

The Problem of Experimentation on Human Beings¹

I. The Research Worker's Point of View

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IT IS CONSIDERED AXIOMATIC that the purpose of medical research, perhaps in contrast with more general research, is to discover, improve, or extend information regarding man, his functions, and his relationships to his environment. It follows that a primary scientific criterion of usefulness in medical research is whether the observed phenomena can verily be produced in, or applied to, human beings. Findings on other species may have general or specific validity for man, but the ultimate establishment of such validity must rest in each instance upon direct observations on man. At some point in any medical research, therefore, the investigation must be performed with human beings, if that research is to fulfill its primary objective.

Despite these obvious considerations, and despite the demonstrated value of medical research in terms of saving life, relieving pain, and achieving other goals considered worthy, the use of human beings for experimental purposes often encounters vigorous opposition. Proposal of such investigations, even to groups trained in scientific disciplines, may result in outright rejection or in the suggestion that animal experiments that *a priori* can be seen to be inadequate for the solution of the problem be substituted.

Analysis of the reasons for these attitudes is essential if experimentation on human beings is to be pursued on a scale commensurate with its importance. In my opinion, three primary considerations are involved.

The first is the basic question as to what constitutes an experiment. An experiment is a sequence resulting from an active determination to pursue a certain course and to record and interpret the ensuing observations. Hence, to do nothing, or to prevent others from doing anything, is itself a type of experiment, for the prevention of experimentation is tantamount to the assumption of responsibility for an experiment different from the one proposed. As much knowledge and as weighty reasons are required for one course of action as for the other, and it should be demonstrated that the proposed experiment is more dangerous or more painful than the known results of inaction.

The second consideration is that medical experimentation on human beings, in its broadest meaning and

for the good of the individual patient, takes place continually in every doctor's office (1). Hence the general question of human experimentation is one of degree rather than of kind. Deliberate experimentation on a group of cases with adequate controls rather than on individual patients is merely an efficient and convenient means of collecting and interpreting data that would otherwise be dispersed and inaccessible. A specific study may still be rejected because of its hazards, expense, or relative lack of utility, but at least it should not be rejected outright simply because it is an experiment on human beings.

The third consideration is that of the nature of medical responsibility. The responsibility of the individual physician to an individual patient has been clearly defined, maturely considered, and almost universally accepted; it has been tried and found good. Deliberate experimentation would seem to introduce a break with the accepted type and a replacement by forms of so-called responsibility, which should be deeply and rightly distrusted—the sort of thing that is called the duty of scientific man to society and the obligation of individuals to the race, under which all sorts of monstrosities have been practiced in absolutist states. But abuse does not preclude use. Responsibilities do exist, and it is better to define them and see that they are not abused than to deny their existence and to accept the consequences of denial. There is no basic difference between the experiment on an individual patient and the extension of the experiment to a group of similar patients. Both the physician and the patient, in fact, benefit from the increased facilities for consultation and comparison, stronger checks, and the accelerated collection of data. Here, again, a proposed experiment may be rejected on adequate grounds, but not merely because of general condemnation of the type of responsibility involved.

It is in the deliberate mass-experimental situations on man that traditional, unanalyzed attitudes make scientific studies inordinately difficult to initiate and to perform. And because of the absence of analysis, investigations that do not achieve diagnostic or therapeutic goals may remain unreported, to the detriment of further research and the repetition of futile procedures. Similarly, the untoward results of a procedure may be deleted from a published report in order to reduce possible criticisms of the study.

Research on human beings, of course, involves

¹ Based on a symposium held at the Medical Staff Conference, Oct. 10, 1951, Division of Medicine, University of California School of Medicine, San Francisco.

unique hazards, precautions, and responsibilities. Whenever human beings are to experiment on human beings, the mores of human conduct, including ethical, religious (2), and legal (3) considerations, cannot and must not be ignored or minimized.

What, then, are the proper rules of conduct that can be utilized in judging whether human beings should be involved in experimentation? Perhaps the clearest formulation of such rules was made at the Nuremberg medical trial (4). In its decision rendered on August 19, 1947, the Tribunal stated:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

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

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

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

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

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

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

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

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

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the

exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Much the same rules in regard to medical experiments on human beings have been delineated by the American Medical Association (5) and by the Green Committee (6) on the use of prisoners in investigations. Analysis of the rules shows that they can be reduced to two primary principles: First, the investigators must be thoroughly trained in the scientific disciplines of the problem, must understand and appreciate the ethics involved, and must thus be competent to undertake and to carry out the experiment. Second, the human experimental subject must understand and voluntarily consent to the procedure, and must not be selected upon any basis such as race, religion, level of education, or economic status. In other words, *the investigators and the subjects are human beings with entirely equal, inalienable rights* that supersede any considerations of science or general public welfare. Finally, research on human beings is too hazardous and implies too many responsibilities to be undertaken by lone investigators. It should be a group effort supported by a proper consultative body. Experimentation even on oneself without such collaboration and consultation seems as indefensible as similar experimentation on another individual.

Once these primary principles are accepted, the application of the stated rules to any specific situation involving human experimentation is modified by several factors and is relative to these factors. The factors can be divided into two classes: the physical and mental condition of the prospective subject, and the type of experiment contemplated.

1. *The condition of the subject.* Human subjects of medical investigations can be divided into three categories:

- a) *The normal subject.* The rules of conduct governing research on human beings basically stress and primarily refer to experimentation that may be carried out on normal, healthy individuals. It is here that the most thorough information must be available from animal studies and from clinical studies on patients before experimentation can be considered as justified. It is obvious that opinion regarding the thoroughness and completeness of the preliminary studies will vary widely, and it will be modified by the importance and the immediate nature of the problem. The best final criterion for the justification of the use of normal individuals is the voluntary participation of the experimenters themselves as the subjects.

- b) *The subject with reversible disease.* Another class of persons who may participate in an investigation is one with a reversible or nonfatal disease. It is rather evident that these individuals should ordinarily be involved in research only after data are obtained on animals or on patients with more serious conditions which show that the procedure has promise of curing the disease more quickly, reducing more serious complications, or affording more complete symptomatic

relief. In other words, the experimentation is more or less limited to research in therapy, and even here the hazards of the drug or procedure must be weighed against the hazards of the disease in each instance and individual (7).

c) *The subject with fatal disease.* The third group of human beings that can be considered for experimentation are patients with incurable, inexorably fatal afflictions. No better example is afforded than by patients with advanced neoplastic disease. Although palliation still remains the first consideration in proper medical management, an unparalleled opportunity exists for the wider study of these individuals in pharmacologic, physiologic, and other medical investigations. It is the experience of many physicians that this type of patient often wants, and even demands, that something be done for advancement of knowledge if not for personal benefit.

2. *The type of experiment.* Research on human beings can also be divided into three categories, dependent upon the type of investigation contemplated.

a) *"Passive" research.* In this group fall investigations that use human tissues or products that are separated from the individual. Typical examples are biochemical determinations of enzyme reactions on tissue specimens or the measure of amino acids in blood. The investigation may be initiated on human tissue or may be tried on human material after previous determinations on biological systems of animal or plant origin. Unless it involves a deliberate surgical operation or the maintenance of the human subject under special conditions before the material is obtained, the role of the human being is a passive one and does not include actual participation in the research.

b) *"Late active" research.* In this type of research, investigations on man are undertaken after information is available from comparable studies in animals. Typical examples are afforded by the pharmacologic evaluation of new drugs (8). On the basis of *in vitro* and animal studies that show a certain chemical to cure a certain infection, and after comprehensive determinations of the toxic effects on animals, cautious clinical trials must be initiated somewhere and by someone to demonstrate whether the chemical is in fact effective and safe for human use. New diagnostic procedures and new surgical operations also fall in

this category. The human being is an active participant in the research but enters it at its final or late stage.

c) *"Initial active" research.* Certain investigations may be undertaken first, or exclusively, on human beings. Examples of this class of research imply that the study can be pursued best, or only, directly on man. Experiments on the apposition of the thumb can hardly be performed on any but a human hand. Many disease processes cannot be, or at least up to now have not been, successfully reproduced in animals. In other instances the occurrence of an abnormality is so rare and difficult to find in animals that no study except on human beings is practicable. Investigations that necessitate cooperative, complex psychologic reactions, which are either lacking or not comprehensible in animals, also require active initial participation by human subjects.

This is the category of research in man that is most difficult and complex in its ethical and other ramifications and implications. It is here that therapeutic or diagnostic indications may be unfounded or nonexistent. It is here, also, that fundamental physiologic or psychologic information of immediate application and import to man may be obtained.

The complex problem of the use of human subjects in medical research involves many suprascientific considerations. The guiding principles that have been developed would have general acceptance within the framework of our culture. The application of these principles to specific experimental situations, however, is still open to individual interpretations and differences. It is appropriate to indicate in this connection that science per se is neither moral nor immoral; it becomes moral or immoral only as moral or immoral human beings use its powerful techniques.

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II. The Physician's Point of View

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I THINK, from Dr. Shimkin's comprehensive and lucid presentation, it has become crystal clear—if it was not agreed to before—that experimentation on human beings, including the sick, must be performed if we are to advance our conquest of disease. There can be no question of the value of this type of investigation for the improvement of the care

of the sick, and the fact is that experimentation on human beings is nothing new. It has taken place, is taking place, will take place, whenever physicians are in the process of introducing new diagnostic and therapeutic procedures or agents—new in general or new for the patient—or whenever investigations on the sick are being made that are of no immediate value

to them but are made to confirm or disprove some doubtful or suggested biological generalization.

Recently, however, the latter type of experimentation has become more and more extensive. At least three developments are evolving at present that seem to call for an appraisal from the physician's point of view; for it is predominantly physicians who are the experimenters, and it is the patient-physician relationship, in the broadest sense of the term—including the patient's and physician's attitudes toward life—which is deeply affected by these developments. The historical developments to which I refer are as follows: (1) The application of force, as in experiments performed in the insane asylums and concentration camps under the National Socialistic regime in Germany; (2) The frequent recourse to "hopelessly incurable" patients; (3) The increased technicalities of many problems and procedures.

The recent literature on the topic in this country has been contributed mainly by A. C. Ivy (1), Willard L. Sperry (2), and W. B. Bean, who published a perceptive article after this symposium was held (3). In Germany A. Mitscherlich and F. Mielke (4), and V. von Weizsaecker (5) wrote on it most penetratingly in connection with the well-known Nuremberg trials in 1947 against twenty National Socialistic physicians. Weizsaecker's publication shows particular insight into the problem, and I shall make further reference to it.

To be more explicit, some remarks are in order about (a) the type of experimentation we are discussing, (b) the technical necessity that physicians carry out the experiments, (c) the patient-physician relationship.

a) The type of experiments with which we are concerned is of no immediate value to the patient but is made to confirm or disprove some doubtful or suggested biological generalization. We assume, of course, that all types of experiments discussed here have a common denominator—a physical or chemical relationship, and, in this sense, all may be considered to be of value to the individual experimented on. However, to the person under observation there are significantly different encroachments in an experiment. In the words of Hippocrates, "Art is long, but life is short," and not all experiments performed on men will ever be of value to these particular men. And it is with these breathing men that we are concerned as physicians.

b) There is no legalized profession of experimenters on human beings outside the medical profession, and no other group is privileged to perform any but the simplest somatic experiments on human beings. Paragraphs 2137 and 2141 of the Business and Professional Code of the State of California cover this subject, and it should be noted that the Principles of Medical Ethics of the American Medical Association (6) nowhere forbids experimentation. As a matter of fact, experimentation for the patient's immediate good forms an integral part of the physician's care of his patients; and experiments to confirm or dis-

prove a biological generalization with regard to man certainly cannot be better performed than by the profession that is trained more completely than any other in comprehending the somatic and psychological aspects of human life, be it healthy or diseased. There is another reason why the medical profession is so uniquely privileged. It is closely related to what we shall call the *original* patient-physician relationship.

c) The patient-physician relationship is fully understood only when viewed from two aspects. The relationship of the one who performs experiments of no immediate value to the person under observation is impersonal and objective because of the character of the research. Experimentation is the basis on which the two meet, the original bond between them. The fact that the experimenter is a physician is, from this point of view, almost incidental, although he occupies this position because of the legal technicalities mentioned above and because of his special training. At the same time, the person experimented on is studied solely because of the special set of symptoms he presents. He is sick in the objective sense—i.e., he is different from the healthy man as measured against some common standard, just as one piece of ore may be different from another. He is indeed an object in the grammatical sense, too. The physician, like any experimenter in the field of physics and chemistry, is the subject, for it is he who does the experimenting. But even though he is the subject in the grammatical sense, he is not the subject in the real, personal sense. Every effort is made, and must be made, to depersonalize him and to eliminate every subjective factor. Invoked by the drive for generalization and specialization, objectivity is the password throughout.

Obviously, there exists a second, quite different, relationship between a physician and a sick person. Historically, it is the *original* and, indeed, the basic justification for our profession. Here one human being is in distress, in need, crying for help; and another fellow human being is concerned and wants to assist him. The cry for help and the desire to render it precipitate the relationship. Here *both* the healthy and the sick persons are subjects, fellow-companions, partners to conquer a common enemy who has overwhelmed one of them. Theirs is a relationship between two "I's," like that between lovers, friends, pupil and teacher (4). I have called it "mutual obligations of equals," or, to use Weizsaecker's term, it is "solidarity." Objective experimentation to confirm or disprove some doubtful or suggested biological generalization is foreign to this relationship. It is not the point of contact between the two partners, for it would involve taking advantage of the patient's cry for help, and of his insecurity. Moreover, in his role as a fellow human being, the physician is only too keenly aware that all our lives are limited, one-way trips, and that death per se, despite its absence from physiological texts, is a physiological phenomenon, befalling us all (7).

Still another problem related to the aspect of man as a subject is pertinent to our discussion. Noting

that "man finds himself in the peculiar situation of being a finite creature and yet gifted to survey eternity," the theologian Reinhold Niebuhr has expressed it in the statement: "Self intrudes itself into every ideal when thought gives place to action" (8). Marx and Freud are perhaps the best-known modern authors who have implemented this thought and challenged the rationalistic faith that action depends on conscious reasoning alone and is not conditioned by the egotism of our finiteness, although one should add, perhaps, that Christian dialectics penetrate much deeper.

It may be concluded that the relationship in experimentation between experimenter and experimented-on, entered upon not to help but to confirm or disprove some doubtful or suggested biological generalization, is impersonal and objective. The *original*, basic patient-physician relationship implies the concept of solidarity, of life's finiteness, of man's indigenous selfishness. Experimentation as just described is foreign to it.

The language differentiates between the objective "being-sick" and the subjective "being-a-patient." It does not differentiate these two aspects with regard to the term "physician," although one may differentiate between the two facets of the physician as the physician-experimenter and the physician-friend.

Against this background let us view the recent extension of experimentation as illustrated by the three developments mentioned early in these remarks.

1) *The application of force.* Although the question is more intricate than it may seem at first sight, apparently no problem exists in American culture. I think the overwhelming majority of physician-experimenters, if not thoroughly aware of the nature of the original patient-physician relationship, are so deeply rooted in the democratic spirit that they agree, and will continue to agree, that the use of force is not justified on a single person, even if millions of other lives could be saved by such an act. They realize that the act would not just save millions of lives but that, as an amoral act from the standpoint of democratic brotherhood, it might create millions of amoral sequels, and that the moral history of mankind is more important than the scientific.

2) *The problem of the "hopelessly incurable."* This question illustrates the chaos that results when the two aspects of the patient-physician relationship are not clearly recognized, and no conscious attempt is made to separate the two. All—the science of medicine, the suffering patient, the physician-experimenter, and the physician-friend—lose by this confusion. The literature suggests that the classification of persons as "hopelessly sick" is not intended to be merely a presentation of fact in the objective sense on the part of the experimenter, but, by its characterization as "hopeless," is intended to justify an experimenter's self-permit for greater boldness. It is an apparent attempt to express a conscious effort of restraint on his part when, in performing experiments that endanger the lives of the experimented-on sick, the experimenter restricts himself to those "marked by

death." It is meant to be noble in the democratic spirit, yet it unconsciously challenges this spirit more subtly but no less than the use of force, because it violates the concept of equality or brotherhood in violating the principle of the original patient-physician relationship. From the experimenter's point of view, the description "hopelessly incurable" is not germane to his purpose. The designation is inadequate, because it does not specify the time element—hopeless within hours, days, months, years? And, if months or years are concerned, do all experts agree on the status of their respective sciences and deny the possibility of discovering effective agents within such a period? The term is also unnecessary, for unless he wants to study mechanisms of death, it does not make any difference to the experimenter whether the experimented-on is hopelessly affected by the disease under observation.

From the standpoint of the physician-friend, the assertion is not germane to his purpose, either. To him it is an expression of detachment between physician and patient, the announcement of a scale of partnership vs. domination quite contrary to its original spirit. As a matter of fact, it creates the paradox that the healthier the patient, the more he should be the concern of his physician; the sicker, the less. From the standpoint of solidarity we all are finite individuals who have to die; to restore or preserve health is the physician-friend's concern, not to trespass presumptuously upon our inevitable "mortal lot." Whatever other requests for adjustments our society may make of the individual (except for the soldier, who holds a unique place), our culture does not, under any circumstances, intend to endanger individual life.

There are, as Weizsaecker points out, two aspects concerning the "hopelessly sick" that emerge from the concept of a true patient-physician relationship—the aspect of pity and the aspect of sacrifice. Dr. Shimkin also mentioned the latter. I follow Weizsaecker when he says that pity, as such, does not imply the spirit of solidarity. It is not pity that the patient wants, but help. Selfish motivation, entirely unconscious, may enter in the guise of pity; and, on the other hand, conscious selfishness—for instance, the physician's greed for money—may help a patient more than the physician's pity. A second justification for experimentation on the "hopelessly sick" on the basis of the original patient-physician relationship would be the patient's wish to sacrifice himself, similar to that of a conscientious objector. The physician-friend who wants to experiment might most humbly accept such a wish as the highest form of human transcendence, being aware that true equality does not exist under such circumstances, for the offering of one partner happens to coincide with the self-interest of the other. Experimentation on the so-called hopelessly sick requires, therefore, a tremendous amount of self-criticism, self-discipline, and understanding of life's essential attributes, lest it be perverted to unconscious barbarity. The phrase needs to be eliminated, and an objective and more precise terminology used instead.

3) *The increased technicalities.* It is obvious to

every physician, be he an experimenter or a physician-friend, that, even in the field of daily practice, assertions that, following explanations of the seriousness of an operation and the nature of the patient's disease, it was "agreed" between patient and physician to operate, can be true only in the vaguest sense of the term "agree." The agreement refers only to acts of commission and not to those of omission, and one has only to think of present-day specialization in medicine in order to realize that the patient is frequently not able to grasp all the implications of a certain procedure so far as his health is concerned. Only the spirit of the original patient-physician relationship, faith on the part of the patient and the attitude expressed by the Hippocratic Oath, can bridge this gap. How much greater is this difficulty in an experimental procedure, where selfishness plays a role?

Present types of experimentation on the sick clearly challenge tremendously the basic concepts of the original patient-physician relationship. All the encroachments imposed by society upon this relationship, such as reporting certain diseases, requesting certain types of inoculations, evaluating fitness for work or right to compensation, shrink before the challenge the profession itself raises. Yet Dr. Shimkin has pointed out—and we all agree—the great significance of human experimentation for the cure of the sick. We are facing a dilemma which can never be decided in final terms but only on a temporal basis.

Perhaps a glance at the way the legal profession meets the moral and technical demands of society and the individual when a conflict arises between the two will offer a cue to a solution of our problem. As we all know, that profession provides each of the two with a representative of equal stature: there, the prosecuting attorney, and here, the defense attorney. Similar arrangements may have to be developed in the field of human experimentation, performed not for the good of the individual patient but made to confirm or disprove a doubtful or suggested biological generalization. Research and care would not be pursued by the same doctor for the same person, but would be kept distinct. The physician-friend and the physician-experimenter would be two different persons as far as a single patient is concerned—for instance, my patients would become research objects for someone else, and I would be permitted to experiment only with the patients of another physician. The responsibility for the patient as patient would rest, during the experimental period, with the physician-friend, unless the patient decided differently. Retaining his original physician as personal adviser, the patient would at least be under less conflict than he is at present when the question of experimentation arises.

With reference to increasing technicalities, the forms that patients must sign when about to volunteer for experimentation, or even to undergo an operation, might be so phrased as to state not only the patient's consent, but also the physician's affirmation of his utmost effort to protect the patient from harm and of his most careful judgment in deciding on an operation. Under those circumstances the obligations of the profession toward the individual and society would not be blurred.

The problem we face thus presents a true dilemma, being tragic in the classical sense; both its aspects are of equal value in thought, and a course of action must be decided anew for each actual situation, because the varieties of actual situations are as infinite as history itself. A given situation may demand that the attitude of the physician-experimenter and that of the physician-friend be embodied in one person. Unless we recognize the basic differences of the two attitudes, each will suffer, as demonstrated by the confused concept of the "hopelessly incurable;" or one will be needlessly neglected, as demonstrated by our failure to supplement forms requesting consent from a patient with some corresponding affirmation of utmost concern for his welfare on the part of the attending physician.

It is not the conquest of nature but the re-evaluation of man that appears to be the basic problem of our times. It is the re-evaluation of man as—to express it in old yet valid terms—"created in the image of God and tempted by the devil," not as a replica of innocent beasts, which, however cruel, cannot commit any crime. We must be alert with ourselves lest, in our zeal for truth, we create healthy bodies at the cost of morally dulled minds.

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III. Limits of the Right of a Person to Consent to Experimentation on Himself

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MEDICOLEGAL CONFERENCES are, I think, usually unsatisfactory from the legal side. The lawyers who know the subject best generally dodge the responsibility and leave it to someone like myself to rush in where they fear to tread. There is a reason why the lawyer dislikes to express an opinion. The Anglo-American lawyer wisely refuses to commit himself on a suppositious case. The courts refuse to render advisory opinions. They will decide only an actual case presented to them by the parties in the regular way. You may say, "Well, I am asking you now, 'Can I do this?'" To which I reply, "Is this an actual case in which you are about to take action?" In an actual case, you have all the facts, and it is the concrete situation and not the abstract theory that dictates the decision. If it is a question of experimental treatment of a real person, all the considerations presented by Dr. Shimkin are relevant and affect the conclusions. The rules referred to by Dr. Shimkin should be memorized and applied in every case by doctors and research workers. Even then the lawyer cannot guarantee his answer, any more than a doctor will guarantee a cure.

In general, a medical man may not treat or operate on a human being without his consent. It makes no difference that the person needs treatment or will die if he does not get it. If the consent has not been obtained, it is no defense that the operation was skillfully performed and saved the patient's life. Where the patient is unconscious and needs immediate treatment, it can be done; but even there, if the husband or wife is present, his or her consent may be necessary. Consent to an appendectomy is not consent to a gall bladder operation. In practice the surgeon gets a complete authorization, even if the operation is for what appears to be a minor condition, because what seems to be superficial may turn out to be serious. But this does not solve all the questions. Consent itself, even if written, may be effective only if there has been a complete disclosure. The lay patient cannot understand the process of treatment, but the possible end results must be made clear to him. I doubt whether the printed forms of consent are adequate in some cases. The patient may claim, perhaps correctly, that he did not understand what was meant.

In many medical cases this consent is not obtained. There are difficult diseases of which little is known. New drugs are coming out with bewildering rapidity, and enthusiastic discoverers give optimistic accounts. Physicians try the drugs on patients, commonly without informing them. It is not practical to get a written waiver in advance, or each time an experimental drug is used. Death, blindness, and serious injuries

have sometimes resulted from treatment—more often than we may realize. Some modern drugs cure a disease but produce serious side effects. On the other hand, brilliant medical men or their insurance carriers have had to pay damages for unsuccessful treatments where the usual but unsatisfactory procedures had not been followed. This discourages progress. The opinions of some courts read as if the judge seemed to think that there is a prescribed cure for every ailment of the patient. As a matter of fact, in a large number of cases, the doctor must experiment to make the diagnosis, as well as to carry out the treatment. Each person is apt to present an individual case, in some respects not conforming to general rules.

This kind of experimentation—if it can be called experimentation—is clearly not the kind condemned by the law. Where, however, there is a clear-cut case in which there is a well-recognized treatment, but the doctor has discovered what he believes to be a better treatment, the law puts the risk on the doctor if the treatment fails. As one court put it, "We have little doubt that, if the first case of vaccination had proved disastrous and injured the patient, the physician should have been held liable." It seems unfair to put such a risk on the doctor. The above quotation was not necessary for the decision. The cases that have actually come before the appellate courts have been actions against quacks and charlatans. None involved a real scientist observing the proper precautions.²

Practically, there is not much danger where sound rules for experimentation are observed: careful preliminary study by a well-trained man, animal experimentation where possible, desperate remedies resorted to only in hopeless cases, treatment stopped at the first danger sign. In the exceptional case the doctor can protect himself by full disclosure and the written consent of the patient. The rules laid down at the Nuremberg trial might well be taken by the courts as the standard by which the doctor should be judged. The malpractice suit is a headache to the medical profession, but some doctors say that, if it were not the law, doctors would have to make it the law, for it is a powerful stimulus to keep the doctor on his toes, up to date, and careful.

There is the fundamental difficulty to which Dr. Guttentag has called attention. It is the business of the doctor to do his best for his patient. Research on the patient for purposes other than his welfare has no place; yet, if the doctor is not also a research man, he is not the best kind of doctor, and if the research specialist is not interested in the welfare of the patient entrusted to him, he is not the best researcher.

² The cases are examined in *Calif. Law Rev.*, 40, 159, and in *Ann. Western Med. and Surg.*, 6, 164 (Mar. 1952).

Americans who studied at Vienna, Leipzig, and other medical centers in Europe before the first world war admired the skill of the doctors but were shocked at treatment administered and operations performed which would never have been undertaken had the welfare of the patient been the sole consideration.

Although there is no legal authority, and consent is theoretically necessary, it may be that, on the maxim "*De minimis non curat lex*"—"The law does not regard trifles"—an extra drop of blood to build up a control group for a research study, or the use of tissue that has been properly severed would not be condemned by the court. But the medical profession should consider carefully whether, as a matter of good public relations, nothing should be done to a patient except for his benefit, and whether he should not be used either directly or indirectly as a guinea pig without his consent. A doctor who has the reputation of experimenting with his patient is avoided by those who know that reputation.

That brings us to the question of experimentation on persons—with their consent—not for any disease and not for any direct benefit to the patient, but solely for the advancement of science. How far can one consent to serious injury to himself? The analogies are not close. Abortion, except for therapeutic reasons, is a crime, and the consent of the woman is no defense for the doctor. A person cannot legally consent to his own death; it is murder by the person who kills him. Societies in England and the United States are trying to legalize euthanasia for those suffering from incurable disease, and juries have sometimes acquitted a parent who has put a suffering child out of his misery. If it had been his dog instead of his child, he would have been punished for not killing it. In the case of the birth of monstrosities the doctor may perform the killing and no one be any the wiser, but legally it is murder. A person may not consent to a serious injury amounting to a maim. The classical case was the man who cut off his hand to make himself a more successful beggar. Injuries inflicted to avoid military service are not unknown, and are criminal.

Sterilization presents a more difficult problem. The late Lord Riddell seemed to condemn it without exception but, in the same volume, approved it for the feeble-minded. Statutes concerning the feeble-minded have been sustained. In this country what little au-

thority there is seems to permit sterilization where death, insanity, or serious disability would result from pregnancy. Economic considerations based on the number of children are a doubtful basis, and it probably would not be sanctioned simply to avoid the possibility of having children.

These situations all involve serious injury inflicted by consent for the direct advantage of the one permitting it. The motive of the advancement of science presents a different case.

The use of prisoners, racial minorities, or religious groups for experiments resulting in death has been universally condemned. Yet the state drafts men for war and death. Perhaps Colonel Johnson will tell us whether men could be drafted to undergo dangerous experiments in order to save the lives of as many soldiers as possible. There are other hazardous occupations. No prosecution seems to have followed where antivaccinationists have been encouraged to receive smallpox germs, or religious fanatics to submit to snake bites. Although there are no cases, it could not be considered a crime of the experimenter where the highest public praise is accorded to those incurables who offer themselves for experimental purposes in order that persons may not have to suffer in the future as they have. The airmen who have died in pressure experiments to make air travel possible for others, the Walter Reeds who have risked disease germs to determine causation where animal experimentation has failed, and other martyrs to science who have missed success except in a negative way so that that particular experiment need not be repeated, are heroes.

Just a word on consent for those incapable of giving consent. Where the parent of a child refuses to allow treatment essential to save his life, the doctor cannot act. In some cases the matter has been brought to the court on the theory that the parents are not providing for the child. The child is declared a ward of the court, and the court can then give permission for the treatment.

We would probably agree that the poor, the aged, the insane, and the feeble-minded should not be guinea pigs for experimentation. Reasonable experiments to improve their condition under the rules laid down should be approved. Prisoners can usually give consent, but in all such cases great care should be taken to make sure that consent is not coerced.

IV. Civil Rights of Military Personnel Regarding Medical Care and Experimental Procedures

W. H. Johnson

Judge Advocate Corps, United States Army

THE RIGHT OF MILITARY PERSONNEL to refuse to submit to medical care and the limitation of their rights to volunteer or consent to experimentation in the medical field

present several questions. It is obvious, of course, that a soldier has the right, the same as any other individual, to submit voluntarily to medical care provided by the military establishment for the purpose of cor-

recting any defect or curing any ailment with which he is afflicted. The important question, which is most germane to this discussion, is whether the military authorities can require him to submit to medical treatment for such defect or ailment, regardless of his choice in the matter. We all know that a civilian need not submit to medical treatment unless he so desires.

Paragraph 24, Army Regulations 600-10, 10 November 1950, provides that persons in the military service who refuse to submit to medical or surgical (including dental) operation, treatment, or diagnostic procedures will be examined by a board of three medical officers, and if, in their opinion, the operation, treatment, or diagnostic procedure advised or recommended is necessary to enable such a person to perform properly his military duties, and that the treatment will have such curative effect, the patient must consent to the treatment or be subject to disciplinary action, including trial by court-martial if warranted under the circumstances. All such cases must be referred to the Surgeon General for consideration and review prior to the institution of any disciplinary action.

The reason for the distinction between the civil rights of civilians and military personnel under such circumstances is, of course, based upon military necessity. Not only does a person in the military service have the responsibility to take all reasonable measures to remain physically qualified for duty, but it would be grossly unfair, particularly in time of war, to allow personnel to be relieved of service in the Armed Forces because of a physical defect that could be completely cured by operation or treatment.

Although cases arising in this field are rare, the Judge Advocate General of the Army has been called upon to render opinions in some instances. In order to understand fully the safeguards which, by judicial opinion and decision, are afforded to military personnel in this situation, it may be interesting to review briefly a few of the decisions:

1) In GCM 120385, it was held that inoculation or vaccination is not such "medical treatment" as is contemplated by Army Regulations, and refusal by military personnel to submit to this form of treatment is an offense under military law, without the necessity of obtaining the opinion of a board of officers or reference of the matter to the Office of the Surgeon General. It was stated that inoculation and vaccination are preventive measures for the protection of the health not only of the soldier himself, but of others, and are expressly required of every person entering the service.

2) In GCM 121820, a soldier was convicted for refusal to submit to a surgical operation for goiter. In reviewing the record of trial, the Judge Advocate General held that the evidence was legally insufficient to sustain the conviction because the accused was in a state of nervous instability, excitement, and fear resulting from pathological conditions arising from his ailment, and that it would be unjust in the last degree to punish the accused for declining to submit to an operation, when the very diseased condition from which he was suffering caused him to refuse to submit to treatment.

3) In GCM 125224, the accused was convicted by court-

martial for refusal to submit to a surgical operation known as vesiculotomy. It appeared that the operation consisted of a particular kind of draining first used many years ago by the officer who recommended it in this case, and used to some extent by other physicians. It was not shown, however, that the particular operation or any similar operation had been universally accepted by the medical profession as a cure for the disease from which the accused was suffering. In determining that the conviction could not be sustained, the Judge Advocate General based his opinion on the fact that the regulation contemplates, as far as major operations are concerned, only those so thoroughly tried and generally used by the medical profession that they have definitely and finally passed the novel and experimental stages, and have been accepted as standard operations in surgery. Not only must this requirement be clearly met, but it must also be shown that such an operation is generally recognized by the profession as being a cure for the particular disease with which the subject of the operation is afflicted.

4) In GCM 156980, the Judge Advocate General stated that, to support a conviction of having refused to submit to certain medical treatments prescribed by the attending surgeon and alleged to have been necessary and without risk to the life of the accused, there must be evidence that the treatment was, in fact, necessary to make the accused physically fit to perform his military duties.

5) In a court-martial case arising during World War II, a soldier refused to submit to certain dental treatment, including oral surgery, for an ailment the existence of which rendered him unfit for overseas or combat duty. The board of officers concluded that the operation recommended by the attending surgeon was a very simple procedure, universally accepted by the profession as a cure for the condition of the accused. In sustaining the conviction, the Judge Advocate General held that all requirements of the regulation had been complied with, the operation was one universally accepted by the profession as a cure for the ailment, hence the accused, as a person in the military service, had committed an offense against the Articles of War in refusing to submit to the treatment.

Briefly summarized, I think the foregoing regulations and decisions thereunder require military personnel to submit to medical treatment for existing ailments that render them unfit for further military service, provided: (a) the board of medical officers convened pursuant to the regulation and the Surgeon General concur in the diagnosis; and (b) the treatment or operation is one generally accepted by the profession as a complete cure for the ailment or disease with which the accused is afflicted.

The right of military personnel to volunteer for experimentation on themselves is a field in which few, if any, actual precedents exist. Paragraph 12, AR 600-10, reads as follows:

There are limitations upon the activities of officers and other personnel subject to military law. The general principle underlying such limitations is that all members of the Army Establishment, when subject to military law, are bound to refrain from all business and professional activities and interests not directly connected with their military duties which would tend to interfere with or hamper in any degree their full and proper discharge of their duties or which would normally give rise to a reasonable suspicion that such participation would have that effect. Any substantial departure from this underlying

principle will constitute conduct punishable under the Uniform Code of Military Justice.

Although this paragraph does not specifically refer to the exact topic under discussion, it is, nevertheless, sufficiently broad in its terms that I believe it is safe to say that a soldier is prohibited from consenting to any form of experimentation upon himself which would "interfere with or hamper in any degree his full and proper discharge of his duties, or which would normally give rise to a reasonable suspicion that such participation would have that effect." Although this would not necessarily be considered "misconduct" on the part of military personnel, it certainly would be considered "not in line of duty" if undergoing such experimentation incapacitated the man in any degree for the performance of his military duties. As a practical matter, questions of this kind are considered in Army terminology as "matters of command." I mean by this that it is possible for military personnel who voluntarily desire to undergo experimentation upon themselves to obtain permission from competent authority with assigned powers to grant such requests. As a matter of fact, we are all cognizant of the results obtained by Walter Reed in Cuba in the early 1900s when, assisted by volunteer military personnel, he was able to determine the cause of, and initiate successful preventive measures in, the yellow fever epidemic. That comparable experimentation and research in various fields are continuing at this time is apparent.

The Department of the Army has issued Special Regulation 70-30-1 24 January 1949, Subject: Research in Human Resources and Military Psychology. This regulation sets forth the interest of the Army in basic and applied research in the field of human resources and military psychology, and attempts to establish organizational policies and responsibilities for supervision, official channels of communication, and coordination for such programs. The regulation identifies the responsible agencies in the military establishment and the fields of interest in this subject. Authority is granted to contract with responsible agencies for research after study at Department of the Army level determines the necessity and probability of the results to be achieved.

The fields of research enumerated in this Special Regulation, for which the Medical Department is designated as the responsible agency, are as follows:

- 1) *Psychophysiology and psychopathology*
 - a) Sensory discrimination and perception
 - b) Psychomotor functions and motor skills
 - c) Biomechanics and human engineering
 - d) General and special organic conditions (including tension, shock, deprivation, motivation, emotions, fatigue, sleep, glandular conditions, and nutrition)
 - e) General and special environmental conditions (including temperature, humidity, ventilation, noise, etc.)
 - f) Analysis of adjustment levels and mental disorders for purposes of prevention, diagnosis, therapy, and rehabilitation

2) *Training research*

- a) Adjustment and rehabilitation methods (including personnel counseling techniques, psychotherapeutic methods, and the sociopsychological rehabilitation of the physically handicapped)

All proposals for research projects in these fields that are of Army-wide interest will be transmitted to the Office of the Surgeon General for allocation. Initiation of, or contracting for, such projects will take place only after study and authorization by the Medical Department, and with such coordination and authorization as directed for the purpose of proper allocation, and for the achievement of the necessary balance between research and development programs. Every effort will be made to set up a strong and well-integrated program of research in human resources and military psychology.

Although this regulation is, of course, primarily concerned with fields of research and experimentation in which the Army is interested, it also indicates that, if such a program involves experimentation on the human body, authorization for the use of volunteer military personnel as subjects could be obtained. Needless to say, the Medical Department would not receive volunteers in this field if it considered the experimentation unduly hazardous or unnecessary.

One project in this field, which has been approved by the Medical Department of the Army and is now in operation, is treatment, experimentation, and research in burn cases. The procedures implementing this program, set forth in a recent circular from the Surgeon General's office, can be summarized as follows:

1) A burn study project was established approximately two years ago at the Surgical Research Unit, Brooke Army Hospital, Brooke Army Medical Center, Fort Sam Houston, Texas. It is expected that this project will be continued and expanded if adequate numbers of cases are available for study. Cases suitable for study are considered to be those severe burns in excess of 10 per cent of body surface involvement. The facilities available at Brooke Army Hospital for the treatment and study of these cases are outstanding.

2) Accordingly, severe burn cases may be transferred to Brooke Army Hospital for observation, treatment, and study when it is determined that they are transportable and are appropriate cases for treatment at that hospital. In the interest of expeditious movement of these patients, direct communication with the Commanding General, Brooke Army Medical Center, is authorized to determine availability of a bed and whether the case is appropriate for transfer. After concurrence for transfer has been given by the Commanding General, Brooke Army Medical Center, transfer may be made as an emergency case, without prior authority from the Armed Services Medical Regulating Office. The Armed Services Medical Regulating Office will be advised of action taken by the transferring hospital in all such cases. A special research team at the Surgical Research Unit, Brooke Army Hospital, is available for dispatch to any hospital in the United States to aid in the early treatment of burn cases, and to advise hospital commanders on the trans-

portability of such cases. To obtain this team, hospital commanders should telephone or telegraph the Commanding General, Brooke Army Medical Center, Attention: Director, Surgical Research Unit. In order to provide for proper selection of cases for research and to make available the aid of highly qualified personnel of the research group, the Director of the Surgical Research Unit should

be advised of the admission to any Zone of Interior Army hospital of all severe burn cases at the earliest practicable date. The importance of early notification cannot be emphasized too strongly.

3) Each case will be considered on an individual basis, with the welfare of the patient being the basic consideration as determined by sound professional judgment.



News and Notes

Scientists in the News

James G. Baxter has been appointed assistant director of research in Eastman Kodak Company's Distillation Products Industries Division. Dr. Baxter has been with Kodak since 1934, and in the 1940s he and his assistants prepared the first pure crystals of vitamins E and A.

David D. Bonnet has been appointed associate research entomologist, Department of Infectious Diseases, School of Medicine, UCLA, where he will be in charge of the Mosquito Control Program of the Pacific Tropic Diseases Project directed by John F. Kessel. Dr. Bonnet was formerly medical entomologist, Department of Health, Territory of Hawaii.

Dean A. Clark has been appointed clinical professor of preventive medicine at Harvard Medical School, where he will instruct students in preventive medicine, and in the social aspects of medicine and medical economics. Dr. Clark will also continue as general director of the Massachusetts General Hospital.

Charles S. Davidson has been appointed associate physician in the Thorndike Memorial Laboratory, Boston City Hospital, and associate professor of medicine, Harvard University. Dr. Davidson's research has centered on nutrition and diseases of the blood and liver, and he has been on the staffs of the university and hospital since 1941.

Robert J. Ferlauto, director of the Microbiological Laboratories of Smith, Kline & French, has been named associate director of development. He will be in charge of exploratory and specialty development, taking over the duties of **Robert H. Tully**, now on active duty with the Army Medical Corps.

Rowan Gaither, Jr., has been appointed acting president of the Ford Foundation, and will direct the work of the foundation until the election of a successor to **Paul G. Hoffman**, who has resigned, effective Mar. 1. Mr. Gaither is a San Francisco lawyer, and has been associated with the foundation since 1948.

Charles F. Gregory, orthopedic surgery instructor of Indiana University Medical Center, now on a Korean War hospital ship, has received the Kappa Delta sorority's national award for research aid to crippled children.

Beno Gutenberg, professor of geophysics and director of the Seismological Laboratory, California Institute of Technology, has been selected to receive the William Bowie Medal of the American Geophysical Union, in recognition of his work on earthquakes, seismicity of the earth, geophysics, and the nature of the earth's core.

Nathan O. Kaplan, of Johns Hopkins University, will receive the annual Eli Lilly and Company Award in Biological Chemistry. Dr. Kaplan helped to discover coenzyme A.

James E. LuValle has resigned as research associate at Eastman Kodak Research Laboratories to take a position as project director with Technical Operations, Incorporated, Arlington, Mass. He will direct a project on fundamental photographic theory, under sponsorship of the Chemistry Division of the Air Research and Development Command.

J. Roscoe Miller, president of Northwestern University, and **Tom D. Spies**, chairman of the Department of Nutrition and Metabolism at Northwestern, have been voted honorary degrees by the medical school faculty of the University of Havana. The degrees are in recognition of Northwestern's studies on foods and their relation to health. Others who will receive honorary degrees are **J. R. Killian, Jr.**, **Robert S. Harris**, and **Robert R. Williams**.

Eger V. Murphree, president of the Permanent Council of the World Petroleum Congress, and president of the Standard Oil Development Company, has recently returned to New York from Rapallo, Italy. He had been attending a meeting of the council to discuss the program and to outline the arrangements for the meeting of the Fourth World Petroleum Congress, to be held in Venice, June 1-8, 1955.

Robert Cushman Murphy, Lamont curator of birds, American Museum of Natural History, has been admitted as one of the 25 foreign fellows of the Zoological Society of London.

Bruce M. Pollock has been appointed plant physiologist, Department of Biological Sciences, University of Delaware, to succeed **J. E. Graustein**, who retired Feb. 1. Dr. Pollock was awarded a National Institutes of Health postdoctoral fellowship for 1950-51, and