and stressed, there is necessarily a risk, large or minute, physiological or psychological. Whenever individuals are entrapped in experiments, it is clear that their individual rights have been violated. Whenever agreement is given to participate in experiments without any information as to their nature, it is obvious that the participant is not "informed" and a large measure of faith in the investigator is assumed. Perhaps this is the ultimate limit of the patient-physician relationship, but in this instance, there may frequently be no disease or condition as the focal point of interaction, but only the investigator's desire to conduct his studies in the name of science and whatever personal motivations are operative in him at the time. Can the compelling abstractions and realities of science, humanity and the individual rights of both the subject and the investigator be served in these instances? I do not believe it possible.

There is no doubt that a rigid, literal interpretation of voluntary, informed consent restricts scientific freedom in some areas, notably behavioral research. It is obvious too that society has legitimate interests and needs in many areas of science, just as it does in matters of national security, public health and welfare. Certainly, public interest compels society to invade privacy, condemn (and therefore seize) private property, and quarantine or institutionalize citizens with certain diseases or disturbances without consent, yet each situation is weighed and no absolute license to do so exists.

John Stuart Mill has eloquently stated that "over himself, over his own body and mind, the individual is sovereign,"[15] but he concluded that there exists a need for rules of conduct to be imposed "by the law in the first place, and by opinion on many things which are not fit subjects for the operation of law. What these rules should be, is the principal question in human affairs . . . . "[16] What then constitutes the bounds of decent inquiry, privacy and necessity for research? In a penetrating and illuminating article, Ruebhausen and Brim suggest that, "[w]hat is needed is wisdom and restraint, compromise and tolerance, and as wholesome a respect for the dignity of the individual as the respect accorded the dignity of science."[17]

15. J.S. Mill, On Liberty 13 (Liberal Arts Press 1956).

16. Id. at 8.

17. Ruebhausen & Brim, Privacy and Behavioral Research, 65 Colum. L. Rev. 1184, 1195 (1965).

There is another important practical consideration involved in informed consent for human experimentation when the proposed participant is incompetent by reason of age or mental impairment. The so-called third party consent is then sought from the parent or legal guardian which in some circumstances may be the state. For many kinds of biomedical studies the populations of institutionalized individuals are an ideal group for human experimentations. They generally live in a stable environment and are under a fairly rigid control with respect to diet and nutrition, sleep, exercise and environmental exposure. In short, they represent what the investigator likes to have in his animal rooms and he is reasonably sure the animals will be there for some time. Naturally, such human populations in institutions are not truly random, even if their common denominator is the absence of both parents.

There are studies, thankfully minuscule in number compared to the bulk of published human studies, that have clearly demonstrated a cavalier disregard for some institutionalized groups of mentally defective children or a complete indifference to the investigator's first role as a physician.[18] These studies were authorized by the duly constituted authorities of the inmate's institution and were said to be proper from the legal standpoint. It is not certain that they were approved by a research committee of the investigator's institution, but at the time some of them were conducted, there were not many universities with such committees. Indeed, there continues today, apart from the granting agencies' requirement that these committees be constituted, a minority dissent that these expert and dispassionate committees in some way abridge academic freedom. However, it is worth noting that academic freedom has never been a license for irresponsibility. It is a guarantee for a responsible searching for truth with explicit admonitions to respect the rights and opinions of others.

It has always seemed cruel and inhumane to regard institutionalized minors or incompetents as a kind of experimental animal colony where the investigator is blessed by a stable ecology and captive subjects. I do not believe the use of these individuals can be rationalized on the grounds that they "owe" society their participation or because the third party guardian, frequently the state or other local authority, may be detached about them. I submit that such individuals should become involved in experiments only when:

(1) The experiment is relevant (on the basis of available data) to the *condition* that caused them to be institutionalized;

(2) A panel of peers responsible to the investigator's institution, uninterested in his fortunes and competent in the area of the proposed study has approved the protocol for the investigation in the same way that NIH study committees approve grant requests; and,

18. See Beecher, Ethics and Clinical Research, 274 New Engl. J. Med. 1354 (1966).

(3) The details and procedures of the experiment conform to the principles set forth in the Declaration of Helsinki.

(4) Finally, the legal guardian has given permission on the basis of the above information.

Such a procedure would not inhibit meaningful investigations and hopefully might benefit the participants or those like them. It is evident that it will rule out the use of mentally incompetent children for the initial testing of some new drugs or immunizing agents having no bearing on their condition. Surely these and other agents are meant to be used on other than institutionalized subjects. Non-parametric statistics can be applied to evaluate studies of the general population, in which all the variables are not controlled. Surely we as scientists have compassion for our fellows who are institutionalized.

It should be clearly understood that I have no desire to inhibit or curtail meaningful studies and that the above suggestions are not intended to preclude children's participation in medical studies. If the "condition" is age and if neonatal, juvenile, pubertal, etc. conditions are to be investigated, it is obviously appropriate to study children at these ages. However, I see no reason to use them as subjects when the condition is not germane to childhood, and no reason to use mentally incompetent or disturbed individuals unless the condition to be investigated bears on their state.

It is essential that while humanity and science are served, the individual's rights must be protected with vigor and vigilance. If this means that certain experiments cannot be conducted, it is appropriate that they are not. Medical scientists in the laboratory are privileged to embrace an operative pragmatism during the continuum of inductive and deductive reasoning, intuition, imagination and possibly even serendipity that comprise the scientific method. Occasionally, the means and the end are blurred and may even be indistinguishable. In the clinical experiment with human subjects this facile laboratory stratagem cannot be permitted, for here the end can never justify the means if human rights and dignity are violated. There is a special meaning for the scientist in this cliché, for he above all others exalts in his freedom to seek the truth of life and he is first a human, then a scientist.

With his customary grace and eloquence, Professor Freund has written:

> [M]edicine and law and art have an essential affinity. As the artist himself finds his freedom in the constraints of his medium, in the canons of taste and in respect for the limitations of his material, so the judge and the physician too find their freedom in their fetters, in the symbolic codes that assign them their roles and render it tolerable to make judgments involving life and death—fetters that somehow make it possible to surmount the agony and the absurdity of human decisions.[19]

19. Freund, Ethical Problems in Human Experimentation, 273 New Engl. J. Med. 687, 692 (1965).