

ON BEING A HUMAN SUBJECT: INTEREST AND  
OBLIGATION IN THE EXPERIMENTAL TREATMENT OF  
INCURABLE DISEASE

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INTRODUCTION

Many patients with chronic incurable diseases wish to participate in clinical research, yet opportunities to do so are scarce. Like other victims of incurable diseases, these patients feel driven to such measures as unsupervised self-experimentation, enrollment in unconventional treatment programs, and the formation of patient organizations to raise funds for scientific research. In their eyes *experimentation is a legitimate form of treatment* for incurable disease, a form of treatment from which they feel arbitrarily excluded by the medical community and the Food and Drug Administration (FDA).

Until quite recently, most physicians and ethicists dismissed this view of experimentation as irrational. But the regulation of research on human subjects has been weakened dramatically by acquired immune deficiency syndrome (AIDS) patients. The current trend tends to confirm the intuition of those patients and physician investigators who, long before the present turmoil began, concluded that *the ethical obligation to the patient is better fulfilled by extraordinary efforts to achieve a higher quality of consent rather than by restricting opportunities to participate in research*. If this obligation is taken seriously, then physicians and patients with chronic incurable illnesses will be able to find relief from the tensions surrounding experimental participation in the more permissive environment now emerging.

The purpose of this paper is to consider the medical and ethical implications of this changed approach to clinical research for patients with AIDS and other similar diseases. I treat this problem simultaneously from a social and a philosophical standpoint. Too often questions about medical ethics are posed against an unexamined background consensus concerning medical procedures, physician-patient relations, and other institutional aspects of medicine (Lowy 1987,

pp. 597-601). As a result, the philosophical discussion is artificially confined to what can be done within a set of unquestioned institutional constraints. I will argue that many of the problems of experimental participation are actually due to the social structure of modern medicine and are not inherent in the nature of either illness or medical research.

I develop this argument in terms of the concept of "participant interests" in clinical research, a concept which I distinguish from the rights of human subjects. I discuss three bodies of research that are especially helpful for understanding participant interests. These concern:

- 1) the "placebo effect" as an instance of the nonspecific healing power of medical attention and care;
  - 2) the "sick role" in its connection with problems of chronic illness;
  - 3) the ethical significance of collaboration between researchers and subjects.
- But before turning to these matters, I would like briefly to survey the current state of regulatory politics in the domain of clinical research.

#### THE REVOLT AGAINST ETHICAL REGULATION

The welfare of human subjects usually concerns the protection of patients from doctors more concerned with science than humanity. Codes of ethics and philosophical reflection focus on such matters as the patient's right to refuse to lend his or her body for use by others, the right to information about risks, the right to withdraw at any time, the right to treatment for complications arising out of experimental participation, and so on. In 1966 the FDA issued strict regulations on human research and since then the ethical climate surrounding such research has in fact changed for the better (Curran 1969). These regulations were designed to achieve both ethical goals and consumer protection, the first, by protecting the rights of human subjects, and the second, by preventing the sale of drugs lacking scientific proof of safety and effectiveness.

The negative emphasis on rights is understandable, given the origins of our current conception of legitimate clinical research in revulsion against the abuse of patients and prisoners. Yet many chronically ill and dying patients resist protection and seek to enter experimental treatment programs even at the risk of being defrauded or injured by quacks. As the *Report on the National Commission on Orphan Diseases* concluded, "A majority of patients and families are willing to use investigational drugs but find it difficult to locate information on research projects in which they could participate" (p. xiii). Their wishes are systematically ignored. Paternalistic attitudes toward patients, rationalized by concern for their rights, justify dismissing their desire to participate.

After all, it is frequently said or implied, only desperation can explain why a

sick person would want to join a scientific experiment he or she cannot understand and which has little likelihood of offering a cure (Ingelfinger 1972, p. 466; Mackillop and Johnston 1986, pp. 182-83). Hans Jonas writes that "everything connected with his condition and situation makes the sick person inherently less of a sovereign person than the healthy one. Spontaneity of self-offering has almost to be ruled out; consent is marred by lower resistance or captive circumstance . . ." (Jonas 1969, p. 239). Thus what one commentator describes as "excessive ethical fastidiousness" inspires the suspicion that patients are not truly autonomous moral agents capable of making their own decisions (Jaffe 1969, p. 424).

Yet in recent years, it is precisely these "desperate" patients who have provoked a crisis of experimental medicine that promises to change it as radically as did the post-World War II reaction in favor of ethical procedures. The AIDS patients who are bringing this about entered the medical arena at the height of a major political organizing drive in the homosexual community. They were therefore better equipped to resist paternalism than any previous group of patients. Energies mobilized around social and political rights during the preceding decade were turned on the medical system, and networks of patient education and support arose on a scale never before seen in connection with any other disease. The result has been rapidly expanding access to experimental drugs and a drastic weakening of the shield of protections enforced by the FDA and other medical institutions with such pride until quite recently.

The collapse of barriers to the use of unproven drugs occurred gradually under intense political pressure from 1987 to 1989. The initial measures proposed by the FDA included accelerated administrative reviews of AIDS drugs (the "1AA review process"), the public announcement by the FDA of the legality of importing unapproved drugs for personal use, and an expanded program of "compassionate investigational new drug exemptions," or "treatment Investigative New Drugs (INDs)" to make it possible to sell as yet untested drugs to dying victims of AIDS. These measures were all dismissed as electoral ploys by AIDS organizations, a criticism that was perhaps exaggerated for political effect.

Although the new regulations were not in fact very effective in opening access to new drugs, they did tend to shift the burden of proof from drug manufacturers to the FDA, a change noted with concern by Senator Edward Kennedy (Marwick 1987, p. 3020). Kennedy was not wrong about the implications of the FDA's new policy. In June of 1989, the Agency caved in completely and, in conjunction with the National Institute of Allergy and Infectious Diseases (NIAID), instituted a new "parallel-track" drug testing system. Under this system, physicians were authorized to prescribe unproven drugs that had passed toxicity tests just as they would a licensed drug, simultaneously with the regular controlled studies. "If's



a great step forward,' said Dr. Mathilde Krim, a founder of the American Foundation for AIDS Research. 'It represents a new consensus on how to handle drug development for AIDS and life threatening diseases in general' " (Kolata 1989, p. B5).

The FDA resolved the political crisis over AIDS drug testing, but Dr. Krim is certainly wrong to suggest that there is a consensus in favor of the new rules through which this was accomplished. Rather, there is grave concern among researchers about the harm they may do both to patients and to the process of scientific evaluation of new drugs (Marwick 1987, p. 3020; Reidenberg 1987, pp. 599-650). Perhaps even more worrisome than drug company profiteering on unproven remedies at patients' expense is the possibility that scientific research will be crippled by the new system. How can patients be recruited to studies with placebo controls when they can obtain the very same experimental drug with 100% certainty directly through their physician (Goyan 1988, pp. 3052-53)? How can drugs be compared when patients can obtain and use all of them at the same time? And how can the results of the rather informal parallel track be rigorously assessed?

These questions appear to be unanswerable today, but the new rules are probably less to blame than they seem to be. In fact compliance among patients in controlled trials was already breaking down before the new rules were issued (Bariaga 1988, p. 485). In the long run, that trend would have had all the dire consequences brought on in the short run by the action of the National Institutes of Health (NIH). The problem is thus not really a regulatory one but is due to a shift in the public perception of the balance between the scientific and the curative functions of clinical research.

That shift will force the research community to rethink the concept of informed consent by bringing it face-to-face with its own unwavering reliance on the absence of alternative access to care and treatment to recruit patients to controlled trials. Medical science must respond to this unpleasant discovery by establishing a new framework for patient education and treatment within which recruiting for controlled trials can compete with the parallel-track. That objective can be achieved, as I will show in the remainder of this paper, only where medicine fully accepts its responsibilities toward patients with incurable diseases.

It would be a mistake to blame our current problems entirely on the AIDS crisis; rather, victims of AIDS are simply saying loud and clear, with political clout, what many patients and a few doctors had been saying for years. The message is simple: the desire to participate in programs of experimental treatment has been unfairly ignored to the detriment of large numbers of mentally competent patients with incurable diseases. These patients argue that exclusion from research diminishes their dignity, harms their physical and mental health

more than would the experimental risks they might undergo, and thrusts them into the arms of unorthodox healers. Medicine has been forced by the AIDS crisis to recognize this desire for experimental participation as a legitimate interest of patients which can no longer be paternalistically dismissed. Science will have to find new ways to adjust to the problems posed by this moral advance, just as it adjusted to earlier limitations placed on research out of concern for the welfare of patients. Then and only then will the consensus to which Dr. Krim refers truly emerge.

#### PARTICIPANT INTERESTS

We take it for granted that all interests are represented to some degree in the public debates that determine social policy and law in a democratic society. Yet in the case under discussion here, the expressed wish of a significant number of citizens was systematically dismissed, not so much because they were judged to be wrong as because they were not even granted the right to participate in the discussion in the first place. This sort of injustice may occur wherever wishes are subject to "interpretation" by superiors such as parents or religious leaders, or by professional agents such as physicians or social workers who are credited with the right to define the legitimately constituted "interests" of their clients.

In this case, the agents' conceptual scheme, used to interpret the clients' own self-expression, effectively delegitimized it by emphasizing such incapacitating factors as ignorance and irrational hopes. This example shows that the demands of social groups are not immediately "interests," but become so only through an authorized interpretation of some sort. To recover a voice, the clients had to reclaim that hermeneutic authority through a political movement.

The intrusion of politics into medical policy provokes very different reactions. Those who stick to the dismissive interpretation of patients' demands can rely on the same conceptual scheme to attribute patients' political successes to demagoguery. However, I believe that the mere fact that a dominated group achieves political success signals that a reevaluation of its claims is long overdue. Such a reevaluation is attempted here.

In the new climate of protest, it is sometimes suggested that we ought to reject professionalism altogether and affirm the absolute right of medical "consumers" to select whatever treatment they want (Illich 1976, pp. 252-53). If this were the only alternative to the present system, the case for reform would indeed be weak given the very real knowledge differential between physicians and patients.

But there is another possibility that will be explored here: to preserve professionalism but in the context of enhanced knowledge sharing and patient initiative (Ladd 1980, p. 1128). This approach requires physicians to show a new respect for patients' demand to participate in research. That respect might be justified by

eliciting the self-understanding of human subjects in order to refute the usual imputation of irrationality, but sociological studies of clinical research are almost entirely confined to determining the effectiveness of consent procedures.

I cannot fill this gap, but propose instead to outline an alternative conceptual scheme in terms of which it is possible to give a legitimate form, as medicine understands it, to patients' wishes. Elements of this scheme might be tested empirically. I hope that it will also be useful in indicating the most responsible way for medical institutions to deal with demands they can no longer channel in the accustomed manner.

I will argue that the existing regulatory framework ignores important beneficial effects of experimental participation on the welfare of patients. It is this which is responsible for the current crisis and the challenge to professionalism it implies. These overlooked effects belong to the general class of incentives to participate in research, a subject which is treated in the literature with great caution because of the difficulty of distinguishing between positive benefits and subtle forms of coercion (Freedman 1975). The slippery slope leading from compensation to compulsion is most difficult to negotiate in such cases as monetary rewards or shortened prison terms. Ethicists have rarely rejected any appeal to extrinsic rewards; but most commentators insist, with due qualification, on "the right of the volunteer to volunteer" and to receive compensation for doing so (Edsall 1969, p. 476).

In fact, I do not believe these cases to be directly relevant to our discussion, but they must be mentioned because it is sometimes claimed that the hope of cure is a "reward" sought by the sick on the same order as payment by a volunteer. This identification is confusing. To treat cure as a mere extrinsic reward overlooks the tragic dimension of the patient's dilemma in accepting the risks of experimental participation, reduces a moral sacrifice to a mere market relationship, and makes a fool of the patient who dies despite joining a research program.

I will call the specifically health related incentives for patients to participate in clinical research "intrinsic" or "participant" interests. These interests arise naturally in the experimental context and include not only the hope of cure, but also access to physicians, test results, advice, and education about one's condition or disease. The importance of these concerns to volunteers is widely recognized although insufficiently studied. Cassileth found that over half of his respondents gave the desire for the best medical care as their main reason for willingness to participate in research (Cassileth 1982, pp. 968-70). In justifying the parallel-track, Dr. Anthony Fauci of NIAID reportedly said that "many people join clinical trials for altruistic reasons and also to obtain the medical care that goes with participation—even knowing they may not receive the experimental drug" (Kolata 1989, p. B5). In the next section, I will offer a fuller

account of these surprising explanations for patients' desire to participate in research.

A more robust recognition of participant interests would not tell against moral restraint in recruiting poorly informed or incompetent individuals as subjects, nor would it detract from the principal purpose of experimentation, which must be the acquisition of new knowledge. However, within these limits, recognition of participant interests would affect the volume of opportunities to participate and the design of experiments.

Until recently, the supply of places was regulated entirely by scientific considerations without regard for the number of patients wishing to participate. Many physicians and philosophers considered the scarcity of places as a blessing in disguise, since it prevented masses of presumably self-deluding patients from entering the experimental setting with unrealistic hopes. Whether justified or not, this attitude has proven untenable in the face of current protests. Instead of regulating the number of places in terms of statistical minimums required to determine effectiveness, places are now multiplied to serve participant interests.

This point has been made effectively in the political arena but there remains a subtler implication of participant interests that is not yet sufficiently appreciated. Under the assumptions introduced here, experimental medicine has an *obligation* not simply to avoid harm so far as possible, but to serve patients while simultaneously serving science through appropriate experimental design. Certain designs further participant interests, while others frustrate them unnecessarily, independent of the scientific validity of the alternatives. It is a matter of ethics to choose designs and procedures that best serve participant interests within the limits of scientifically sound experimentation.

Thus one AIDS activist rejects "perspectives [on design] categorically de-emphasizing the needs and rights of patients in favor of the primacy of data collection" (Smith 1989, p. 1547). And in response to such concerns, a medical commentator writes that the new FDA regulations create a situation in which "we need to consider alternative study designs that allow the patient maximum hope for cure and the opportunity for some control over his or her destiny" (Goyan 1988, p. 3053).

But the argument must be carried even further once participation in research is recognized as a legitimate form of treatment. It is necessary to rethink the whole structure of care for those classes of patients whose involvement in research can be expected to increase dramatically in the coming years. The fact is that medical institutions rarely accept the heavy responsibility for patient education that could alone give meaning to informed consent. This flaw, which we have so long tolerated in our medical system, risks becoming a source of egregious abuse as access to clinical research broadens to include millions of sick individuals.



## EXPERIMENTAL TREATMENT AS A FORM OF CARE

The key to legitimating participant interests within the professional framework is the determination that clinical research confers a properly medical benefit on subjects. But in the research situation, it is difficult if not impossible to guarantee that the likelihood of cure will outweigh risks. Even in the case of dying patients, where risk is of less concern, cure is such an improbable result of research that it is dishonest to hold up the tantalizing promise of success (Glaser and Strauss 1965, pp. 1098-1100). Thus, while an argument can be made for the generally beneficial character of hope, from a medical standpoint that alone cannot justify the current loosening of controls.

The conflict between patients' desires and their interests as interpreted by most physicians can only be resolved by discovering benefits of participation that are independent of success or failure in achieving cure. That approach in turn implies that medicine has benefits other than cure, a fact attested to by a voluminous literature which shows that patients place at least as great store on the "caring" functions of medicine as on actual healing (Powles 1973, pp. 16-24). *If participation in research were seen as an effective dimension of "caring" rather than as a defective mode of "curing," it could be more easily justified.*

Fletcher and his collaborators found, for example, that what patients most valued in their doctor was compassion and availability rather than technical achievements (Fletcher et al. 1963). Studies of homeopathic and chiropractic medicine indicate that many patients today, especially those with chronic illnesses, seek alternative therapy because they miss these caring benefits in the conventional setting (Avina and Schneiderman 1978; Kane et al. 1974). Dissatisfaction with scientific medicine may be explained by studies which show that the chronically ill are signified negatively in medical culture (Kuttner 1978). Negative attitudes are sometimes signalled to the patients themselves, as in the case of one multiple sclerosis (MS) patient whose doctor reportedly said: "You have multiple sclerosis; don't worry; get a book from the library and read about it; if you have any questions, call me" (Hartings et al. 1976, p. 68).

The importance these studies attribute to "caring" might be taken to mean that patients reject the application of medical technology, but that would be a mistaken conclusion. Compassion is often expressed through the administration of medicine, even when it is known to be of little value. Powles writes that

the almost exclusive concentration, within modern medical culture, on the technical mastery of disease is more apparent than real. For in addition to countering the challenges to human well-being on the biological level, this technology is serving also to meet the emotional and existential challenges that disease involves (Powles 1973, p. 20).

Participation in clinical trials obviously possesses somewhat the same "caring" significance for physicians and patients as the commonplace prescription of symbolically charged but marginally effective drugs. This suggests that clinical trials may be one way in which a highly technologized medical system can care for those it cannot yet cure.

These observations converge with our growing understanding of the so-called "placebo effect," the most *predictable* benefit of experimental participation. If the placebo effect were recognized as a normal dimension of medical care, then experimental participation would fall into place as a form of treatment most particularly suited to patients with incurable diseases. Unfortunately, the very term connotes deception which, even if it is to patients' benefit, reduces their dignity. We seem to have reverted to the dilemma of false hopes vs. medical responsibilities.

But something very much like the placebo effect occurs constantly in medical practice without the deceptive administration of sugar pills or other fraudulent substitutes for "real" medicine. These results are due to what anthropologists call the "symbolic efficacy" of medicine, which is independent of its technical effectiveness and in fact explains much of its value in premodern societies (Levi-Strauss 1966, p. 198).

In view of the widespread role of placebos, Shapiro and Morris accordingly propose the following definition: "any therapy or component of therapy that is deliberately used for its nonspecific, psychological, or psychophysiological effect, or that is used for its presumed specific effect, but is without specific activity for the condition being treated" (Shapiro and Morris 1978, p. 371). This definition suits many aspects of doctor-patient interaction that have a generalized therapeutic effect through mechanisms that are still unclear (Brody 1980, pp. 8-24). In fact, such phenomena are so commonplace there is a risk doctors will confuse nonspecific effects of care with specific effects of drugs and procedures (Shapiro and Morris 1978, p. 397).

Howard Brody argues that since deception is not actually required to achieve the placebo effect, patients should not be deceived to obtain its benefits (Brody 1980, p. 110). Thus, even if the placebo effect is the principal source of benefits to patients in clinical research, that would not justify lying to them about the likelihood of success, or enlisting them in incompetent or purely symbolic experiments "for their own good." The demand inscribed in all codes of experimental medicine that patients be honestly informed and research be scientifically sound stands as before although the significance of the research may be quite different for scientists and patients.

A better understanding of the placebo effect can aid in the design of more therapeutically effective participation in research. Adler and Hammett analyze

the placebo effect in terms of the therapeutic power of "meaning" supplied by a shared "systematic" understanding of disease and social support. They write:

It is suggested here that these two factors—group formation and system formation—which are as essential to psychic functioning as nourishment is to physical functioning, [as] the basic factors composing what is subjectively experienced as a feeling of "meaning," are invariably used in all successful interpersonal therapies, and are the necessary and sufficient components of the placebo effect (Adler and Hammett 1973, p. 597).

Applied to clinical research design, this would suggest that the physician can maximize the beneficial effects of participation by organizing the medical intervention in a "symbolically effective" way to promote "group formation and system formation." These goals should therefore be coordinated with scientific objectives in experimental design. This requirement holds, incidentally, regardless of whether the trial aims to cure patients or merely to contribute to knowledge.

#### THE SICK ROLE

The crisis over AIDS has dramatized two interconnected problems already painfully familiar to many other victims of incurable diseases and their physicians: modern medicine is less and less able to treat patients with chronic illnesses, and it is not designed to deliver experimental treatment. The poor fit between the social structure of the institution, the needs of the chronically ill, and the requirements of research accounts for such problems of experimental medicine as poorly informed subjects, the consequent dubious validity of consent, the interruption of continuity of care on exit from experiments, recruiting difficulties, poor compliance, and so on. These problems can only worsen as the public comes to see the research mission less as a scientific activity than as a dimension of treatment. Ultimately, the survival of the scientific model of the controlled trial is at stake.

These problems suggest the urgent need for reforms in the social organization of medicine. The place to begin consideration of this complex question is the so-called "sick role," one of the foundations of the medical institution. The maladaptation of medicine to the new demands for experimental treatment is due in large part to a definition of the sick role which makes "group formation and system formation" nearly impossible to achieve. This in turn explains why few patients understand the research enterprise well enough to choose to participate freely in it, and hence why researchers have such problems recruiting participants for controlled trials once access to unproven drugs is eased.

Contrary to a commonplace usage, the sick role is not a state of pathological psychological withdrawal. The term was originally introduced by Talcott Par-

sons to define illness in its social aspect as a form of "deviance" involving legitimate temporary release from normal social responsibility in exchange for a sincere effort to recover.

The sick role . . . channels deviance so that the two most dangerous potentialities, namely, group formation and successful establishment of the claim to legitimacy are avoided. The sick are tied up, not with other deviants to form a "sub-culture" of the sick, but each with a group of non-sick, his personal circle and, above all, physicians. The sick . . . are deprived of the possibility of forming a solidary collectivity (Parsons 1951, p. 477).

While these conditions are not particularly onerous for individuals suffering from brief acute illnesses, two of the characteristics of the sick role appear incompatible with the situation of the chronically ill and conflict with important ethical requirements of clinical research. Medical "deviants," on Parsons' hypothesis, must be isolated from each other and must demonstrate a will to health, conditions which are either undesirable or impossible for chronic patients on the face of it.

To accurately describe the actual behavior of sick people, Parsons' model requires some modifications. It is obvious that the provision for conditional exemption from responsibilities has no application to individuals who will never recover. Freidson removes this difficulty by offering an "expanded classification" of illness types which recognizes the unconditional legitimacy of withdrawal from social responsibility in the case of serious chronic illness (Freidson 1970, pp. 238-39).

But the other problem, the social isolation of patients, is quite real and is undoubtedly bad for chronic patients. There is considerable evidence that the chronically ill benefit from contact with others who share the same disease. Renée Fox's classic study of clinical research on such patients shows the overwhelming importance of the shared experience of mission and risk in the experimental setting. Her observations are particularly interesting in the light of the role ascribed to meaning in the previous section. She writes,

Seen in the broadest possible perspective, what we observed in the conference room, laboratory, and on the ward were two groups of men who were faced with common stresses of magnitude: great uncertainty, limitation, hazards, and death. Through a process of interaction with members of their own group and with one another, physicians and patients arrived at comparable ways of dealing with their stresses. . . . Each derived support and guidance from the tight-knit group to which they belonged, and also from their intimate contact and close identification with one another (Fox 1959, p. 253).

While the Parsonian isolation is not always maintained, it remains the norm from which departures such as this only occasionally occur, sometimes against considerable medical resistance (Brossat and Pinell, 1990). Where social contacts



among patients are encouraged, they are in the nature of *ad hoc* adaptations of "standard" care to the needs of "special" patients, usually with a psychotherapeutic alibi of some sort. But the crisis of experimental medicine suggests the usefulness of far more drastic and systematic changes than have so far occurred. The benefits René Fox attributes to the close-knit research group cannot otherwise be achieved, nor when isolated, can patients be properly educated for consent and joined in groups capable of supporting the pursuit of "meaning."

Studies of group activity by patients are rare, perhaps because physicians and researchers are not normally involved. But the application of group therapy to the chronically ill offers a favorable terrain for study. Interestingly, no matter how the therapists conceived and designed their therapeutic groups, the results confirm the need for a fundamental revision in the sick role. I would like to look briefly at three studies that offer excellent reasons to end the social isolation of chronically ill patients. The full implications of this change for experimental treatment will be taken up in the conclusion to this article.

Chafetz and his collaborators noted at the beginning of their group therapy program for victims of Parkinson's disease that self-imposed isolation characterized all the patients, regardless of the severity of their illness, and sometimes beginning immediately on diagnosis (Chafetz et al. 1955, pp. 961-62). Here is the characteristic "sick role" phenomenon as it is frequently interpreted in the literature. Yet these patients quickly opened up in group therapy around the exchange of information about symptoms. They soon went on to share each other's complaints about being mistaken for drunks or blamed for slowness (Chafetz et al. 1955, p. 962). Hartings and his collaborators found that in their groups, MS patients forged a similar common bond through criticism of the medical profession, particularly its slowness in diagnosing their illness (Hartings et al. 1976, p. 68).

The groups were intended to reduce anxiety and depression through therapeutic intervention. In fact discussion remained fairly superficial from a psychological standpoint and achieved the goal in ways the organizers had not always anticipated. For example, Chafetz had not planned to have his group leaders educate the patients about their condition, but education turned out to be one of the patients' chief demands (Chafetz et al. 1955, pp. 963).

Similar experiences are reported by Hartings with MS patients and by Buchanan with kidney transplant patients. These latter groups were formally charged with an educational as well as a psychological mission. "An attempt is made to impart a base of accurate information about MS, so that coupled with an on-going relationship to the Center staff, a patient might more easily resist faddish cures, plan realistically, and feel more in control of his life" (Hartings et al. 1976, p. 66). Buchanan had his group leaders answer questions and invited

medical experts to address the groups (Buchanan 1975, p. 529). These educational activities were very effective in reducing anxiety and fear.

These "system"-forming consequences of group therapy were complemented by properly social effects. When patients form a "subculture" through voluntary association, they supply each other with social support, a more and more widely recognized factor in maintaining health (Nuckolls et al. 1972). That the benefits of the groups had less to do with psychological therapy in the usual sense of the term than with the reform of the sick role can be seen from the following descriptions of the typical course of discussions.

Minimization of the severity of symptoms of colleagues and reassurance that all were suffering similar impairments was one method of group self-support. Another was through identification with famous people who had continued to function successfully in spite of their illness. The emphasis on research in the clinic, which carried over as one of the purposes of the group, provided tangible proof of interest in them and in the course of their disease (Chafetz et al. 1955, p. 962).

Going still further, Hartings' groups formed an incipient voluntary health agency:

Patients have generated helpful activities of their own. They publish a Newsletter four times a year and disseminate information on financial resources, recreational and cultural opportunities, new equipment, tax benefits and insurance, helpful hints for day-to-day living, good books, etc. Staff have encouraged these individuals to experience and exercise their power and ability to change adverse situations in helping one another (Hartings et al. 1976, p. 73).

The patients made friends in all the groups and desired continued interaction, requesting further meetings even a year after the end of Chafetz's experiment, but the organizers concluded for reasons they do not explain that "the advantages of more protracted groups are questionable" (Chafetz et al. 1955, p. 963). Like Chafetz, Buchanan also favors a time-limited approach (Buchanan 1978, p. 426). These researchers appear to want their patients to return to the conventional sick role as soon as possible despite the latter's interest in innovating new relationships.

Hartings was more accepting of patients' demands that the groups continue, an outcome that seems appropriate given the manifold functions they performed for their members. It is on the basis of these functions and the new sick role they define that we can build a collaborative model of care for the incurably ill. As can be seen from the examples discussed above, this model offers a variety of improvements in the situation of such patients including a more favorable environment for responsible experimental participation.

## THE COLLABORATIVE MODEL

From an ethical standpoint, the chief danger in the new regulations is the possibility that vast numbers of uncomprehending patients will be recruited into experiments they would never have joined had they understood the implications of participation and felt really free to refuse. Studies tend to support Ingelfinger's fear that "the process of obtaining informed consent with all its regulations and conditions is no more than an elaborate ritual, a device that, when the subject is uneducated and uncomprehending, confers no more than the semblance of propriety on human experimentation" (Ingelfinger 1972, p. 466). The sad truth is that most "patients consent to trials simply because they trust their doctors" (Mackliopp and Johnston 1986, p. 187).

There is some evidence that this pessimistic conclusion is less applicable to the chronic patients with whom we are concerned here. One study reports "striking differences" in the management of their own care by acute and chronic sufferers (Lidz et al. 1983, p. 542). The former tend to deliver themselves over to the physician unreservedly while the latter often participate actively in decisionmaking, discussing options, and suggesting or rejecting treatment alternatives. The study relates these differences in behavior to the different attitudes of acute and chronic patients toward the conventional passive sick role. The authors conclude that "with certain types of chronic patients and in certain types of organizational structures, an active patient role is feasible" (Lidz et al. 1983, p. 543). These conclusions concur with Szasz and Hollander's suggestion that chronic care involves "mutual participation" of patient and physician in the search for the best course of action (Szasz and Hollander 1956).

Such mutual participation can be routinely observed in the symptomatic treatment of chronic illnesses and in the decisions about treatment during the final weeks or days of life. For example, physicians skilled in managing illnesses such as MS or amyotrophic lateral sclerosis (ALS) learn to listen to patients' discoveries about how to live with their illness and often pass along suggestions from one patient to another. Patients themselves exchange information about symptomatic treatment wherever they have the opportunity to meet. Relief of symptoms has implications not only for comfort but also for life extension, and here too patients and physicians often work together to achieve results that could not be achieved in the conventional physician-patient relationship. Finally, patients who depend on such aids as respirators are increasingly involved in the timing of their own death.

It is in this context that one must evaluate the frequently expressed hope that experimental medicine be carried on in an atmosphere of collaboration between researchers and subjects. This hope, which appears quixotic with regard to the majority of acutely ill patients, may not be so inappropriate in the case of those

patients in chronic care who, having already learned to participate in their own treatment, decide to enlist in research programs. Here in any case is the argument for the collaborative model.

Unlike cure, which is essentially an individual matter, experimental treatment involves joining a collective effort to solve a scientific problem (Parsons 1969, pp. 350-51). Admission to that collective should properly be open only to those who share its spirit, whatever personal benefits they may also expect. In a powerful article on this theme, Hans Jonas argues that for the subject to rise above the proverbial "guinea pig" status in the experiment more is required than voluntary submission to being used.

Mere "consent" (mostly amounting to no more than permission) does not right this reification. The "wrong" of it can only be made "right" by such authentic identification with the cause that it is the subject's as well as the researcher's cause—whereby his role in its service is not just permitted by him, but *willed*. That sovereign will of his which embraces the end as his own restores his personhood to the otherwise depersonalizing context (Jonas 1969, p. 236).

Perhaps a sense of these moral issues motivated the founders of the clinical research center at the NIH when, in 1953, they laid down the following principle for themselves: "The patient or subject of clinical study is considered a member of the research team . . ." (Curran 1969, p. 575). Such identification is an ideal to which experimental medicine does not always aspire and which it rarely achieves. But despite the difficulties, the collaborative model is not utopian. It was followed in the experimental ward studied by Renée Fox. Jean Dausset, discoverer of Human Leukocyte Antigen (HLA) typing, lived up to this ideal in the design of his experiments. He organized an elaborate series of informational meetings and conferences to insure that the hundreds of volunteers he required would understand the enterprise in which they were engaged. Dausset's subjects have been called "*les héros instruits*"—educated heroes—a term which ought someday to apply to all human subjects (Bernard 1978, p. 197).

If such successes are possible, it is necessary to reevaluate the often expressed concern of ethicists that patients suffering from incurable ailments are "coerced" by their illness into agreeing to participate. This position is reasonable if patients are ignorant victims of an experimental process that is likely to yield only knowledge. But it is paternalistic if there are participant interests other than cure. As with ordinary treatment, only the informed patient is qualified to weigh the risks against these benefits to self that are involved in experimental participation. The ethical obligation of medicine is fulfilled not by prohibitions but by insuring that patients are well equipped to make such a judgment.

Among the most important obstacles to this goal is the isolation and ignorance imposed by the conventional sick role, which prevents patients from forming a community within which to receive and extend education and social support. In



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- this context, patients would learn to understand enough about research to appreciate the risks of participation, to gain a realistic idea of the therapeutic prospects, and to understand the usefulness of non-therapeutic experiments and controlled trials. It is reasonable to hope that a sufficient number would come forward willing to aid the research effort despite the increasing availability of unproven drugs. Their participation would be known to their community and their generosity perceived by actual beneficiaries instead of remaining an abstract supposition as it is for most human subjects today.
- How can medical practice adapt itself to the new educational requirements of widespread experimental participation by the chronically ill? It can be done, but not in the context of the usual program of experimental therapy, carried out with little or no associated educational effort, and no long-term commitment to the patients. If the enlargement of opportunities for experimental participation is to be a blessing rather than a curse, it will be necessary to make innovations in the delivery of chronic care and clinical trials. Fortunately, the chronically ill are uniquely qualified to contribute to the creation of a new framework. Given their active orientation toward care and their positive attitude toward group activities, educational programs can be established by and for these patients to prepare them for participation in research.
- Two basic desiderata can be identified:
- *to remove all pressures to participate*: implementing clinical trials in the context of a program of continuing symptomatic care and support for patients that does not require their experimental participation and that is not tied to the duration or success of experiments;
  - *to insure adequate understanding*: systematically using patient meetings to prepare patients to understand their disease, the role of human subjects in research, and the experimental options.
- A trend in this direction has been slowly emerging. Perhaps the crisis brought on by AIDS will finally result in the institutionalization of an alternative system of care for chronically ill patients based on a redefinition of the sick role and recognition of the educational functions of medicine. Instead of being mere objects of medicine, awaiting cure, patients might then become active partners in a larger research enterprise.
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