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PROTECTION OF HUMAN SUBJECTS AND PATIENTS: A SOCIAL CONTINGENCY ANALYSIS OF DISTINCTIONS BETWEEN RESEARCH AND PRACTICE, AND ITS IMPLICATIONS

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[2]Prepared under contract with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, January, 1976. The Commission is required, under section 202 (a) (1) (B) of the National Research Act (P.L. 93-348), to consider "the boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine."

The charge to the author was to "prepare an essay on the usefulness of intent as an operational concept for distinguishing between research and practice [and to] relate intent to other possible distinguishing criteria such as: degree of innovation, predictability of outcome, formality of the contractual relationship, requirements for disclosure and informed consent, payment for services, and pragmatic impact on the patient/subject."

The title of the paper submitted to the Commission reflects this charge: "On the usefulness of intent for distinguishing between research and practice, and its replacement by social contingency analysis: implications for standard and innovative procedures, coercion and informed consent, and fiduciary and contractual relationships." The author is grateful to the Commission for the papers made available to him. These suggested to the author that the "routine practice" to be considered be broadened to include treatment modalities other than medicine, e.g., behavioral, correctional, and educational. It will be noted that the Commission's research mandate extends beyond the biomedical modalities to include behavioral research. Accordingly, parallel consideration of treatment seems to be required.

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Advances in biomedical and behavioral research have aroused public concern in at least two areas. These are the social implications of the advances and the human means necessary to produce them. The present discussion centers on the latter, specifically as it

relates to human experimental subjects undergoing experimentation and human patients undergoing treatment. In both cases, there is professional manipulation of outcomes, which can contribute to advances. Nevertheless, a commission has been established to consider the protection of subjects, rather than patients, or than both.

If there are distinctions between the two areas, as is implied by the Commission's mandate, then there are at least three reasons to make them explicit. First, such distinction is necessary if the scope of deliberation by the Commission is to be defined. Second, such distinction will tend to curtail expansion into one area of controls properly directed at the other. In legislative terms, in the absence of clear distinctions, rulings directed specifically at, say, experimentation, may come to be extended to treatment, and rulings which specifically exclude treatment may come to exclude experimentation. Third, if meaningful distinction is not possible, there may be repercussions far beyond these, given the present social climate. Reports of abuse of human subjects have occasioned the present scrutiny of the means for such abuse, which adhere to experimentation. If treatment is indistinguishable from experimentation, then the same means for abuse are also inherent in treatment. Accordingly, whatever social winds sweep at experimentation will also sweep at treatment. Indeed, Senate hearings (Hearings before the Subcommittee on Health, 1973) on S. 974, training in "implications of advances in biomedical research and technology;" on S.J. Res. 71, evaluation of implications of such advances; and S. 878, "provision of restrictions on funds for experimental use" are published under the title *Quality of Health Care – Human Experimentation 1973*. In addition to not being immune from incorporation into the questioning of research, the routine and accepted practice of medicine is becoming routinely less accepted on its own, as suggested by the rising cost of malpractice insurance and the increasing scrutiny represented by books such as *The End of Medicine* (Carlson, 1973).

That the distinction between practice and research is not self-evident derives in part from the fact that research is often performed in the context of treatment: the person who is a patient may at the same time be a subject in a biomedical or behavioral experiment. Indeed, much of the research upon which advances in treatment often depend can be conducted only under such circumstances. Even when practice and research are separated, it seems to be generally accepted by reviewers that treatment is often indistinguishable from experimentation. Thus, Beecher states that "whenever the physician tries out a new drug or a new technique . . . he is experimenting in his effort to relieve or cure the individual involved" (1970, p. 83) but this is extended to "every medical procedure, no matter how simple or accepted," by Ladimer. Treatment "is an experiment since it is applied in a new context each time" (1963, p. 190). F. Moore expands this into several experiments in the course of one treatment episode: "Every surgical operation is an experiment in bacteriology," he states, and is simultaneously an experiment "in the pharmacology of anesthetic drugs . . . in the conformity to anatomical norms, and often in the biology of malignant tumors" (1975, p. 15). Levine's overview is indeed apt: "Even a superficial exploration . . . will reveal the impossibility of describing mutually exclusive subsets (one called research and one called practice)" (1975a, p. 1).

In both cases, manipulations derive from systematic approaches; the intervention procedures used and the results obtained are recorded; these are evaluated in terms of baselines, basal measures, or other norms; the interventions are subject to change

depending on their outcomes. Other similarities exist. Given the social importance of distinguishing the two subsets, and given the overlap between observable behaviors, the use of a subjective unobservable to distinguish the two is understandable. The history of psychology is replete with the introduction of such terms to distinguish between processes which it is important to separate, but which the verbal-observational system in use does not permit. (As will be noted, the history of psychology also reports correctives.) In this case, the "taxonomic" function is assigned to *intent*. Thus, regardless of overlap between procedures described, they are classified as treatment where there is "therapeutic intent," and as experimentation when the professional's "motive is indirect benefit to society, not benefit to the patient" (Blumgart, 1969, p. 252). And this holds even if the patient benefits thereby; conversely, if the professional "believes (even if only on the basis of advertising) that [the treatment] will do the patient good, then he is acting as a physician," presumably even if it does him no good (Edsall, 1969, p. 466). The general opinion is summarized by Levine: "If a physician proceeds in his interaction with a patient to bring what he considers to be the best available techniques and technology to bear on the problems of that patient with the intent of doing the most possible good for that patient, this may be considered the pure practice of medicine." (1975a, p. 6). He reports a second system of classification, namely, a group acceptance or approval, presumably of a particular procedure as treatment. The two systems can conflict, as when a physician uses a new drug with the intent of doing the most possible good for the patient, while this drug has not yet been approved for "safe use" in such cases by a procedure-accrediting group — here, the Food and Drug Administration (1975a, p. 11). Intent would then be overridden. In such situations, research would be defined by efforts deriving from an intent to distinguish between classes of patients for whom a treatment should be approved or disapproved, since the intent is to provide generally useful information. Treatment would be restricted to the use of the procedure, when approved, with the intent of doing the most possible good for a particular patient.

Undoubtedly, there are differences in intent when research or treatment is undertaken, and subjects and patients do have different expectations. While these differences may be along the lines noted, it would seem that intent is a rather slender reed upon which to build public policy, especially where issues as important as those noted rest upon this platform. That intent is used in its subjective sense is made clear by Levine's quotations from the dictionary, e.g., "the state of mind or mental attitude with which an act is done" (1975b, p. 2a). The question arises of how one ascertains intent or, more properly, ascertains individuals' "state of mind or mental attitude" in the performance of their acts, or in their "concentra[tion] on some end or purpose" (ibid.). The definition of someone's intent through consensus by experts is no more valid than such assignment by a single person and, ever since Freud, at least, we have learned to question even self-assignment of intent, no matter how sincerely or tenaciously held.

Subjective terms such as intent, expectation, desire, motive cluster around a common core close to the subjective dictionary definition noted. They may be used in several ways, among which are the following: (1) *Subjective*: The terms are used with reference to this common cluster. Specifically, research and treatment are distinguished by differences in intent and expectations (Ladimer, 1963, p. 192). This usage imposes the validational difficulty noted, with its attendant problems for social policy. (2) *Indicator*:

The subjective terms may be considered as indicated by clearly stated relations between explicit sets of procedures, called *indicators*. The indicators do not define the subjective processes, which are independent of them. Specifically, the different monetary exchanges in research (professional pays subject) and treatment (patient pays professional) stem from differences in intent; they may indicate the existence of such differences but do not define them (Levine, 1975b, p. 8a). Although the indicators may be readily defined, the validational difficulty of the referent remains, as do the social consequences noted. (3) *Operational*: Terms with an originally subjective meaning may be used as a metaphor or simply as a convenient label for clearly stated relations between explicit sets of procedures, which define the terms. Specifically, research intent is defined by certain stipulated procedures, and treatment intent by yet others. The terms have no other properties. This is the most familiar form of the operational definition. It couples clarity and ready validation with what is often the exclusion of the area of concern. (4) *Operant contingency*: The social importance attached to subjective distinctions may be considered as representing important differences in social and personal consequences which are *contingent* on the behaviors which are occasioned by the systems discussed. Specifically, if differences in intent are consistently used to separate research and treatment, this may derive from important differences in the social and personal consequences contingent on behavior in the two institutions.

Overlap between many of the behaviors in the systems necessitates the introduction of a classification system other than behavior. This can be intent which, unfortunately, leads to validational problems, since it is unobservable. However, the alternative classification system can also be the operant (as opposed to operational, cf., J. Moore, 1975) contingency, which does not define terms simply by the behaviors, but also by their relation to the consequences differently contingent on them in the two settings. These, too, are observable and can be validated. They fulfill the same logical necessity to which subjective intent is addressed, and may serve the same social functions. The system of analysis, however, is not as familiar as the others, nor has it been used as extensively in discussions of social issues. Accordingly, it can not be referred to as readily, nor stated as simply. The simplest statement, of course, is intent. However, the complexities and difficulties encountered when one tries to apply it meaningfully to matters of social policy suggest that the verbal simplicity provides little help in systematizing the issues to which it is addressed. This drawback is also encountered in subjective definitions of consent (i.e., did the person really understand?) and the coercion which jeopardizes its legal acceptance.

This discussion is addressed to the problem of making explicit the social and personal contingencies to which terms such as intent, coercion, and consent are addressed, in the context of distinguishing research from treatment and, therefore, of distinguishing human subjects of biomedical and behavioral research from human patients of biomedical and behavioral treatment. In the process, I shall note ancillary issues such as the different types of contractual relations involved, as well as some assumptions on which these are based.

The discussion will open with a brief exposition of the analytic system and its commonalities with cognate systems in the social sciences and in law. I shall examine a

legal use of intent as a taxonomic device to apply differential treatments, for the clues it contributes to this discussion.

1. Social Contingencies and Legal Intent

The opening discussion of operant contingencies will be confined to that which is necessary for the later presentation.

The "three-term" formulation of an operant contingency requires that at least the following elements be specified: (1) the *occasions* upon which (2) *consequences* are contingent (3) on *behavior* (cf. Skinner, 1969, p. 7). The term *contingency* refers to the fact that unless the behaviors occur, the consequences will not follow. Another way of stating this is that the behavior is required (if the consequence is to occur) or is a requirement (for its occurrence). The consequence, however, need not follow every behavior occurrence: a fixed or variable number of responses, or a period of no behavior may be required, among others. The event in (1) may be said to occasion the behavior or provide the opportunity for it. Presented in order of appearance, the contingency is described as (1) occasion, (2) behavior, (3) consequence.

Where, given the occasion-behavior-consequence contingency, the behavior *increases* in likelihood when the appropriate occasion occurs, a *reinforcement* contingency is defined. In positive reinforcement, the behavior-increasing consequence is the presentation of an event. In negative reinforcement, the behavior-increasing consequence is the postponement (avoidance) or elimination of an event (escape). Given occasion-behavior-consequence relations, and the behavior *decreases* in likelihood, a *punishment* contingency is defined. Punishment can involve postponement or elimination of an event (typically, one whose presentation is positively reinforcing), or it can involve presentation of an event (typically the events whose withdrawal is negatively reinforcing).

It will be noted that whether the contingency is defined as reinforcement or as punishment depends on whether or not behavior was increased or attenuated, respectively, and not upon the intent of the wielder. A parent who intends to stop a child's annoying behavior or to prevent its recurrence, and behaves in a manner judged by self and others to be punitive, will be defined as having instituted a reinforcement contingency — if there was an ensuing increase in behavior. If the behavior did indeed cease, this outcome might then reinforce the parent's punitive behavior on those occasions when the child misbehaves. Being punitive is the requirement for obtaining relief.

One last point will be made. Whether or not presentation of a consequence will affect behavior will depend on antecedent conditions which must be specified. Whether food can reinforce behavior depends on the organism's degree of deprivation, upon the cultural definition of that food as permissible or forbidden, and upon still other factors that might be specified. Further, events may acquire reinforcing or punitive properties through their relation to other events. Where the behavior required for reinforcement is an extended sequence of interactions with the environment, each component link in that chain may be considered as an occasion-behavior-consequence link. This consequence derives its reinforcing property from its progressive relation to that consequence for which the whole sequence is required.

The formulations may be used to analyze social relations, and the procedures

developed may be used to change them. When one person is engaged in extended interaction with another or with a system, the behaviors of each may be viewed as occasions and consequences which bracket the behaviors of the other. Each consequence may derive its reinforcing properties from its relation to a consequence at the end of the chain-requirement, or for other reasons.

The relation can be considered in terms of gains for each. The advantage can be considered positive, e.g., obtaining something valued, or negative, e.g., obtaining relief from distress. The relationship can be described in terms borrowed from the market-place: there are transactions involved, with one person's behavior providing the other with something valued, and the other providing something valued in return. In its original usage (before its corruption by psychotherapists), transactional analysis referred to such relationships, often involving extended verbal intercourse. The descriptive metaphor may be a barter system, with exchange theory being the model. Decision theory may be viewed as a related development. A decision requires at least two well-defined sets of behavior, which intersect with at least two states of the environment. A 2 x 2 matrix is thereby defined, with the entry in each being the consequence of that behavior under the particular environmental occasion. All four consequences must be considered, in accord with some decision rule, and the analysis often consists of ascertaining which decision rule rationalizes the empirical data obtained, that is, which provides the best fit. It will be noted that where the states of the environment, present or future, are unknown, there is risk attached to either behavior, since the consequence may or may not be a gain, depending on the state of the environment. Cost-benefit analysis also considers the consequences which are contingent on behavior, but in contrast to the decision model presented, in which either of two consequences is contingent on behavior (depending on the occasion), in cost-benefit analysis, at least two consequences are often both attached to the same behavior.

Each of these models covers overlapping terrain, and also considers variables not considered by the others. Differences in metaphors — that is, the languages they use and the concepts they relate these to, as well as differences in variables considered — derive from the different requirements of the academic disciplines, e.g., transactional analysis in anthropology, exchange analysis in sociology, decision theory in economics, and operant contingency analysis in the conditioning laboratory, from whose requirements much of the terminology and procedures derive. Differences in terminology and metaphors have tended to restrict communication between models. Where a model has been applied to a discipline other than its origin, it has often led to bursts of progress (e.g., decision theory applied to perception and clinical decisions), since it contributes procedures which are new to the adopting discipline. Although the language has often been subjective, e.g., participants have expectations, they make decisions, they hope or intend to optimize net gain, what makes the adoption useful is the procedures for analysis it provides. I shall consider the relevance of such procedural analysis for the analysis of legal intent.

It would be surprising if the legal system, faced with decisions which have social consequences, had not come up with similar procedures. Where power over life, liberty, and property is involved, the consequences of definitions in terms which are open to a variety of interpretations in practice, and in terms which are quite specific and limited,

can be markedly different. For example, Currie (1968) attributes differences in the number of witches executed in Renaissance Europe on the Continent (500,000 estimated executions) and in England (less than 200) to differences in the stringency of the definitions of witchcraft applied by the different legal systems, and to the different consequences of conviction to the accusing system. Intent, as noted, is a difficult term to define. I shall consider its legal use in *mens rea*, or criminal intent, specifically with regard to intent to commit murder.

Wexler, a legal scholar, notes that "the law is ripe for contingency analysis" (1975, p. 174) and that such analysis "can help to clarify the definitional and evidentiary aspects of hazy and imprecise legal concepts" (p. 175). He also notes that previous attempts "to purge the penal law of the concept of *mens rea* ('criminal intent') ran head-on into numerous obstacles and objections" (p. 175). However, as was discussed, there is a difference between the operational definitions associated with classical behaviorism and the operant contingency definitions associated with radical behaviorism (Skinner, 1974).

Two types of contingencies will be noted which are related to the statement that someone "did willfully and knowingly intend" to commit murder and then carried out his intent. The first contingency to be discussed defines the intent which distinguishes first degree murder. The second defines the social consequences contingent on differentation of murder by intent and other types of killing.

1. Intent defined. Three things are involved here: motive, opportunity, and means.

Motive is defined by the consequences of the act. A victim is found dead in Trenton with a bullet hole through his head. If it turns out that a nephew is bequeathed $50 million as a result, the nephew is considered as having a motive. The French maxim, "Cherchez la femme" suggests a prevailing consequence (motive) in that society.

Opportunity. This is where the alibi enters. If the newphew was in San Francisco at the time, he may not be as likely a suspect as if he had been in Trenton, in the neighborhood of the crime, at the time. He will then be a suspect.

Means. The nephew has recently purchased a carbine, has practiced, and the murder bullet was .30 caliber; the nephew reports that the rifle had been stolen the week before.

The nephew is the prime target, and the state will make every effort to demonstrate that the means was probable behavior. He may be indicted and, despite his strenuous denials, a jury of his peers may find him guilty of murder with intent, that is, first degree murder.

It will be noted that the three-way operant contingency discussed earlier is considered to be present: opportunity, consequence, behavior. Intent is thereby defined.

2. Social necessity. If the uncle is killed in what appears to be a traffic accident, and the driver had no motive, the law will treat this differently. If, in addition, the driver had exceeded the speed-limit, the law will treat this yet differently. If, in addition, the driver was fleeing the scene of a robbery he had committed, this will be considered the equivalent of first degree murder. To the immediate family, the results are operationally the same: they have lost a beloved member of the family. He is just as dead in each case, including the murder case. The law will not bring him back, yet it treats the killings differently.

On (a) the *occasions* of the offenses cited (b) the *consequences* for society (c) of classifying the offenses in actionable categories must be considered in accord with a

particular social policy. Inspection of the offenses, classes established, and social consequences suggests what the policy may be. With regard to the intent-to-kill contingency discussed, societies apparently abound with people whose elimination would be useful to other people. Societies also abound with earnings which may be obtained by theft and other felonious behaviors. Both the temptations and behaviors which yield to them are prevalent. In addition, the behaviors are amenable to social control. Accordingly, the law intervenes to decrease the likelihood of these behaviors by threatening its most drastic punishment, and applies the general term "first degree" killing. However, to paraphrase La Place's maxim on the improbable, accidents allow themselves the luxury of occurring. No legal sanctions can prevent them from occurring, so the law will not apply its deterrent. A component of social policy may be inferred from the discussion, namely, that severity of consequence be directly proportional to its efficacy in decreasing the likelihood of the offense. The more effective the punishment on behavior, the more severe it should be. Another component of social policy may be inferred from the different punishments attached to killing when the speed limit was exceeded or when a felony was committed. Both speeding and felonies may be amenable to control by social deterrents, but the offenses differ in a variety of ways, including prevalance, and the likelihood of general damage to the social fabric. The presence of yet a different component is suggested by *lex talionis* (e.g., a life for a life), whereby the severeity of the legal consequence is governed by the general severity of the offense. Here, all types of killing might be treated similarly.

No pretense is made that the discussion is exhaustive; the writer is a legal layman. Nevertheless, the two contingencies presented suggest that legal resolution, although often couched in subjective terms such as intent (coercion and consent will be considered later), is amenable to contingency analysis and possibly was formulated in that accord. It was noted earlier that various social disciplines have almost independently developed forms of contingency analysis and there is no reason to assume that this is not the case for law. It is of interest that decision theory, a system of complex contingency analyses, employs, as does the law, subjective metaphors to label its components, e.g., a decision is made, a strategy is followed, it may be governed by its expectations. The terms, however, are names for explicit procedures and explicit formal (mathematical) relations between procedures and data. *The bases for classification are the observables and their relations, and not the subjective designations given them*, nor, for that matter the dictionary definitions of the designations.

Nor should it be assumed that the contingencies presented are those which actually occur. Only a careful fine-grain analysis of the actual workings of each system can indicate what contingencies are actually operating in that system, as opposed to those which "should be," as defined ethically or as stipulated by its empowering group or by its own members. The contingencies presented are purely heuristic, and service to suggest some necessary considerations for social definition.

Contingencies of classification of social activity

Assuming that contingencies are employed in classification (if human behavior is under consideration, such contingency analysis is suggested since it is sensitive to

influence by consequences) the discussion suggests that at least *two* social contingencies are required. One is the particular contingency which defines the class to be treated. The other contingency governs the specification of a classificatory scheme, whereby the first contingency is distinguished from others in the scheme.

A variety of classificatory schemes can be proposed, each of which can be stated as a contingency. The social policy which affects the choice of one rather than the other should be made explicit. A parallel is found in decision theory where, for the same sets of contingencies, different *decision criteria* or decision goals, are offered (e.g., minimax, maximin, Neyman-Pearson criteria) which set different types of outcomes as acceptable, and thereby require different policies, or *strategies* of choices.

Decision theory may be employed normatively, that is, to suggest strategies which accord with the policy, e.g., if average losses are to be kept below a certain level (minimax), a specified strategy *should be* followed.

Decision theory may also be employed descriptively. For the actual choices and their consequences, the question may be raised as to which decision criterion best rationalizes the data, that is, which best fits the data. This postdiction may then be validated by prediction of experimental or other research outcomes. It should be noted that it is not necessary to assume that the choices were governed by rational intent. Animals have been excellent subjects for decision research. The decision criterion which rationalizes the data is the one which makes the most sense to the analyst, not the "decision maker."

Finally, a discrepancy between socially normative criteria and descriptively inferred criteria may be used to orient programs of change. Indeed, as Gray (1975) concludes, "relatively little consideration has been given to mechanisms or procedures that might help assure that the ideals are achieved" (p. 245). He notes that an institution may set up peer review committees only because consequences such as protection of the institution and a continued flow of research funds are contingent on such behavior. Further, the very review procedures chosen may be those whose consequences are simply to "*appear to meet the official goal*" (1975, p. 46, original emphasis).

Decision theory specifies its requirements, procedures, and outcomes in explicit terms which are related mathematically and are often so defined. Obviously, all of these can not be met — what quantity do we assign a human right or an iatrogenic dysfunction (even if a jury does)? Nevertheless, it may be worthwhile to specify those classes of observations and relations which the theory requires, and consider them explicitly, for policy formulation.

Contingency analysis, as used in decision theory and in operant behavior analysis, would appear to be useful in consideration of social issues and policy. We shall now consider such definitions of treatment and research.

II. Treatment and Research

The first two terms of the three-term contingency which specifically define treatment and research will be considered together since (a) the occasions and (b) the consequences (which will then be contingent on behavior) are defined in terms of each other in a manner to be noted. The third element, (c) the behaviors then required, will be considered separately. The different contingencies for patients and subjects and for their correspond-

ing professionals will be noted in a separate section which will also consider the means-ends differences often assumed to distinguish patients from subjects.

Discussion of the social contingencies and policy which specify a particular classificatory scheme will be dispersed throughout and accordingly will not be restricted to a separate section.

Occasions and consequences in the social definitions of treatment and research

There are interesting parallels between the occasion-consequences relations of the treatment and research systems. These parallels are along lines other than patients and subjects.

In the various *treatment* systems, the events which occasion treatment are individuals (collectives may be considered as such) who present functioning which is less than adequate or which poses problems; and the consequences which maintain treatment are progress toward, and it is hoped, production of functioning which is more adequate than before, for the same individuals. The individual units can be humans who are designated as patients going through a clinical system, as students through an educational system, as trainees through a training system, and so on. The units can be animals going through clinical or training systems. The units can also be automobiles or electrical appliances going through their repair systems. The transmutations in functioning may be designated in terms such as correction, enhancement, innovation, limitation, repair, restoration, and treatment, among others.

In the various *research* systems, the events which occasion research are somewhat systematized and organized statements or related problems, and the consequences which maintain research are progress toward and, it is hoped, better organized statements. The criteria used to evaluate the organization include, among other things, changes in consistency, parsimony, coverage and, for those empirical systems we call scientific, validation by prediction or control. The transmutations along these lines may, like treatment, be designated as correction, enhancement (extension), innovation, limitation, repair, restoration, and treatment, among others.

The changes attributed to the two systems may be described as the *positive* reinforcers of functioning, healthy, or educated individuals in the treatment systems and of better-systematized statements or new knowledge in the research systems. The changes attributed to the two systems may also be described as the *negative* reinforcers of relief from distress or ignorance. Although these consequences whether viewed "constructionally" or "pathologically" (Goldiamond, 1974) are not always produced by the social institutions (n.b., school ineffectiveness), they are considered to be contingent upon their proper functioning, and the consequences (no matter how variable) therefore maintain social support of the institutions. The support can be financial, as in research, or partly financial and partly also in the granting of virtual state monopoly, as in the school systems and medical licensing systems.

This cursory analysis suggests that in the clinical treatment enterprise and in the biomedical-behavioral research enterprise, the patient and the systematic formulation ("Nature") are analogous. The human patient and the human research subject are not analogous in considerations of the two enterprises as enterprises.

Behaviors in the contingencies defining treatment and research

Whereas the differences between occasion-consequences in treatment and occasions-consequences in research seem clear, there is considerable confusion in the literature on differences between the third terms of the contingency, namely, behavior. As was noted in the introduction, "every medical procedure, no matter how simple or accepted" is considered to be "an experiment since it is applied in a new context each time" (Ladimer, 1963, p. 190). Since the outcome is never certain, "all or nearly all therapy is experimental" in this sense (Beecher, 1970, p. 94; cf. Freund, 1969, p. viii).

Where there is uncertainty of outcome, the effort must be considered as a trial or as an attempt whose outcome is to be related to the trial to produce a type of knowledge or inference which is never certain, is fallible, and is therefore subject to change. When one contrasts the certainty of the *a priori* knowledge which derives from faith, the classical distinction between the *a posteriori* knowledge derived from experience and that derived from faith is evident. Indeed, the French word for experiment is *expérience*, defined in my Larousse *Petit dictionnaire* (1936) as "n.f. *Essai, épreuve. Connaissance acquise par la pratique, par l'observation*" as distinguished from knowledge gained through faith. Its specific meaning is "*Particul. Essais, opérations pour demontrer ou vérifier une chose.*" The same term catches the common tentative quality of what English separates as experience and experiment. Indeed, to experiment is given by "*expérimenter, v. tr. Eprouver par des expériences.*" The terms were not always separated in English. The OED reports that in 1382, Wyclif's translation of Genesis xiii, 15 (Revised Standard Version, 1952, "By this you shall be tested") opens "Now y schal take experyment of zou", but in the 1388 edition, it is "Now y schal take experience of zou."

Indeed, if this close linkage makes experiments of all experiences (both are derived from L. *experiri*, to try) then not only does all medical treatment become biomedical experimentation, as we are told, but all sensory experience and knowledge gained thereby becomes experimental. Possibly, this is what Moore was leading up to when he noted that "every surgical operation is an experiment in bacteriology, . . . [in] pharmacology, . . . [in] anatom[y], [in] biology" (F. Moore, 1975, p. 15), for shortly thereafter he speaks of "this basic experimental nature of clinical medicine and, *indeed, of all human intercourse*" (p. 16, emphasis added). Since teaching "is applied in a new context each time," as is serving customers and conversing, these too become experimentation with human beings.

A simple test which distinguishes scientific experimentation from the practices of clinical medicine, routine or innovative, of teaching etc., would be to apply the principle of concordance, in the form of a simple question: Would a group such as the National Science Foundation give research grants in bacteriology, pharmacology, anatomy, and biology for "every surgical operation," for every classroom session, and so on? If the distinction is not clear between the scientific usage of "experimental" and the lay or professional usage of the term, or if the distinction between experimentation and treatment is not clear to any investigator or practitioner who submits a research proposal, these distinctions will be clear after review.

What defines research varies with the discipline, the research strategy, and the review agency or journal, and no definition will therefore be offered here. The peer review

committees of the various granting agencies and the editorial reviewers of scientific journals and agendas of scientific meetings offer sufficient definition. Whether or not a particular project is proposed for such review, its designation as a research project might depend on an affirmative answer to the concordance question, which in this case is put hypothetically, and only to define the behavior.

Whether activity qualifies as acceptable treatment might similarly be defined by peer review, in this case weighted toward post-hoc review. If scientific review is to be used as an example, "track-records" of each practitioner might serve evaluative functions, just as department heads file publications of faculty for consideration of tenure and promotion, and just as grant review committees require such listings and evaluation of quality.

Where committees are institutional, its members are subject to the same contingencies which govern the person under review. Independence is preferable. To assert that the public is best protected by having reviewers who are outside the specialty and are therefore personally impartial misses the point. The critical issue is to ensure independence of contingency control. In areas where specialized knowledge is required it becomes all the more important to build in independent contingencies since the special interest groups being regulated are the ones which possess the special knowledge needed to regulate. Indeed, the history of governmental regulatory agencies shows that they wind up being run by the groups they are supposed to regulate. It should not be assumed that research and treatment will be exceptions. Even where the contingencies governing regulator and regulated are separated, there can be "deferred bribes" — that is, hiring by the regulated once the term of the regulator is up.

The existence of yet a different type of public protection is implied by statements such as "doctors (or other professionals) always stick together." Where the implied consequence of a coverup of a person or agency is protection of a profession or other specialty group, the argument that only such specialists have the evaluative skills may be beside the point. The solution in practice is to have a review group comprising members of other specialty groups. However, this solution of professional impartiality may also miss the point, which is to ensure independence of contingency control.

For research in the context of treatment, if the research is to be meaningful it should meet the concordance criterion mentioned. If the treatment is to be considered acceptable, it should meet the criteria for treatment. Stated otherwise, clinical research should meet both criteria.

The concordance solution may also apply to a practitioner who, having provided acceptable treatment for some time, would now like to go over the records for their possible contributions to science or general treatment. It should be noted that research grants are made for historical and archival analysis, and the research concordance principle would apply to the procedures for analysis, the records available, and so on. If types of patients (students, etc.) and types of treatments selected allow comparisons and facilitate research, the use of intent as a taxonomic device poses a problem, since it may be inferred that choices for treatment were governed by the "intent of developing new knowledge" (Levine, 1975a, p. 6), that is, of research. The procedures are, after all, in concordance with research. If the treatment provided was concordant with treatment, it also meets this test. Selection of patients and treatments is also concordant with treatment, as evident by professional specializations in both patients and treatments;

economic and other selection criteria ("I can't treat that type") abound. Using a particular type of procedure for a particular type of patient is, after all, what diagnosis is about. And if the particular patient-treatment interactions are treatment-concordant, the fact that they are also research-concordant may be the concern of the research review committee.

In all events, now that treatment is coming under public scrutiny, treatment systems might profitably examine the procedures developed by cognate systems governed by similar contingencies, namely, scientific research systems whose major funding has come from the same public sources that will be increasingly tapped for treatment, with the same requirements for accountability.

Effects on innovation and the accepted practice of medicine

The fact that innovative treatments or treatments in new contexts are defined as experimental (cf. Beecher, 1970; Freund, 1969; Ladimer, 1963; McDermott, 1975; F.D. Moore, 1975) is of concern to lexicographers and will not be pursued further here. New procedures and new conditions can be concordant with treatment and, when so used, Freund sees "no quarrel" (1969, p. 317). Our concern will be with the *testing* of innovative treatments, which may fit the research contingency noted, although review committees tend to regard such proposals as "demonstration proposals" rather than "research proposals." Since innovation may be defined as a departure from "the routine and accepted practice of medicine," henceforth to be abbreviated raapo medicine, we shall also discuss raapo medicine when implications of innovation apply here as well. Research and treatment contexts will be treated separately.

If innovations are not to be accepted until it is demonstrated that the gains are worth the "risks," an issue that immediately arises is our satisfaction with raapo treatment. Are the gains worth the "risks" here? And how do they compare with innovation? Or do we apply a grandfather clause to raapo treatment? The issue, Robbins notes, "not only applies to procedures that are developmental or experimental but also to many procedures that are considered established and about which questions of risk are no longer raised" (1975, p. 4). And Eisenberg notes that the requirements for therapeutic trials may be standards of "safety and efficiency beyond those that can be offered for the best of medical practice" (1975, p. 96). With regard to raapo medicine, he cites the case of Benjamin Rush, who is considered to be one of the fathers of American medicine. During the plague of 1793, he remained at his post in Philadelphia, ministering to the stricken, instead of joining most of his colleagues in their escape to the country:

> "Messianic in his zeal for purging and blood-letting, *therapeutic maneuvers based on contemporary authority*, he went from home to plague-ridden home, causing more carnage than the disease itself. Good intention . . . provided no substitute for knowledge then, nor . . . now" (1975, p. 96; emphasis added).

And Beecher notes that "a number of examples come to mind to suggest the need for healthy skepticism as to how readily established a standard may be," (1970, p. 92).

In discussing private and public good and harm, over short and long run, Barber suggests that "a rough functional calculus" be applied which "shows some definite net advantage all around" (1967, p. 100). What he is proposing has some elements of a

decision approach. Some optimization criterion is to be applied to a 2 x 2 matrix, whose columns are private and public and whose rows are short and long run, with specific consequences in the cells. I am proposing that we begin considering the application of formal decision theory to the assessment of innovative approaches, since these are, after all, social decisions.

The decision criterion to be applied must be specified. Claude Bernard's implied criterion of no "ill to one's neighbor" is moderated by Beecher's "shades of gray" (quoted in Barber, p. 98). The decision criterion would be applied to a matrix whose columns are types of treatment and whose rows may be that which the treatments are to be applied to. These may be different diagnoses, or different assumed stages of an illness. In cancer research, for example, chemotherapy and radiation might be applied to cases where the probability of metastasis was $>.2$ and $\leq .2$, and all four empirically obtained effects (entries in the cells of the matrix) might help obtain comparative "expected values" (a decision criterion) of these two (or more) treatments for these probabilities. Similar matrices might be applied for other probability levels. No ready prescription is offered for the row entries, nor are the possibilities exhausted.

Outcomes need not be restricted to gains and losses, or benefits and damages. Elsewhere (Goldiamond, 1974) I have noted that two treatments which equally control self-damage (physical constraints and occasional slaps upon head-banging by an autistic child), may have different effects on what new behaviors may be taught (none in raapo constraint, and progress toward developmental norms in behavior modification), and protection of civil liberties and right to treatment might also be considered (Goldiamond, 1975b). A matrix was offered to rationalize the tendency to overdiagnose and undertreat found in some psychiatric hospitals (Goldiamond, 1974).

What is being proposed is that the valuation of benefits and damages of an innovative procedure *never* be assessed purely in terms such as how much damage are we willing to tolerate for how much benefit, that is, in terms of effects of the procedure alone, but that comparison with the benefits and damages of raapo treatment be the routine strategy. Formal decision theory minimally requires a 2 x 2 matrix, and a decision is not defined in terms of weighing alternative outcomes of simply one course of action. Ordinarily, it would seem that a control group provides such a possibility, but I am suggesting that raapo treatment be that control, or one of two controls. This might give a 3 x 2 matrix, with the columns being innovative treatment, raapo treatment, and placebo.

Where the "expected outcome" data are available for raapo treatment, such data would be useful in comparing projections from innovative treatment as results are obtained. Where several types of treatment had been used, a historical analysis might supply cell entries which would be useful in establishing "expected values" of the treatments for different conditions. It should be noted that it is possible to construct such matrices only to the extent that the requirements of decision analysis (implicitly or explicitly) entered into data collection procedures. Where there are no data even approximating this requirement for raapo treatment, one might question the bases for having accepted or continuing to accept this treatment as standard, and question whether it should be used as a standard against which innovation is to be measured.

The use of raapo treatment as a standard for defining innovation (that which deviates from raapo treatment) is carried to a logical conclusion when Levine extends this

definition of innovation to the social sciences, namely, as that "which differs in any way from customary medical (or other professional) practice" (1975a, p. 24). The innovations would thus require all sorts of protections not provided in raapo social discipline. One example given of a parallel to the investigator-doctor role confusion is a criminologist-law-enforcement officer. But suppose some highly undesirable hole (solitary confinement) is raapo prison treatment, as indeed is the case — in one prison in Illinois a cubicle within a cube within a cube is standard — and suppose a warden-penologist wishes to see if such treatment is necessary (a general statement). For half the prisoners so consigned, he converts the cubicle to a larger room, provides options, and so on. He records differences between the two situations. Would we require the imposition of informed consent and all the other safeguards for this deviation from "customary [penal] practice," when they were not required for the standard procedures? A decision matrix might prove quite useful (procedures x assumed severity of offense) in convincing the outside world to adopt the change, or to whom to apply it.

All of the foregoing may be summarized by a common expression: when innovative treatments are assessed, comparative raapo treatments should be "up for grabs." By this process, raapo treatments might gradually be clarified as innovations progress.

This maxim should not hold where the treatment practices of a practitioner are under scrutiny, since the practitioner should not be faulted for what was then not known. Thus raapo treatment would remain as the safeguard it has been for the practitioner who uses it, but would lose this position in the evaluation of innovative treatment. The two functions would be separated.

Separating the evaluative (research or demonstration) and treatment functions provides safeguards for the practitioner of raapo treatment. But what of the practitioner of innovative treatment? Given the uncertain nature of raapo treatment outcomes, and given the fact that research is not the only avenue to discovery, and that treatment may also provide such an avenue, the social and personal stakes in innovative treatment are high. I submit that the principle of concordance also extends to innovative treatment. Here, it is treatment concordance which is involved. With regard to analogous *raapo treatment*, whatever consent procedures obtain; whatever degree of prior specification of procedures and alternatives is required; whatever degree of evidence of effectiveness and evaluation in terms of cost of treatment, duration, and possible harm are required; whatever proscription holds against use of an explicitly designated procedure until it is evaluated further; whatever degree of post-hoc review is required — these might also be required in innovative treatment. In addition to protecting the social and personal stake in innovative treatment, such treatment concordance might also protect the patients (clients, students, etc.) at least as well as they are now protected by the analogous raapo treatments. Where such concordance exists, the fact that innovative treatments differ from raapo treatments should concern neither type of practitioner — until innovative *and* raapo treatments are evaluated. As was suggested, evaluation of innovation would routinely call for simultaneous and comparative evaluation of analogous raapo treatment.

The social and personal ends (consequences) contingent on innovation and research are not served by confusing them, and they are best protected by clear definitions and distinctions between them. That innovation (discovery) is not congruent with science was discussed in a philosophic context by Reichenbach (1951), who distinguished

between the *context of discovery* and the *context of justification* (p. 231). It is a particular set of formulations of the *latter* which distinguishes science, and its is "the adequacy of the empirical procedures [which] governs the adequacy of the experiment and minimally demonstrates the competence of the scientist" (Goldiamond, 1962, p. 310). What it is that is evaluated in this manner can have been suggested to the investigator "by a theoretical issue, by a procedural issue, by his own subjective experience, by accident, by mistake, by serendipity, or in some other way" (ibid.), including treatment. As was noted, the continued confusion between innovative and experimental is of concern to lexicographers. The formulators of social policy have other concerns.

Innovation which is governed by scientific contingencies should be considered as scientific in concordance with defining criteria of the relevant scientific communities, and innovation which is governed by treatment contingencies should be considered as treatment in concordance with such defining criteria of the relevant treatment communities. The concordance required for research in the context of treatment is that of both communities for the contingencies in their respective domains. The evaluation of innovative treatment would require evaluation of raapo treatment. Such joint-evaluation, since it is governed by scientific contingencies, should meet the defining criteria of that community, as well as raapo treatment concordance for both innovative and raapo treatments (unless concordance were already there, as in evaluation through historical research). Evaluation of different raapo treatments would be similarly considered by both communities.

It would seem that the principle of concordance contributes not only to the definition of treatment and research, but also to evaluation of innovation and treatment, and to protection of the social and personal stake in innovation, as well as to the protection of individuals treated thereby.

III. Different Contingencies Governing Patients, Subjects, and Relevant Professionals

In the discussion of occasions-consequences for treatment and research, it was noted that the patient and the systematic formulation are analogous, but patient and research subjects are not. This implies that patient and formulation will be treated with analogous respect (or disrespect) since social support for the systems involved may ultimately be contingent on how successfully the systems produce their assigned outcomes. This also implies that patients and research subjects, since their positions are not analogous, will occasion nonanalogous professional behaviors in the treatment and research enterprises, *as enterprises*. The conclusion that the protection of patients and subjects requires different types of review procedures is accordingly a valid one — as long as the discussion is confined to the enterprises as enterprises. However, as will be noted in Section IV, there are overriding commonalities in other social contingencies which dictate a different conclusion.

In treatment, an extended sequence of interactions between patient (student) and professional is often required for each. An operant chain is thereby described; the link reinforcers derive their reinforcing properties from their progressive relation to those consequences for which the whole sequence is required. On a day-to-day basis, the

practitioner's treatment efforts along certain lines are reinforced or weakened by ensuing changes (depending on direction) of the patient; these then occasion further efforts on the practitioner's part, these are then strengthened or weakened, and so on. The three-term contingency is clearly evident. In this interactive arrangement, the patient's outcomes control the professional's behavior, providing both occasions and maintaining consequences for it. The *patient's behaviors* are reciprocal: the presentation of complaints and reports of relief are patient behaviors which are the occasioning and reinforcing stimuli which bracket the practitioner's behaviors. These patient behaviors, as well as compliance with other "orders" (the "patient role") are maintained by the same consequences which maintain the practitioner's behaviors, namely, their progressive approach to the outcome which maintains the entire sequence. Thus the (*patient-practitioner*) "mutuality of outcomes" which is used to describe the terminal outcome of "successful practice" also applies to the links in the sequential chain. There is not only mutuality of outcomes but reciprocity of behaviors. As Parsons observes, "each participant receives in the short run a *quo* for the *quid* that he contributes" (1969, p. 338). It should also be noted that a third party enters into this mutuality. It is the social system, for whom this outcome is also meaningful, and to obtain which it supports the treatment system.

In experimental research, investigators are engaged in an extended sequence of interactions with their data. In *operant* and related *single-organism* research, the investigator's manipulations along certain lines are strengthened or weakened by ensuing changes (depending on direction) in the dependent variable, these then occasion further manipulations on the investigator's part, these are then strengthened or weakened, and so on. The three-term contingency is clearly evident. The orderliness of the data controls the investigator's behavior, providing both occasions and maintaining consequences for it. In most research using *statistical inference*, this progressive control by increasing orderliness is evident in a *series* of experiments, by one or several investigators. Ensuing experiments are governed by outcomes of the preceding ones. The outcome which maintains the sequence of investigator-behaviors in a single-organism operant investigation, or in a series of statistical studies, is increased orderliness or systematization of statements. The third party here is the granting agency, for whom this outcome is also meaningful, and to obtain which it supports the research system.

Since the patient's outcomes control the practitioner's behavior, and the experiment's outcomes control the investigator's behavior, it can be said that the patients control the practitioner, and the "data control the experimenter." Indeed, the patient pays the practitioner, who is thus clearly identified as the agent of the patient. In the case of research, it is the social system, through its granting agency, that pays investigators. They are thereby the agents of the granting agency. They write reports for it, agree to provide time for it, and so on. The mutuality of outcomes and reciprocity of behaviors which characterize relations between patients and practitioners in treatment also characterize relations between granting agencies and investigators in research. Patient and granting agency are in parallel relation. Payment is accordingly critical, and not extraneous, as Levine suggests (1975b). It helps define and separate agent from client in both treatment and research, in adddition to filling other functions to be discussed in Sections IV and V.

Research subjects do not enter this realm of discussion. They play yet a different role. This role is evident if one first summarizes profession-agent roles in treatment and research.

A. Treatment:	1a. Professional is agent of patient
	1b. Patient is client of professional
	2. Professional agent is paid by client patient
B. Research:	1a. Professional is agent of grantor
	1b. Grantor is client of professional
	2. Professional agent is paid by client grantor
C. Research Subject:	1a. Subject is agent of professional
	1b. Professional is client of subject
	2. Subject agent is paid by client professional

Vis-a-vis the subject, the professional is in a reversed position from either of the two preceding ones. Since the professional is an agent of the granting agency, the subject by extension is also. The subject can be described as being in a "line position" rather than in one of continual interaction with the professional or the granting agency.

A fourth relation of interest can now be considered. This is the situation where research is conducted in the context of treatment.

D. Research-Treatment:	1a. Professional is agent of patient (A-1)
	1b. Professional is client of subject (C-1)

Since the subject is also the patient, the same person is both client and agent. If the practitioner is also the investigator, this confounding holds on this side, as well. If practitioner and investigator are separate in person, both may be similar in role, since they are agents of the same client institution (hospital or university) which pays their salaries. Unless the relations are made explicit, and steps are taken to separate the functions (some of which will be discussed), there will be problems in a variety of areas, including coercion and consent (see Gray, 1975, for some of the contamination).

Since the investigator pays the subject and the patient pays the professional (when investigator and professional are the same, and subject and patient are the same) each should both pay and be paid. Indeed, the cancellation or lowering of patient fees in many clinical-research units supports this statement.

Means-ends relations

It is frequently asserted that since the research subject lacks whatever protection the patient gets from the mutuality of patient-practitioner outcomes, the subject requires special protection. The particular jeopardy in this case is that the subject may be used as a *means* to obtain the investigator's *end*, namely, general knowledge. This may not only be not helpful to the subject, it may be harmful. Where research is conducted in the context of treatment, it is at best simply extraneous to the outcome of treatment, and at worst, in opposition to it.

In research, human subjects are considered specially subject to abuse since a variety of social consequences are contingent upon the investigator's contribution to knowledge. Dependent on publication are prestige, promotion, income, research funds. These outcomes for the professional can not be characterized by the mutuality of patient-

practitioner outcomes which characterize treatment. Nor are they even congruent with the payment or course grade used to maintain subject participation. The subject is therefore liable to abuse — the consequences cited are strong ones and are not shared by the subject.

In treatment, however, similar consequences are also likely to hold. Presumably, dependent on the practitioner's success in treatment are such consequences as prestige, promotion, income, and access to facilities. These outcomes are not characterized by mutuality of patient-practitioner-social outcome. Such divergence in outcomes between professional and client was the occasion for the anguished cries of Linus in the Peanuts comic strip series when he discovered that his teacher was getting paid; he was broken-hearted to discover she was not governed by his learning. (The consequences for students in elementary school systems for which the governing outcomes are other than student progress are more disastrous.) The dimensions along which critical differences may lie, when one views the systems as systems, are in the different socially-defined contingencies previously discussed, which distinguish treatment from research. The ethical issues, in part, reside in the fact that the outcomes determined by the social systems in the two cases do not consider research subjects. The outcomes are, in one case, treated patients, educated students, trained technicians, and so on, and, in the other case, are treated and better organized systems of knowledge. Where there is abuse, it resides partly in the *specific procedures* used by particular systems, partly in the relations which research and treatment share with a host of other social institutions (to be discussed in Section IV), and not simply in the use of the subject as a means, since the patient may also be used in this manner.

IV. Abuse of Power: Coercion and Consent

A variety of interpersonal relations including thsoe of research and treatment may be described as power relations. The common contingencies related to this common descriptive term make possible the abuse of power they share. The issue of consent is addressed, in part, to such abuse in the context of coercion. The present section will consider coercion as it applies to the abuse of power and to consent. Section V, which follows, will consider informed consent in the context of contractual relations.

Ethical issues are raised when power is abused. Interpersonal power relations may be found not only for investigators and their subjects, and doctors and their patients, but for governors and governed, officers and enlisted men, employers and employees, teachers and students, ward committeemen and appointees, husbands and wives, and parents and children, to mention but a few. In each of these, power flows both ways, but the alternating powers, unlike alternating currents, differ in topography. The focus here will be on the first party, who may be said to be the "exclusive vendor" or distributor of the occasions and consequences which critically bracket socially-relevant behavior of the second party and may thereby control it. In this model, the comparable control exerted by the second party is trivial. Since control over exercise of the powers of the first party does not derive from consequences supplied by the second party, it would appear to be under other control.

One model used to describe such other control is "self-control," which may (or may not) be related to an ethical code. That such codes are addressed to the asymmetric power

flow described is suggested by consideration of "the moral law as such [as being governed by] a transcendent motivation" (Jonas, 1969, p. 232; cf. Goldiamond, 1968). Stated otherwise, it transcends control by the consequences supplied by the second party. Violating the code is immoral or unethical and censure is applied by peers — that is, by those with parallel dispensation powers.

The appropriate exercise of these powers may be considered to be a trust, as defined by an explicit social fiduciary model. Thus kings, officers, employers, bankers, and husbands exercise their powers for protection and benefit of their wards (not only did the French general address his enlisted men as "mes enfants," but the Russian enlisted man addressed his commander as "Otyets," i.e., Father). Fulfillment of a trust is involved. Hence *fiduciary* (L.*fidere*, to trust).

Needless to say, when the behaviors by which one party controls the behaviors of a second are not controlled by the second, and the first party is then considered to be under self-control or control by a code of ethics, the underlying assumption is that the first party's behavior is under some from of control. The necessity of internalizing the control, in the form of ethical adherence to a trust, derives from dissatisfaction with an explanation of control by a subordinate. However, the control may derive from a superordinate system which establishes and maintains the institutionalized relation between *both* parties, both of whom are therefore its agents. The social behavior of establishing and developing institutionalized trust contingencies, like the support given the treatment, research, and legal institutions, is maintained by the outcomes the system gets when it provides such support. As in the case of the use of a term as difficult to define as intent, the problem to which a term as difficult to define as internalized adherence is addressed may be resolved by consideration of social contingencies. That they bear on an important social problem is indicated by consideration of at least one form of abuse of power.

Such a case of abuse of power is defined when a member of the first party makes the social contingency (which governs the institutionalized relation) contingent on behaviors by the other which are outside the social contingency, or applies the social contingency in other ways to get such behaviors. The David and Bathsheba episode is an early instance and provided the occasion for an explicit moral sermon. In a more modern vein, Peters, in *Ethics and Education*, notes that "it is one thing for a university teacher to have an affair with his colleague's wife, but it is quite another thing for him to seduce one of his students" (1967, p. 210). The latter case permits an abuse interpretation: grades and prestige, socially approved to govern academic compliance, are made contingent on a different pattern of compliance. Thereby, it will be noted, society is not obtaining the occasion-consequence reversal which reinforces social support of universities: the untrained student has not become (academically) trained thereby. The teacher, accordingly, may be jeopardizing social support of universities. His university-supported peers may therefore suffer and may then censure him in some way. And the social system is frustrated (nonreinforced). He has "hurt his profession" by his "antisocial behavior." These terms approximate the relevant terms in the social contingency. "He has violated his trust" refers to the fiduciary model. "His unethical abuse of power" refers to the asymmetrical power model. All derive from the social contingencies discussed.

An interpersonal relation in which power derives from coercion is fertile ground for unethical abuse since it permits easy control of behaviors outside the contingency. Thus,

a patient under tremendous distress which can be alleviated only by an emergency treatment is subject to abuse by the sole dispenser of that treatment. The dispenser can make dispensation contingent on a variety of requirements — including consent for research as well as for a variety of treatments. The validity of consent obtained under such conditions, no matter how well-informed the consent was, might be questioned. It might be argued that the procedures represented a flagrant abuse of power and that the consent was spurious. It was obtained under coercion and was not freely given. The person was not in a position to consent.

Contingencies of freedom and coercion

Freedom will be defined in terms of the genuine choices available. Choice will be defined by *degrees of freedom (df)*, a scientific term which will be used here to define the number of variables in a system whose values have to be specified to determine the system. The volume of a cube is given by V =lwh, and given any three values, the fourth is determined (vlw to determine h, vwh to determine l, and so on). Thus, $df = 3$, since it is to specify the coordinates of a point in 3 dimensional space. Our concern is with alternative *behaviors*, and we shall use decision theory as our model. Here at least two *well-defined* sets of behavior are required (for example, being at home or at work are well-defined alternatives, but being at home or elsewhere introduces the poorly-defined set of elsewhere, which can include a moon and Jupiter), and the sets are related by the equation $a + b = 1.00$. Since the value of either then determines the value of the other, $df = 1$. Where $a+b+c+d+e = 1.00$, $df = 4$. There is a greater *degree* of choice — that is, there are more degrees of freedom. The *df* term is a useful one. It not only suggests that freedom is a matter of degrees, but also implies that coercion (to be defined presently) is also a matter of degrees.

The parallel between intuitive notions of freedom and the *df* usages is suggested by the fact that when the only work available is in a mine, and otherwise the person goes hungry, then working in a mine may not be considered a matter of free choice and, indeed, union experience has taught that miners are then more vulnerable to abuse than they are at other times. With regard to work as the referent, since there are no work alternatives, $df = 0$. There are no degrees of freedom. This accords with the common expression. If there is a choice between mine, mill, factory, or farm, then there is greater freedom, workers can feel "more independent," and abuse is less likely. Here, $df = 3$. Freedom, as defined intuitively or by values of *df*, is greater.

Freedom is related to coercion in the following manner. To the extent that a critical consequence (to be defined) is contingent solely on a class of activities, then *dc*, or *degree of coercion*, is inversely related (the term is used figuratively, rather than exactly) to *df*. Assuming temporarily that survival is one such critical consequence, then when one works in the mines or starves, coercion is maximal, since the maximum value of *dc* will be given when $df = 0$. Where there was a choice between mine, mill, factory, and farm, coercion was less since *df* had a higher value. But for the set of unskilled labors represented and starvation, there is coercion; and the complaint of the uneducated that

their freedom of choice is confined to jobs undesired by others becomes understandable. At any point, of course, the set of all possible tasks as opposed to survival can be considered coerced. Accordingly, the issue is never coercion versus no coercion, since $df + dc = 1.00$ (roughly — that is, one defines the other, and they are codefined). The issue is the amount and type of coercion we are willing to accept, and the protections against abuse we set up. These should be defined.

It was noted at the beginning of this section that choices had to be genuine. Genuineness relates to contingency repertoires. Someone with a high school education who scans the want-ads has no choices when all openings require a college education. He does not have a choice between working as a miner or as a physician when there are openings in both fields. Here, $df = 0$ because of the *behavioral* repertoire. Where job availability is not announced, or is circulated in channels not available to the seeker, or is presented in a language the seeker cannot read, the existence of the appropriate repertoires is irrelevant. Here $df = 0$ because of the *opportunity* component of the contingency repertoire. Further, there is experimental evidence that given occasions which are in the repertoire, given behaviors in the repertoire, and given potent consequences, the individual may persist in behaviors which result in loss of consequences or may switch to those which rapidly produce them, depending on the manner in which the consequences were *previously contingent* on behavior (Weiner, 1972). Finally, the *consequences* enter, as when the type of food available is forbidden by a powerful religious code. Failure to distinguish genuine choice from simple availability of alternatives, no matter how well their availability is made known in an informed consent procedure, is reminiscent of Anatole France's statement on the impartiality of the law which "in its majestic equality forbids the rich as well as the poor to sleep on the bridges, to beg on the streets, and to steal bread" (*Le Lys Rouge*, Chapter 7).

Some consequences are at certain times more critical than others, depending on a variety of conditions whose investigation is being pursued in the laboratory. In one branch of such research, the organism may be offered a choice between two consequences, with response costs and other variables held equal. The extent to which one is valued more than the other can not only be measured but can be manipulated experimentally. One method is through deprivation, often referred to as need or drive. Organisms at full body weight may prefer the opportunity to exercise over the opportunity to eat, but if they are deprived of food the order of preference may be reversed. Other procedures may be utilized by the investigator, and all of these will be subsumed under the general term of conditions which make a consequence critical — that is, one which is preferred in all choice situations.

Coercion accordingly may be defined as most severe when there are no genuine choices ($df = 0$), and the consequences contingent on behavior are critical. Coercion obviously relates to consent, since to the extent that coercion is involved, giving consent may simply be one more behavior added to the packet required to obtain the critical consequences. Where indignities are required, consent may simply become another indignity required to get the critical consequence or to avoid its absence, to state it in terms of negative rather than positive reinforcement. (For fuller discussion of coercion under negative reinforcement, see Goldiamond, 1974, and for both negative and positive reinforcement, see Goldiamond, 1975a, b.)

Two types of institutional coercion will be distinguished. In the first, the institution which delivers a critical consequence has set up the very conditions which make the consequence critical. In the second, the institution which delivers a critical consequence has not made it so. It is merely capitalizing, so to speak, on an opportunity provided by a state of nature (actual or manmade). I shall designate these as Institutionally Instigated Coercion (IIC) and Institutionally Opportune Coercion (IOC). They will be considered separately.

Instituionally Instigated Coercion. A familiar research example with a nonhuman subject is the conventional operant pigeon experiment. Here, the experimenter (or the assistant agent) deprives the pigeon of food and brings him down to 65-70% of normal body weight. The investigator then makes access to food contingent on required patterns of behavior. By careful programing of these patterns, the occasioning stimuli, or both, it has been possible to establish extremely complex patterns of behavior and discrimination, almost without error. In technical jargon, delivery of food serves to reinforce the response required to make it available; it is the experimenters who have so arranged it that delivery of food serves as a reinforcing stimulus. This they have done through prior deprivation of the organism. They need not deprive the organism to achieve this effect. They may simply provide a few doses of heroin to an animal with an indwelling catheter. Yet other conditions may be manipulated.

If deprived pigeons could consent, and were required to do so, before undertaking the training program which is their only means of obtaining food, such consent could be considered as having been obtained under severe coercion, rendered all the more severe by the fact that it was the experimental system itself which made potent the reinforcer it provides. For example, to a four-link chain required to make food available (pull a wire, turn a counterclockwise circle, press a pedal which illuminates a disk, and peck that disk 15 times) and then to get food, a sixth and fifth link would now be added: intelligently discuss your options, then sign consent to participate, then pull a wire, turn a counterclockwise circle, press a pedal which illuminates a disk, and peck that disk 15 times, and get the food — blessed food. The coercion would not be reduced; it might even be exacerbated.

Consider the case of human inmates of a penitentiary. If they participate in a particular biomedical research project, such cooperation, by demonstrating to the parole board the "acquisition of prosocial attitudes," renders them eligible for earlier parole. Stated otherwise, restoration of liberty or earlier release from incarceration (negative reinforcement) is contingent on an institutionally-provided opportunity to participate as a subject. The bicentennial notwithstanding, we do not need a Patrick Henry to remind us how critical a consequence liberty can be. The coercion is made all the more severe by the fact that the very penal system which makes the delivery of liberty a reinforcer is part of the same judicial-penal system which deprives the inmates of liberty. The analogy with the pigeon is almost a homology, and the meaningfulness of any consent obtained under these conditions would be questioned. (Conditions under which prison research does not fall into this category will be considered shortly.) The same strictures hold even if the prisoners are offered their choices of rehabilitative programs, if each is linked to earlier parole. These then become elements in a coerced set.

In one form of "brain-washing" the person is deprived of the usual social support through isolation by physical or pharmacological restraints, or through isolation from the hitherto supporting community by a special communal arrangement. Social support by the new group is then made contingent on individual behaviors which meet its requirements. The most effective behavioral requirements are those behaviors whereby the person, by assaulting the sensibilities of the original referent group, is further isolated from that group by his or her own behavior, making the support of the new group all the more critical. The parent who makes a child dependent is a clinical example.

What is probably the starkest case of institutionally-instigated-coercion is the use of tortue to obtain evidence. Relief from pain is made contingent on behavior which meets the system's requirements. It is the system which supplies the painful stimuli which make relief from it a potent reinforcer. No civilized court would accept consent obtained under such means. Their equation with coercion makes clear the contingencies involved, which are often otherwise obscured by rehabilitative or other idealistic statements.

Continuing on the same stark note, we routinely question the morality of those who create shortages and then profit from the delivery they monopolize.

In a less dramatic manner, the requirement of a department of psychology that each student in an introductory class participate as a subject in some experiment to obtain a passing grade belongs in this coercive category, to the extent that passing this course is critical to the student's academic program. However, the coercion is mitigated by its trivial nature, and the contribution of the experiments is typically in accord.

(In a possibly facetious tone, the statement that "the lawyers" have us in their clutches may reflect not only their inescapability for us, but the existence of some overlap between the legal system which provides relief and the system which sets up the conditions which make its delivery a potent consequence. [The tax lawyers who write rules which only tax lawyers can decipher seem to be a case in point but, in actuality, social and political considerations often govern the rules.] The suggestion that legal practice be reviewed by committees composed of representatives of other interest groups may reflect not only retaliatory pique against legal advocates of "consumer" groups such as patients, prisoners, and students, but may also reflect the regulator-regulated issue raised by expertise which was noted earlier, as well as other professional issues. There is, after all, a legal *profession* which provides services to clients through socially-supported systems. It would be surprising if some of the issues raised in our discussion of treatment and research did not apply here as well. There is legal research as well as legal service delivery.)

In all events, consent to participate in some activity where the consequence contingent on participation was made critical by the consequence-delivery system should be considered as having been obtained under coercion. This does not automatically exclude such consent or such activities from the pale since, as was noted earlier, the issue is not freedom from coercion but rather the degrees and type of coercion we tolerate, and what safeguards against abuse these require. It should also be noted that it is the *peculiar nature of the contingencies described* which designate the activities and consent as coerced. The same activities and consent can be governed by other contingencies which are not institutionally coerced. Given such contingencies, and where the activities are socially and personally beneficial, conditions appropriate to their support might be

considered. To label an institution as coercieve and therefore to assume that all related activities are coerced is akin to certain characterological descriptions of individuals or classes of individuals which then subsume all individuals and all behaviors. Both ignore the different contingencies which govern the different and varying behaviors of any complex social institution or, for that matter, any complex social individual.

Institutionally Opportune Coercion. There are situations in which the system which makes critical consequences contingent on institutionally-defined behavior has not produced the conditions which make these consequences critical. The "helping professions," of which medicine is a prime example, belong in this category (iatrogenic disease is an exception but is considered an undesirable). Where $df = 0$, and the consequences are critical, coercion is still defined. It is not lessened by the fact that it was not institutionally instigated, nor is it lessened by its social prevalence, inevitability, or desirability. The coercion is exacerbated when the institutions set up to treat the problem are operating under a "legally granted monopoly" over "a captive audience" (Freund, 1969b, p. 315). In effect, a critical consequence is not only solely contingent on submission to a particular form of treatment, but in addition, that form of treatment is provided solely by a system with monopoly control over its dispensation. The coercion possibly provides the system with an *opportunity* for socially-appropriate practice or for abuse, which opportunity is not as generally available outside it. Accordingly, any consent obtained under such conditions requires careful examination.

In the next few sections, I shall consider some possible arrangements whereby consent may be considered as possibly meaningful when the person's entry into the system was coerced, whether coercion was institutionally-instigated or institutionally opportune. Where these require different consideration, this will be noted. Three major arrangements will be noted: separating critical consequences from the activities, converting mutuality of outcomes to mutuality of contingencies, and noncoerced participation in programs specific to coercive systems.

Separation of critical consequences and activities

In a prison situation, when earlier parole is independent of whether or not an inmate participates in a program, then consent to participate in that program is not related to the release which the penal-judicial system made critical. If a church provides food during a famine, whether or not the person attends church, then it is clearly not capitalizing on this opportunity. Similarly, if the same treatment is available whether or not the person consents to serve as a research subject, then the situation is similar to the church arrangement. Separation of critical consequences and activity simply removes this form of coercion. It does not, however, automatically instate other requirements to make consent meaningful. These will be considered later.

If making a critical consequence such as treatment contingent on research participation raises questions of appropriateness, it is partly because research is considered extraneous to the occasion-consequence reversal which characterizes treatment, and partly because of social values attached to relief of distress, among other things. These considerations would also hold for making treatment contingent on ability to pay. It is highly likely that the United States will soon join other advanced nations which have

eliminated this requirement. However, in the meantime an ethical and social policy problem is posed by hospitals which make reduced payment or no payment contingent on serving as a research subject. It was noted earlier that this meets the exchange system logic of patient-pay, subject-paid research patient-pay-paid, therefore fees cancelled. Regardless of the goodness of its fit to this model, providing free services in return for research participation poses questions about the ethical fit. Where treatment is contingent on payment the treatment consequence is critical, and where the type of treatment offered is not genuinely (as defined earlier in terms of contingency repertoires) available elsewhere, the payment is coerced. That it is a social necessity is beside the point — it is still coerced. For someone who lacks the financial resources (repertoire), making service as a research subject a substitute for payment substitutes research service for coerced payment in the coercion arrangement described. It must then be recognized that since research is thereby coerced it is open to abuse, and consent must be carefully examined. Few commentators have been sensitive to this issue, but Eisenberg is on target when he doubts "that we will find a way of distributing risk across all segments of society until we have a national health service for all citizens" (Eisenberg, 1975, p. 97). Under such arrangements enrollment in a research-treatment program would be governed by considerations other than research substitution for coerced payment.

Payment also enters into prison research (or special treatment programs). Where early parole and other institutionally-instigated critical consequences are not made the consequences contingent on research-treatment participation, this form of coercion is removed. Money, of course, is an important consequence though not necessarily a critical one for people who are otherwise fed, sheltered, and clothed. To the extent that it approaches being critical in a situation (as judged by its selection above other consequences), and to the extent that *df* approaches 0, the required activity approaches coercion. Critical nature and *df* will be assessed separately.

With regard to critical nature, or uses of money to an inmate, it should be noted that the penal system deprives an inmate not only of liberty, but also of other amenities available in the world outside. Accordingly, institutionally-instigated coercion is defined not only when the system makes liberty contingent on some behavior, but also when it makes the other amenities of which it has deprived the inmate contingent on behavior. Where money buys freedom, it is evident that its payment has been coerced, and the *behaviors* upon which the wherewithall to pay is contingent are also coerced. By the same logic, such coercion also enters into *payments* for amenities of which the prison system has deprived the inmate, and into the research/work programs which produce such payment. Before such programs are hastily condemned, an important qualification raised earlier should be reiterated. This is that coercion is not absolute; there are degrees of coercion as well as of freedom. As was then noted, when work is the issue availability of work in the mines, mills, factories, and farms is described by $df = 3$. However, given the set of menial work (mines, mills, factories, farms) and a starvation alternative to that set, $df = 0$ and menial work is coerced. This can be extended to "higher" levels *ad infinitum*, lending support to Ogden Nash's verse, "I could live my life in ease and insouciance/were it not for making a living, which is rather a nouciance." This form of coercion occurs in the world outside and is acceptable — and, indeed, it is necessary there (exceptions such as inherited wealth exist, of course). The principle of concordance

with such outside facts of life may then be extended to define an acceptable form of work-coercion in the institution as well. The general rule involved would take a form such as: to the extent that the institutional work programs follow the work-requirements of inmates (or people with their skills in legally accepted work) in their usual world, institutional work-requirements provide an acceptable form of coercion. Exceptions derive, of course, from criminal work, e.g., the system would have to provide a forger with other work arrangements. Similarly, inmates who had never worked might be given work concordant with that available for people with skills and experience similar to theirs, or they might get necessary training. Along these lines, it should be noted that at least one European prison provides for daily medical practice outside the walls for physicians serving their terms, and it makes similar provision for construction and factory work, etc., for skilled and unskilled workmen. Earnings on the outside are at the going rates there. In these institutions the inmates also pay, from their earnings, for their room and board, as well as for the extra costs which their incarceration incurs. Such institutions are special institutions, with special programs prior to such arrangements and during them. It should be noted that the world outside provides payments for research subjects, and in some cases such payments are competitive with those for work. (Some nutritional research programs, for example, have provided salaries for college students during their summer breaks.) To deprive inmates of such work/research possibilities has the effect, at the very least, of depriving them of options concordant with those holding outside. Other effects have been cited by advocates of penal reform or abolition and will not be discussed here.

The value of n in $df = n$ is, of course, resolved by application of the foregoing concordance principle. As many options might be available as are given by the socially-accepted skills of the inmates, the positions available, and the exigencies of the institution. And there is no reason to exclude the option of serving as a research subject, providing that the payment, conditions, and protection are concordant with those provided for a volunteer outside for whom other options are available.

This approach to research participation might also enter into institutions whose coercive control is opportune rather than institutionally-instigated. Stated otherwise, arrangements for research participation of patients undergoing treatment might be concordant with the arrangements for research participation of paid normal subjects of the type described. Where the research is related to treatment, and the problem is a rare one, the subject/patient is then not a routine research employee, but one with special and hard-to-find qualifications. Arrangements should be commensurate and concordant with those provided for skilled employees outside. Where the problem is more common, subject/patients should be easier to find, and the situation is more competitive. Even under such conditions, as anyone who has conducted long-term research knows, the investment in the research patient or research pigeon is considerable, and the concordant arrangements discussed earlier would also hold here. It is assumed, of course, that for the patient, research is an option and not a requirement for treatment. Otherwise, institutionally-opportune coercion holds, and the research-patient may be in greater jeopardy than a prisoner with other-than-research options.

The issue of social versus individual needs is, I believe, inappropriate to this context. Edsall (1969) argues, for example, that individual treatment needs must occasionally be

subordinate to social research needs, citing the drafting of young men as soldiers (pp. 472-3). Indeed, Beecher asserts that "parents have the obligation to inculcate into their children attitudes of unselfish service. This can be extended to include participation in research for the public welfare if judged important and there is no discernible risk" (1969, p. 282). The children of mothers on diethylstilbesterole (DES) some twenty years ago might judge that "no discernible risk" to have been otherwise. The war situation is not analogous. The possibility of death and disfigurement is well-publicized. Such outcomes for the enemy accord with social contingencies, and the same fate for the local army accords with social contingencies of the enemy. It might be said that volunteers concentrate on the social contingencies of their side, and draftees concentrate on those of the enemy — hence the coercion applied to their recruitment. Any analogy to research, whether in a medical setting or in a prison, is far-fetched. As Jonas notes: "No one has the right to choose martyrs for science" (1969, p. 222).

Converting mutuality of outcomes to mutuality of contingencies

In a treatment system, it is the individual's responses (behavioral or physiological or both) which provide the occasions and outcomes whose reversed relation ultimately supports the profession and its professionals. To the extent that the individual's behaviors are brought into the same contingencies which govern the professional's behaviors, the professional's task is simplified. This requires that both work toward the same goals, or be motivated by the same outcomes, or that their behaviors be governed by the same consequences, to use three different descriptive systems. This holds for research as well as treatment. We shall consider treatment first, since such mutual outcomes are assumed to characterize treatment systems. Despite the mutuality of outcomes such systems are organized to deliver, the treatment-relevant behaviors of individuals and professionals are often also (or instead) governed by different consequences. These may frustrate one or the other or both. Further, the individuals and professionals may not be apprised of what the other is doing. They may not be apprised of the relation of outcomes to the requirements of the other. Any of these may make informed consent meaningless. Accordingly, it may be worthwhile to examine how a system which is organized to deliver common outcomes might set up arrangements which facilitate such delivery and under which informed consent might be meaningful. We might then see how these arrangements could be extended to a system in which it is assumed that common outcomes do not characterize the individual and the professional — the subjects and investigators of research systems.

Although treatment systems are characterized by "*mutuality* of outcomes," it was noted earlier that they are also characterized by "*reciprocity* of behaviors." The physician orders and prescribes, the patient obeys and follows; the teacher teaches and assigns, the student learns and follows; the trainer trains and provides experiences, the trainee learns and utilizes. Accordingly, although the *culminating* outcomes are mutual, the behaviors required are not. Further, the behaviors of one are the occasions-consequences of the other. The analysis suggests that regardless of identity in culminating chain outcomes, the contingencies in the links of the chains are *different in every component* for professional and individual. Occasions, behaviors, consequences differ.

For the individual's behaviors to be *optimally* governed by the same consequences as are those of the professional, not only must the individual's behaviors be governed by the same general outcomes as the professional, but the explicit occasions, behaviors, and consequences of the links in the chain must also be *the same* for both professional and individual. To make the *contingencies* the same suggests that it is *only when individuals have access to the same data about themselves which the professional has that it becomes possible for these to come to govern their behavior*, as they do govern the behavior of the professional. In the difference between "come to govern" and "do govern" lies the professional training of the practitioner. (The importance of past histories for a contingency analysis was noted earlier in the discussion on genuineness of choice as it relates to contingency repertoires. Among the major considerations was the "manner in which the consequences were *previously contingent* on behavior.") I believe it might then be part of the professional's task to educate the individual. The education need not be of the kind or depth which produces a skilled professional. It might be one which simply supplies the individuals with the tools for analysis and change in the problem areas of treatment concern. The individuals are the experts in the data and conditions of their own lives. If they are taught where and how to look, they can supply data and suggest relations which professionals can use to advantage for the solution of the presenting individual's problems. Such data are otherwise not available. And individuals can also begin to analyze their own responses and occasions of concern and try to figure out what to do about them, trying this tack and that, even as professionals analyze the same responses and try out different approaches — procedures which they and the common language confuse with experimentation. Professionals keep written records and are guided by them. The system suggested would require individuals to do likewise; professionals would then have access to their records in concordance with the individual's access to professional records.

It should be noted that as chronic problems increase in importance, and as the influence of the environment comes increasingly under scrutiny, at least one system of treatment, namely, medicine, is turning increasingly to such individual self-management. Health delivery systems are trying to train individuals in self-examination (e.g., breast cancer) and self-monitoring (e.g., home sphygmomanometers), and physicians are beginning to substitute education and joint-decision making for the assumption that if they fulfill their trust in a fiduciary relation with their patients, these wards should cooperate and meet their obligations of obeisance and recovery.

A treatment system which requires individuals to keep explicit records in concordance with staff records can readily be converted into a research system as well. The extensive data which such records provide are, as was noted, otherwise not available. They provide information about responses of the individual under different conditions, and about the settings in which the problems occur which can be useful for research. Just as professionals often interpret the same data differently, the possibility of different interpretations of data from the same individual records may suggest itself, on the one hand to the individuals when they are required to interpret, or on the other hand to individual and professional in their regular conferences. Just as in the course of professional conferences, the resolution of the situation may be to wait, or to get more data, or to try this and try that. And it should also be noted that waiting (collecting more

observations over time), or getting more data (running the same subject under more conditions), or trying this and that (manipulating different variables) are also means employed by experimental investigations for the resolution of problems or conflicts in explanatory systems. To the extent that the recording system which is supplied to the individuals, the interventions suggested for them to make, and other procedures are in concordance with those behaviors which enter into the definition of a research contingency, individual records can contribute to research. Is such research use of records and interventiosn separate from treatment use? If one views treatment in the context of self-management for prevention, melioration, or maintenance, then *research use by the individual becomes necessary for treatment use* by both individual and professional. Finding out about oneself, about "how I function," through distinguishing poor "explanations" from better ones, can be quite important for self-management or for improved professional management. And the "context of justification" of the scientific method is an excellent means for distinguishing acceptable formulations. Just as the treatment professional educates in the formulations and procedures of that area, the research professional educates in the formulations and procedures of that research area. In a research-treatment system of the kind described, the individuals may gain insights which are important for the practical resolution of their problems. The investigators may gain insights into those general functional relations whose resolution is important for the resolution of systematic problems in their disciplines. In such a research-treatment system, research and treatment go together because each is required for the other. Individual and professional are both "research and therapeutic allies," who share what intelligence the joint effort requires be shared, and who have their own separate sources.

This setting describes for research and treatment the "collegiality" between individual and professionals which Parsons (1969) sees as ideal, and which Mead (1969) reports as obtaining in field anthropology (at least in those projects in which she has been involved).

Where the treatment does not require research for its fulfillment, treatment can take place within the congruent-contingency system discussed for treatment alone. Individual and professional are then "therapeutic allies" who share what intelligence about each other their joint effort requires, and who reserve to themselves what is not required. For research alone, the congruent-contingency system would involve investigator and research subject. As "research allies" they would share and reserve corresponding intelligences.

In certain treatment areas (clinical, educational, or training), the outcome-producing program is well-formulated, with each step having been validated experimentally. In programed instruction (p.i., cf. Hendershot, 1967, 1974), the title of the text gives the outcome. Each of the frames in the text resembles a mini-contingency. An instruction appears, the student responds (usually by writing in a blank provided), and the appropriate answer is then available for comparison. If there is a response-answer correspondence, the student is then presented with the next frame, and so on. Thereby outcome repertoires are established which are far removed from those with which the student entered. The derivation from operant laboratory research is evident. The *instruction* which opens the frame, and the *opportunity* to move ahead (a consequence), contingent on adequacy of the student's response, may be considered as professional surrogates.

They are always explicitly presented — if the individual does not advance to the next step in "treatment" the reason is clear. (In a branching program, the student may be detoured to other steps, i.e., to differences in treatment before the main program is rejoined.) The students have access to their own performance and its adequacy at every step. (The steps are longer in the classroom-systems application known as p.s.i., where the instructions may be entire lessons, cf., Sherman, 1974.) Although individual and professional are not colleagues, or therapeutic or research allies, the *explicit presentation to the individuals of the same information about them which the professional has* (albeit by a surrogate professional), which enters into collegiality, also holds here. In the form of p.i. known as computer-assisted instruction, this electronic surrogate-professional functions almost as freely as a professional (cf. Markle, 1975).

One implication of the quest for collegiality in the p.i. context should not be overlooked. The implication derives from the question, When are individuals and professionals colleagues in such programs, if ever? Students are *presented* with detailed steps, hence they are not allied with the professional in their choice of them. The question is answered through reference to the *development* of the program. Here there was opportunity for collegiality between program developer and individuals in the analysis of each step and its judgement as wheat or chaff. The developmental *research* is done in the context of *treatment* — teaching, in this case. Here there is room for considerable flexibility and trying this and that, which in a good program is concordant with research behavior. Once the program is developed it is simply available for application, and there can be several different programs which explicitly produce the same outcome in different ways. The parallel with clinical treatment is evident. The major implication is that collegiality may be necessary when the steps in the program (linear or branching) have not been validated. Further, such development would require both treatment and research. And a corollary is that when the program is developed it is still necessary to provide individuals access to the same data that the professional gets.

The foregoing arrangements are obviously limited in their applicability. Among other limitations, they assume extended interactions over time. In treatment, such interactions are found in chronic care, education, or training. They are also found in acute care when coupled with long-term recovery, or maintenance, or prevention programs. In research, extended interactions are found in laboratories which require extended experimental intervention, or where acute studies have long-term effects. Establishing arrangements of the type discussed is not an easy task. It requires careful and long-term contingency analysis, which operant investigators and practitioners are familiar with, but in an area which is generally foreign to them, and whose required formulations have not been considered in the simpler operant arrangements studied thus far.

Although such arrangements would seem to be of only limited applicability to acute care or acute research (those situations where interactions between individual and professional cover only a short span of time and are confined to a few episodes per patient-subject), they may suggest some principles which might be applied. This would hold especially if the episodes are considered as condensed interactions which follow the same rules as the more chronic ones. They occur too rapidly for the analysis which the more leisurely and more magnified chronic situation permits.

Other settings and types of relations or problems or individuals may also suggest

limitations. Nevertheless, the extent to which collegiality arrangements apply there might be considered.

An example of one such research-treatment system is provided by our laboratory-clinic (Goldiamond, 1974). We have been developing and working with such an explicit congruent-contingencies system. We have thereby been requiring individuals to keep daily records of the problem-relevant contingencies of their lives, even as we require them of ourselves. We have been trying to have them analyze these records, even as we would. The records are used by us for basic research in behavior analysis and behavior change in the context of treatment. Most of our patients have come from the well-educated middle class, as befits a university clinic, but lately we have been doing research in heroin abuse and have found the recording system to be applicable for urban poor with little education. As an illustration of how collegiality arrangements of the type discussed can lead to application of professional analysis and intervention by patients for their own problems, I shall cite the report of an out-patient upon his return from vacation. He had had a history of hospitalization for schizophrenia and his brother was recently hospitalized for the same problem. During his vacation his wife walked out on him, leaving him alone in the motel. "I found myself sitting in bed the whole morning, and staring at my rigid finger," he said. "So I asked myself: 'Now what would Dr. Goldiamond say was the reason I was doing this?' He'd ask what consequences would ensure. And I'd say: 'Hospitalization.' And he'd say: 'That's right! Just keep it up and they'll take you away.' And then he'd say: 'But what would you be getting there that you're not getting now?' And I'd say: 'I'll be taken care of!' And he'd say: 'You're on target. But is there some way you can get this consequence without going to the hospital and having another hospitalization on your record?' And then I'd think a while and say: 'Hey! My sister. She's a motherly type, and she lives a hundred miles away.' " He reported that he dragged himself together, packed, and hitch-hiked to his sister who took him in with open arms. The education occurred in the process of the analysis of several months of written records.

Noncoerced participation in programs specific to coercive systems

In a system using institutionally-instigated coerion, consent is suspect when it is obtained for participation in some program, research or treatment, whose consequence is diminution of such coercion. Where there is insitutionally-opportune coercion, the same precautions hold. However, in this case as in the first the social task is to define the amount and types of coercion we are willing to accept, and the protections against abuse we set up.

As was noted earlier, one solution is to separate programs from coerced consequences. In a prison, for example, diminution of coercion would not be contingent on research or academic or training programs, but other consequences might be attached. The congruent contingencies of the preceding section might be considered in this connection. The contingencies for noncoerced programs (outcomes and subject matter) in IIC systems would tend not to be specific to those systems, but concordant with those of the world outside.

There is, however, one type of program which is specific to the coercive system, rather than being concordant with the world outside, which might seriously be considered for both IIC and IOC systems. This is a program of research, treatment, or both whose maintaining outcome is nonrecidivism. Under appropriate precautions such programs may be characterized by noncoercive mutuality of outcomes as well as by congruent contingencies for program-relevant behaviors of professionals and inmates/patients/students/research subjects.

In a prison system, a course of study which prisoners often readily enter into is how to avoid being sent up next time. The courses, of course, are informal and are taught by colleagues *sub rosa*. The nonrecidivism at issue is defined by them as *operationally* as it is by any sociologist, namely, nonreturn. The *social* intent, or contingency, is in nonreturn reflecting nonrepetition of offense: the discharged prisoner goes forth and sins no more. The contingencies governing the *inmates* may be otherwise: how to get away with it. Differences between operational definitions and operant contingencies notwithstanding, the popularity of the courses and their prevalence commends them to our attention as indicative of voluntary enrollment. Returning to the operant contingency permits the following suppositions. Suppose we try to develop (research/treatment) a program in the institution which trains complex repertories and skills concordant with those on the outside. Suppose these would then provide consequences critical to the inmate. Suppose the skills are socially acceptable. Suppose enrollment in the program is not governed by consequences made critical by the institution, but by consequences concordant with those outside, as discussed earlier, and that enrollment here is one of several options available?

In a clinical situation, an analogous program, applicable as well to the world outside, would be a prevention or nonremission program.

In a mental hospital setting, Fairweather et al. (1969) set up a research-treatment program whose subject/patients worked together in the insitution to develop skills for each other which would maintain them in their own community-setting outside. A token economy was devised in conjunction with carefully articulated programs of increasing approach to such skills, in accord with p.i. The differences are striking between these patients and controls with similar problems in socially-desired measures such as self-esteem while in the program and recidivism thereafter. Keehn et al. report a related use of a token economy for alcoholics in a community of their own.

Consideration of the specific procedures used and their rationales is beyond the scope of this discussion. The issue is raised only in terms of its relevance for consent, coercion, and social contingencies. Many types of responses can be established within institutional settings involving IIC and IOC. The maintaining consequences are often an increased convenience for the staff, or the demonstration of lawfulness for the investigator. That programing procedures can be applied to the investigation, development, and treatment of nonrecidivism for a variety of socially important contingencies suggests the possibility of noncoerced participation in programs which typically utilize coercion, since their outcomes are specific to the coercive systems involved. These programs provide consequences for the individuals, the professionals, and the social systems which are important to each.

V. Contractual Relations

The social fiduciary model (f.m.) assumes inequality in powers. One party exercises its powers in the fulfillment of a trust for the protection of its wards, the other party. An alternative model is the social contractual model (c.m.) between two consenting parties assumes to be equally capable of consent. The powers are exercised fulfillment of a future exchange for mutual benefit. What each party delivers to the other in the exchange is explicitly stated.

It has been customary for practitioners and investigators to regard themselves as functioning within a f.m., and as being attentive to the welfare of those entrusted to their care. If these professionals are hurt by or are indignant over what they interpret as an unjustified mistrust, they need but reflect on the steady public erosion in acceptance of the social f.m. (as distinguished from legal f.m.), and the steady substitution of social c.m. (as distinguished from legal or commercial c.m.). The change is reflected in relations between governments and citizens (formerly governed), rulers and subjects, employers and employees, and husbands and wives, to mention but a few. Indeed, it would be surprising if treatment or research escaped this trend. The slogan "Sit back and let us do the driving" may sit well in advertisements for a bus company. But when the practitioner states it (trust us to decide for you; we'll keep our own house in order) it is being treated as skeptically as when government officials make such statements about their operations.

It is interesting to note that the Constitution in essence follows a model which tries to balance distrust of those in power with the necessities of the effective exercise of power, and it allows the federal government only those powers explicitly granted it. All nonspecified and residual powers are reserved to the (States and) people, the other socially contracting party. Elsewhere I have discussed the difficulties faced by mental illness professionals consequent on their substitution of a reversed model, in which the treatment system has all powers except those that it grants its charges (Goldiamond, 1974). This model is contrary to the assumptions of the constitutional c.m., and it is much closer to f.m. assumptions.

Each of the contracting parties is assumed to be equally capable of consent. My present concern will be with the equality relation. Capability will be considered in the next section. If there is to be equality, it might be reflected in equal specificity of the terms mutually agreed upon. However contracts are often biased in specificity, imposing greater requirements for specificity upon one side rather than the other.

A familiar example of a contract where the burden of specificity is upon the client (payer) is the apartment lease. Here the responsibilities of the tenant are detailed so explicitly that they must be printed in small type in paragraph after paragraph. Aside from description of the premises provided by the agent (payee), provision of heat, access and other agent responsibilities are stated in general terms, which are kept to a minimum.

On the other hand, the burden of specificity is upon the agent (payee) in the consent forms for patients to sign before admission to hospitals or for procedures within them. What the hospital or staff might or might not do (that is, its responsibilities) are often spelled out in such explicit detail that they require paragraph after paragraph of small type. What is required of patients is minimally explicit, and quite general.

While the burdens of detail imply a breakdown in trust-relations, differences in sidedness of the general-detail relations also imply the direction of whatever trust relation remains. In the hospital, the patients are to entrust the care of their persons to the professionals. For the apartment, the landlords are to entrust the care of their property to the tenants. However, patient-professional relations follow mainly from a f.m., whereas tenant-landlord relations follow mainly from a commercial c.m. Accordingly, trust is involved in both cases. Indeed, mutual obligations and responsibilities entered into the feudal f.m., even as faith and trust enter into commercial c.m. But the fact that I trust the manufacturer from whom I purchase my refrigerator to have exerted reasonable standards and precautions in its manufacture (with legal sanctions contingent on their violation) puts our relations no more on a f.m. than the mutual obligations of feudalism (with sanctions contingent on violation) put relations between noble and serf on a commercial c.m. Commercial c.m. are compatible with assumptions of trust, and one does require a f.m. for a trust relation. We are loyal to certain stores and products and suspicious of certain professionals.

It is likely that the existence of elements of each model in the other derives from differences in social decision rules and other relations that applied historically at different times, with the resultant present situation representing different historical weaves. One outcome of the interaction of these weaves and changing modern conditions is that a fiduciary relation with which professionals had felt comfortable and had worked from since the days of, say, Hippocrates, at least, is being interpreted as delegation of *carte blanche* powers to the professional. Accordingly, legal redress is being sought and other models are being applied. In this period of confusion, certain protections accorded to the individual by the social f.m. are being retained, while obligations upon the professional by the social c.m. are being added. It is probably in this context that statements by professionals that patients have obligations, too, are to be considered. Viewed in c.m. terms, a contract between an institution and individuals should not only spell out in detail what its obligations are (as is the present case), but it should also spell out in equal details what the patient/subject obligations are (as is not the present case). If the field is moving to the social c.m., then the f.m. obligations should be changed to the explicit exchanges required by social c.m. Otherwise, both treatment and research delivery may suffer. Possibly this is necessary to preserve or to produce a balance. Possibly the present division is considered as one-sidedly favoring the professional. Perhaps advancing technology is producing lop-sidedness in this direction, unless correctives are instituted. However necessary such corrections may be, if treatment and research delivery suffer, so too will present and future patients, and the social system.

In all events, we might start making explicit what is involved and required. If a f.m. is to be retained, I am suggesting that this decision be treated as a decision, rather than as an article of faith or precedent. This would involve comparison of this option (retain f.m.) with at least one well-defined alternative (substitute c.m.), in addition to the other explicit requirements of such analysis, including costs and benefits of each, and the decision rule we might follow.

Service and Outcome Contracts. Two types of social c.m. will be noted, a time/effort (service) c.m., and a specific outcome c.m.

In the time/effort c.m., the professional guarantees time and effort and the client pays for these. In return for payment, the practitioners guarantee neither recovery nor cure (occasion-outcome reversal) but simply that they will put in the time and skills necessary and paid for. The physician, teacher, and automobile mechanic are paid for time/effort by their patient, student, customer clients. This type of c.m. also applies to research grants. Here the granting agency pays, and in return the university guarantees neither results nor contributions (occasion-outcome reversal), but simply that it will guarantee the time and skills of its principal investigator.

The time/effort c.m. of a research grant might serve as model with which *treatment* c.m. are to be concordant. The client granting-agency, as was noted earlier, keeps track records of the accomplishments and previous awards of its principal investigator. The university and investigator keep similar records. The p.i. specifies procedures and rationale in detail, and the agency examines these with equal attention.

The patient, of course, is the client in clinical treatment. Lest it seem far-fetched to suggest that clients keep track-records of practitioners, at least one consumer group is now doing so in at least one branch of clinical treatment. Track records of different educational-treatment institutions for client-student use are available to potential students and, in some cases, are prepared by professional educational associations themselves. Peer evaluation is thus made available to clients in education, as it is in grant review (the client is the agency), and this is not considered unprofessional.

The time/effort type of c.m. is generally used when outcomes are uncertain, or procedures have not been expressly validated. This is what research is about, of course, and this may underlie the confusion of experimentation with practice by practitioners. Where outcomes are more certain, where validated procedures are used, a different type of relation holds.

In the specific-outcome c.m., the professionals guarantee the delivery of outcomes or products which will meet explicit specifications. They are paid in return for this guarantee or performance. The research contract belongs in this category. In the educational treatment system, performance contracting has been tried, with mixed results. Here, the educational system is paid contingent on stipulated levels of performance by its students following training. Since specific-outcome c.m. assume validated procedures, the procedures and delivery can be cost-accounted, and fees can be fixed. In health care, the "Blues" and other third-party payers often provide fixed-fee imbursement for specified procedures; this would appear to assume validation and certainty. It is of interest that in the field of psychotherapy, behavior modification is moving in such a direction. Its practitioners speak of imposing upon themselves requirements which generally do not characterize other branches of psychotherapy nor, for that matter, most other branches of treatment. These generally follow the grant model. It is of further interest that behavior modification contracts make explicit not only what the therapist does at each step, but what the client is required to do. Although most such contracts and records are explicit in terms of the chain-transactions of each of the parties in the interactions with regard to payment, the fees at present are mostly for time and services. Accordingly, in most cases the programs belong in the grant category — that is, the first one mentioned.

Contracts in which the agency is paid for time/effort ("professional services rendered") or for outcomes delivered have differing costs and benefits which are beyond the scope of the discussion. (One of the major accusations against time/effort c.m. is that the delivery system, being reinforced for these, may maximize such reinforcement by increasing time rather than improving effort, which can better be accomplished through outcome contingent c.m. On the other hand, the system may then select its treatments in terms of payment, rather than actual service.) However, the fact that the outcome c.m. ("research contract") seems appropriate where the "state of the environment" is known and the time/effort c.m. ("research grant") where it is unknown suggests the possibility of a decision model with shifting strategy criteria, depending on states of knowledge, outcomes, and decision rule to be followed.

Informed consent

The social contractual model assumes that two consenting parties are equally capable of consent and have given it. Fulfillment of the contract is not binding on the party which is deficient in either.

Capability may be considered in terms of much of the preceding discussions, which will be summarized for this purpose. Degrees of coercion are defined by the number of genuine choices between alternative options, by the critical nature of the consequences which govern the behaviors involved, and by the conditions by which the consequences are made critical.

Degrees of coercion are inversely related to degrees of freedom, defined in terms of alternative well-defined sets of behaviors. Minimally, $df = 1$ — that is, there are two equally available options.

Genuine choices involve such options when contingency repertoires are equal. Equality of contingency repertoires requires equally available opportunities or occasions, equally available patterns of behavior, equally potent consequences and, since these are contingency repertories and repertoires require establishment over time, equally functional contingency histories.

Critical consequences are those which are generally potent over others when made contingent on a particular individual's behavior, given certain broad sets of conditions.

Where for genuine choices $df = 0$, and critical consequences are attached to the option(s) and the consequences have been *made critical by the system which provides them*, coercion is then defined for that option, and no consent is meaningful. Where $df \geq 1$, and noncritical consequences are attached, consent is meaningful to the extent that it and the contingencies involved are concordant with those obtaining for similar options in the world outside. If research participation meets these conditions, it is acceptable.

Where for genuine choices $df = 0$, and critical consequences are attached to the option(s), and the consequences were *not made critical* by the system which provides them, consent must be examined critically, unless the other arrangements discussed are provided. These include some of those holding in the preceding case, as well as those holding when mutuality of outcome is converted to mutuality of contingencies.

By and large, these define the conditions under which consent can be meaningfully obtained. By and large they define capability for consent.

What about the retarded, the illiterate, people who do not understand the language, and so on? Illiteracy and differences in language would seem to be governed by unequal-availability of occasions, which was discussed under genuineness of choice. There exists a more readily available guide which covers these cases as well as the retarded and other "incompetents." This derives from consideration of the social and commercial c.m. If we apply the simple rule of concordance of acceptability of consent in the ordinary contractual case to the acceptability of consent in the c.m. governing individuals and patients, few special rules seem necessary. Consent to the terms of a car contract signed by imbeciles would not be binding on them, nor should consent to treatment or research contracts be binding on them. Professionals who proceed under the assumption of validity of consent will face the same problems in a court of law as a car salesman who proceeds likewise, and they will probably face problems more severe if the harm is greater. The same holds for a person speaking a foreign language. Courts have defined other situations as well. Institutionalization in a mental hospital does not deprive mental patients of certain privileges and rights of citizenship, including freedom to enter into or decline certain programs. Whatever genuine surprise is engendered by judicial opinions which question treatment/research consent under such conditions is probably derived from the fact that the professionals are not attuned to the applicability of contractual arrangements to their baliwicks, rather than from their ignorance of the contractual relations involved. They encounter these daily as members of a complex commercial-industrial society.

It would seem that attention to concordance with conventional contractual relations obtaining outside would eliminate at least some of the confusion surrounding the area. Whether the contracts are for time/effort or for outcome, the requirements on each party might be stated explicitly, as they often are outside. Where the issue is disclosure of data obtained during treatment or research for research publication or for didactic presentation to improve treatment, and there is possibility of damage through identification, or invasion of privacy, or in other ways, the tort law prevailing on the outside might be considered for damages unrelated to contractual fulfillment. Or where contracted disclosure was violated, the breach of contract model might be considered.

It is probable that the laws and social arrangements are changing in these areas, even as the social contingencies they reflect are changing. Time-honored models whose definitions are implicit rather than explicit (e.g., intent and fiduciary models) make related social policies subject to varying interpretations and therefore to abuse by those in power who are so inclined. These models are gradually being joined by more explicit models, and the resultant confusion provides no fixed guides. In such cases, solutions to problems in the area of patient-subject protection may provide precedents and help provide solutions for a society that needs all the help it can get.

In the meantime, we might profit from its past efforts and solutions. However this interchange can best be facilitated if the models applied to our areas of concern are consonant with those the rest of the social order is finding to be of increasing applicability. These models include the contributions of the scientific systems of consequential contingency analysis found in behavior analysis, transactional analysis, exchange theory, decision theory and cost-benefit analysis; the contributions of the legal systems

faced with requirements for explicitness; and the contributions of the larger and equally explicit social contractual models they all reflect.

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