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Problems in deceptive medical procedures: an ethical and legal analysis of the administration of placebos

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The use of placebos in therapy or research poses ethical questions. What are the benefits and the costs in ethical terms of condoning deception of the patient or subject? What does the deception mean for the patient's or subject's right to give informed consent to his treatment?

Doctors are rightly expected to disclose to their patient facts which would in their judgement best enable him to give informed consent to treatment. On occasion, the degree of this disclosure may be limited by the need to avoid hazarding the success of treatment of an unstable patient whose condition threatens his life, but doctors should have no right to withhold information just to prevent a patient refusing consent to therapy. No such limitation should apply in experiments where full *disclosure must operate to enable the subject to give his informed consent.*

The potential medical benefits for the patient of placebo therapy have to be weighed against all the ethical costs of the deception and dishonesty involved, including the longer term repercussions on doctor/patient trust: similar ethical costs may arise in experiments involving the use of placebos without disclosure of this as a possibility to the subject. Deception is ethically degrading to both parties not only being a breach of trust, but denying the moral autonomy of the patient or subject to make his own choice.

The writer concludes that placebos should be used only with full disclosure and consent whether in therapy or in research, and that this need not impede the success of either.

Arthur K. Shapiro defines a placebo as 'any therapy or component of therapy that is deliberately or knowingly used for its non-specific, psychologic, or psycho-physiologic effect, or that . . . unknown to the patient or therapist, is without specific activity for the condition being treated.'[1] Dubois lists three classes of placebos:

1) Inert substances, such as lactose and starch;
2) Pseudomedicaments, such as herb extracts and superfluous vitamins;
3) Specific therapeutic agents.[2]

To these classes of placebos, Bok adds that *any medical procedure* may have an implicit placebo effect. She writes 'Nowdays, fewer sugar pills are prescribed, but x-rays, vitamin preparations, antibiotics, and even surgery can function as placebos.'[1]

When we speak of the 'placebo effect,' we are referring to any change in a patient's condition attributable to a pill, potion, or procedure (but *not* due to its specific pharmacodynamic properties), which derives from the significance the patient attaches to the whole therapeutic effort.

Placebos have been used for centuries by physicians under pressure to 'do something' but wishing to do no harm; to pacify without actually benefiting the patient. The benefit, however, has proved unexpectedly lavish, as Wolf suggests:

> Not only has the hopeful reassurance of placebos engendered in patients a feeling of increased well-being, but experimental evidence has shown that placebo administration may be followed by substantial and measurable changes in bodily mechanism.[2]

Patients have come to expect, some even to demand, a medication for every symptom. The placebo appears to be the most expedient 'remedy' for inorganic 'diseases.' One physician explained:

> I cannot understand why those of us trained to take care of organic diseases can't be allowed to take care of them. Why won't these people take our word for it that there is nothing wrong with them and let it go at that? There seems no way of handling them, except that sort of semi-quackery that some highly respected members of our fraternity are able to get away with successfully.[3]

Patient pressure and 'unexpectedly lavish results' may be two of the most potent forces perpetuating the resort to placebos *in lieu* of therapy. Studies indicate that a sugar pill may be half as effective as a standard dose of morphine for some people. Evans has found that in a typical clinical study, three out of twelve persons will gain no relief from pain from any medication, yet four of the twelve – one-third of the patients – will experience equal relief from either the placebo or the morphine.[4] A plethora of studies indicates reaction to placebos may involve practically any organ system in the body. Placebos have provided some degree of relief for an average of 35 per cent of the patients in cases of angina pectoris, arthritis, pain, hayfever, headache, cough, ulcers, and essential hypertension.[5]

Placebo effects are neither imaginary nor suggestive in the usual sense of these words. Careful studies fail to find any relationship between suggestibility, gullibility, and sensitivity to placebos.[3] Although the

physiological details are not clear, the placebo effect seems to be derived from a combination of factors involving the patient, the physician, and the relationship between the two.[5]

The prescription of placebos as therapy has become commonplace. Berton writes: 'The most widely used drugs in the modern medicine cabinet are not really drugs at all . . . They are chemotherapeutically inert. They possess no curative powers whatever, or have none that are contextually relevant.'[6] Some estimates suggest that placebos comprise 30–45 per cent of all prescriptions.[7] Investigations of experimental drugs are almost always designed with a placebo in the control group. Yet, extensive as placebo use is, discussion of ethical issues arising from these inherently deceptive practices is astonishingly limited. Bok writes: 'In a sample of popular recent textbooks in medicine, pediatrics, surgery, anaesthesia, obstetrics, and gynaecology, only three even mention placebos, and none of them deal with either the medical or ethical dilemmas placebos present.'[1] Moral implications of administering placebos are not taken seriously, either because of perceived benefits to the patient, or because of the necessity of a control group when investigating experimental therapy. The prevailing assumption is that trivial deception regarding a harmless substance, balanced against reasonable potential benefits, removes placebos from serious ethical concerns. We ought to challenge this.

In 1971, ethical questions surrounding placebos were raised from obscurity to prominence in a biomedical experiment performed by Dr Goldzieher *et al*, of the Southwest Foundation for Research and Education. The procedure involved a double-blind experiment which took place in San Antonio, Texas. Unknown to patients or experimenters, seventy-six women who had come to the clinic *expressly* to prevent pregnancy (*not* primarily to participate in research), were given dummy pills, while other groups got various levels of hormone contraceptives. The women were instructed that 'the pill' had not been proven completely effective, and it was advised that they use vaginal cream as extra protection against conception. Although the patients were informed that they were participating in research, the records furnished by the researchers do not indicate that the women knew they might be receiving placebos, nor were they made aware of the significantly increased risk of pregnancy by relying on vaginal cream alone. The purpose of the research was to establish whether reported side-effects of 'the pill' were physiological or psychological. Goldzieher reported the outcome of the research to the American Fertility Society: the placebo group did experience many of the same side-effects as those given hormone contraceptives. The placebo group also experienced seven pregnancies.[8]

This article explores two neglected questions posed by the administration of placebos:

1) If we are to analyse the ethical problems in terms of benefits accrued and harm done (using a utilitarian calculus), what is the effect of condoning deception of the patient and/or volunteer subject?
2) *Independently*, what implications does the deception involved in administering placebos have for individual choice, and for the patient's status as an autonomous moral agent?

I analyse the above questions separately, distinguishing between the therapeutic and experimental setting. I conclude that either on the basis of a long term utilitarian calculus of benefits versus harms, or, independently, on the basis of patient autonomy, placebo use ought to be subject to strict controls, which I shall outline.

Requirements of informed consent

IN THERAPY

Based on what the patient needs to know in order to make an informed consent, physicians have been traditionally required to disclose in lay language:

1) A description of the proposed treatment;
2) Alternatives to proposed treatment;
3) Inherent risks of death or serious bodily injury;
4) Problems of recuperation that are anticipated; and
5) Any other information that reasonable physicians in a similar situation would disclose.[9]

If it can be established that the doctor is working in the patient's best interest, many jurisdictions have held that disclosure may be made on the basis of what, *in the physician's judgement*, would best benefit the patient, consistent with informed consent. Justice Schroeder argued in *Natanson* v. *Kline*, 1960:

> The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgement. So long as the disclosure is sufficient to assure an informed consent, the physician's choice of plausible courses should not be called into question if it appears, all circumstances considered, that the physician was motivated by the patient's best therapeutic interests, and he proceeded as competent medical men would have done in a similar situation.[10]

A careful reading of the passage indicates that the physician's discretion of disclosure *cannot* be construed to substitute for informed consent, but rather, implies discretion in the disclosure of facts which are additional to those necessary for such consent. Still, this standard of what reasonable medical practitioners would disclose in similar circumstances is controversial, and has been rejected by some courts in favour of the 'reasonable

person' standard; i.e., a physician has a duty to disclose any material facts that a reasonable person would want to know before receiving such therapy. In *Berkey* v. *Anderson* (1969) the court held:

We cannot agree that the matter of informed consent must be determined on the basis of medical testimony.... We agree with the appellant that a physician's duty to disclose is not governed by the standard practice of the physician's community, but is a duty imposed by law which governs his conduct in the same manner as others in a similar fiduciary relationship. To hold otherwise would permit the medical profession to determine its own responsibilities ... [11]

Similarly, the court held in *Hunter* v. *Brown* (1971) that whether or not a fiduciary duty had been violated in withholding information is a question of fact to be determined by *reasonable person standards*.[12]

It has also been argued that there are cases in which the physician may legally withhold information, the divulgence of which would do the patient harm (preclude or hamper his cure, for example). This is commonly known as 'therapeutic privilege.' In *Natanson* v. *Kline*, Justice Schroder noted that:

There is probably a privilege, on therapeutic grounds, to withhold the specific diagnosis where the disclosure of cancer or some other dread disease would obviously jeopardise the recovery of an unstable, temperamental, or severely depressed patient.[10]

The opinion in this case goes on to state, however, that the discretion given the physician as to the degree of disclosure must be consistent with the *full disclosure of facts necessary for an informed consent*. Moreover, the *Natanson* case does not justify treatment without the patient's informed consent merely because the physician would think it for the patient's benefit:

A doctor might well believe that an operation or form of treatment is desirable or necessary, but the law does not permit him to substitute his own judgement for that of the patient by any form of artifice or deception.[10]

It would be a complete perversion of this principle of 'therapeutic privilege' to argue that a doctor is justified in withholding information because a patient would, quite calmly, on the basis of that information, refuse therapy the doctor deems desirable.[13] Finally, Justice Schroeder's language in *Natanson* implies the privilege only accrues when the patient is severely and exceptionally unstable, and where some 'dread disease' would imperil his life. The court refused in this case to speculate on the applicability of such a privilege where the benefits of non-disclosure are uncertain or marginal, or where human life is not at stake.

INFORMED CONSENT IN RESEARCH

The placebo in the research setting is custom-made to deceive: it exactly replicates the drug under investigation. Of ten studies of the placebo effect surveyed by Bok, only one indicated that those subjected to the experiment were informed they might receive placebos; indeed, in six, there was mention of intentional deception.[1]

The prevalence of deception in these studies indicates the extent of research carried out with less than fully informed consent. According to the (US) Department of Health, Education, and Welfare's Regulation of the Protection of Human Subjects, the basic elements of information necessary to give an informed consent includes:

1) A fair explanation of the procedure to be followed and its purposes, including identification of any procedures that are experimental;
2) A description of any attendant discomforts and risks reasonably to be expected;
3) A description of any benefits reasonably to be expected;
4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
5) An offer to answer any inquiries concerning the procedures; and
6) An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.[14]

These requirements of the DHEW attempt, primarily, to provide protection to the human research participant, rather than to protect the researcher against legal action for damages.[9] When requirements of informed consent are satisfied, the inherent inequalities between subject and investigator are brought *somewhat* closer to a balance (which safeguards the subject's autonomy and limits risk of harm to a level acceptable to him). Thus, as Ramsey maintains, informed consent functions to bring otherwise inherently unequal parties into a 'joint adventure' or 'partnership':

An informed consent establishes medical investigations as voluntary associations of free men in a common cause. . . . It lies at the heart of man's search for cures to all man's diseases as a great human adventure that is carried forward jointly by the investigator and his subjects.[15]

Two non-therapeutic experimentation cases underscore the point that *normal volunteers* can never be considered patients. Whatever privileges of withholding information a physician may have on therapeutic grounds cannot be applied to the non-therapeutic situation. In *Halushka* v. *the University of Saskatchewan* (1965) the appeals court held that:

There can be no exceptions to the ordinary requirements of disclosure in the case of research as three

may well be in ordinary medical practice . . . The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities, and opinions which a reasonable person might be expected to consider before giving consent.[16]

In a case involving proceedings against physician-investigators before the State Licensing Board in New York, for injecting live cancer cells into normal volunteers (without their knowledge of the precise nature of the injections), the written opinion of the Board of Regents held that:

No consent is valid unless it is based on a disclosure of *all material facts*. Any fact which might influence the giving or withholding of consent is material. . . . A physician has no right to withhold from a prospective volunteer any fact which he knows may influence the decision.[17]

Both of these cases expressly revoke any privilege of withholding information (which may or may not accrue in the therapeutic situation) in an experimental situation involving volunteers.

Utilitarian considerations

IN THERAPY

The prevailing ethical norm of the medical profession, rooted in the Hippocratic tradition, is based on benefit to the individual patient. The physician does not pledge to enhance the medical profession, society at large, nor even 'the truth' (insofar as the truth can be ascertained). This perspective led two physicians, Bensen and Epstein, in an article of the *Journal of the American Medical Association* to write in 1975:

Since the beneficial effect is the desired result, should not the placebo effect be further investigated so that we might better explain its *worthwhile consequences?* . . . The placebo effect in most instances enhances the well-being of the patient, and thus is an essential aspect of medicine[5] (author's emphasis).

No mention is made in the article of the deception necessary to achieve such a benefit, much less *condoning such deception as an essential aspect of medicine*. Yet, the use of placebos *may appear* beneficial to patients in isolated cases. For instance, Veatch (who by no means advocates this type of deception), cites an example of a seventy-two year old woman who had been bedridden for the past twelve years of her life, after three operations for cancer of the colon and extensive chemotherapy. Due to difficulty sleeping (for which her doctor could find no organic cause), her doctor prescribed secobarbital, and as tolerance developed, increased the dose. After two years, it was apparent that the patient was an addict. The physician began over a period of a year, prescribing larger and larger portions of lactose to replace the barbiturate. For the last few years of her life the patient was given nothing more than a placebo. The rationale was that this elderly person might be better off spending her last years happily believing she was getting the potent drug.[18]

It is often assumed that the deception involved in the administration of placebos for the patient's own good is trivial. This assumption involves a value judgement which is, by the very nature of the situation in which the patient is in the dark, derived from the *physician's*, rather than the *patient's* value system. In the above example, the elderly woman paid $60 each year (from a very modest income) for nothing more than milk sugar. Moreover, physicians do not seem to consider the sheer humiliation of being deceived. Those who administer placebos must be giving special weight to the expected benefits, since the benefits are seen as overriding the element which makes all human interaction and discourse meaningful: mutual trust and respect. What indication is there that *the deceived* would give the benefits, such as a night's sleep, such special weight? If physicians are to be in the business of deceiving for the patient's own good, are we prepared to extend this prerogative to surgery and superfluous x-rays, which may, too, benefit the patient through an implicit placebo effect?

A digression is in order. The above analysis makes the *generous assumption* that the 'lavish results' described by Wolf in the 1950s is a positive benefit. In reality, benefits are far from certain, and the placebo effect could even be harmful. In a survey of the literature on placebo research, Bok notes such adverse side-effects as nausea, dermatitis, and headaches.[19] In a study by Wolf and Pinsky, 15 to 20 per cent of those subjects given placebos to relieve tension found themselves *worse off than before*.[20] Even Benson and Epstein will admit that 'if the patient reacts adversely to a therapeutic encounter, symptoms can be exacerbated and side-effects manifested by anxiety can be observed.' Moreover, placebos may be as capable of creating addiction as potent drugs for some people.

Bok writes:

In one case where a patient was given pills presented as a 'new major tranquilliser without any side-effects' the result was that after four years she was taking twelve tablets a day and complaining of anxiety and insomnia. After the self-medication reached twenty-five pills a day, a crisis occurred, and the physician succeeded, by interceding at her working place and talking over the problem with the patient, to reduce the dose to two a day. . . . Patients can become addicted to these substances as to all others, to the point of not being able to function without them, at times, even requiring that they be stepped up to very high dosages.[21]

More good would be done in the long run, it seems, if the physician sat down with the patient in

the early stages of the problem and explained the true nature of the problem, indicated either that no medication is necessary, or is known to be effective, and advised the patient how to best cope with or control these symptoms on his own. 'But the patient desires and *expects* the physician to give them medication for their symptom!' some may protest. Where did the patient get the idea that there is a drug for every symptom? To administer a placebo for any complaint is to perpetuate two widespread myths: that medicine *can* solve, and that medication *ought to be used to solve*, any problem a patient may bring to a physician.

Deceptive medical practices have repercussive implications which may go far beyond the immediate individual. The doctor-patient relationship creates certain expectations, reliance, and trust; the physician ratifies the patient's expectations by implicitly acknowledging that they are justified. Deliberately breaking this trust (even for the patient's own good) by prescribing inactive substances when the patient trusts he is receiving a potent drug, is a harm that extends beyond the wronged individual: in acting faithlessly, the very basis of our system of trust itself is eroded.[13]

What would happen if patients discovered that doctors are condoning the widespread use of inert therapy—and collecting high fees for this 'service?' I suggest that it will lead to distrust and eventual hostility—a hostility which is likely to be deeper because of the patient's acute awareness of his dependence on the profession. As this deception is realised, there may be a loss of confidence in all physicians and *bona fide* medicine: a breakdown in trust when trust is needed most.

Once we condone deception in certain situations, where do we draw the line between what must be disclosed and what ought to be withheld? No longer would lucidity carry its former value. Certainly, the justification of non-disclosure could be extended to active drugs or surgery for the desired placebo effect. The details of the condition of the seriously ill or dying patient could be radically distorted or even withheld under this principle. Condoning deception legitimises the claim that patients should have no say in their mode of therapy; it substitutes purely professional, paternalistic judgement for self-determination on the part of the individual.

EXPERIMENTATION

The use of a control group receiving an inactive substance is the only method medical science has devised thus far to compare active experimental drugs to no treatment (or to other drugs). Often such clinical trials contribute to advances in medicine which could benefit thousands of patients in the future.

It is widely believed that divulging the fact that there is a placebo in the experimental design would ruin the experiment by discouraging participation and reducing placebo effectiveness. Lasagna writes:

> When one is trying to diminish prejudice for or against a remedy, it is probably preferable, at least scientifically, for subjects and observers to be kept in the dark. To begin with, patients told that they may receive placebos may refuse to participate in the trial. If such refusals are few, they need not inconvenience the experiment or the experimenter. But if they are frequent, not only will the trial be prolonged but the generalisations possible at the end may be seriously limited, in view of the possible atypical nature of the sample.[22]

Similarly, Libermann has written:

> If subjects were forewarned of placebo administration, many would not cooperate with the experimenter – such candid statements of placebo use early in the experiment would engender suspicion and perhaps hostility in the subjects, making them undesirable, if not unwilling candidates for placebo research.[23]

Lasagna's reasoning is interesting: not only would he approve of subordinating the individual to the purposes of medical science. but also for its *convenience*. He fears that informing participants of the presence of a placebo would prolong the experiment. But he does not claim that it would be impossible for informed consent, nor would the findings be seriously impaired (given that it might be possible to take the placebo effect into account in the interpretation of the data). In short, informing the volunteers of the presence of the placebo in the experimental design would, *at worst*, inconvenience the experiment, but would not make it impossible.

Libermann has a slightly different objection: participants would be suspicious of, and hostile to an experimenter who tells them they might receive a placebo. If Libermann is referring to patients with a disorder which an active experimental drug has a good chance of improving, the hostility is understandable: patients are justifiably more interested in their personal health than advancing medical knowledge. Moreover, a good case can be made that patient-volunteers' consent is less freely given because of their unique dependence on the physician (and their likely vulnerability to any subtle pressure). Whatever the health status of the volunteers, hostility is likely to be much greater if they find out *ex post facto* that they have been deceived, rather than agreeing to be deceived at the onset of the experiment. In any case, such participant resistance, feared by both Lasagna and Libermann when placebos are involved, should *not* be used as a rationale to override informed consent; rather, it should be used as *prima facie* evidence that the experiment, as presently designed, is unacceptable to our society's ethical sensitivities.

When calculating benefits of the research versus

risks, inconvenience, or deception to the volunteering subject, it is the *subject himself* who should determine what weight the various factors in the utilitarian calculus are to be given. This is true because it is the *subject alone* who is in the unique position to make such a judgement: he alone knows the relative value he places on risks, benefits, and deception. (Even where there is no physical risk *per se*, only the volunteer is in the position to weigh the latter two.) The researcher, on the other hand, may have some potential biases which preclude a fair consideration of all factors to be balanced. 'Patient benefit' is not usually the basis for experimentation, nor is the physician-investigator neutral: he is very much an interested party (with vested interests not merely in the public good, but in the scientific enterprise as such, in 'his' project, or even in his career). Ramsey points out that a person rises to the top in medicine by the success and significance of his research.[15] Barber, *et al*, conducted studies which document the changing (weakening) attitude among researchers towards informed consent under such pressures.[24] The investigator *cannot be expected* to give truthfulness the same value as those potentially deceived. Moreover, the physician-investigator may be committed to a benefit/harms method of moral decision-making, while the patient-subject may be committed to some other moral principle (i.e., the inherent value of truth-telling or self determination).

The prevalent reasoning when an experiment is under consideration is often: 'Would the results be worth it?' The above attitudes could well contribute to a utilitarian calculus of future benefits versus present harm and humiliation, in which posterity invariably carries the greater value. One reason we have informed consent is to ask the potential subject, *given all the material facts*, if it would be worth it to *him*. Without this check, individuals are left undefended against such questionable practices as in the 'Experimental Pregnancy' case. Margaret Mead wrote an apt description of the investigator to whom deception has become second nature:

> Ethically, it means that the physician becomes accustomed to tricking, deceiving, and manipulating other human beings, and to that extent, denigrating their humanity.... There are other consequences (as well) – such as increased selective insensitivity or delusions of grandeur or omnipotence.... Encouraging styles of deceptive research and intervention that involve lying to other human beings tends to establish a corps of progressively calloused individuals, insulated from self-criticism, who can become outspokenly cynical in their manipulating of other human beings, individually and in the mass.[25]

Lest we take Mead's warning too lightly, recall Goldzieher in the 'Experimental Pregnancy' case: had the law not been in limbo in Texas at the time, he could have aborted these women, free of charge.

Formalist considerations

The above analysis assumes that it is sufficient merely to look at the consequences of a particular action in deciding if that action is ethical. But even if placebos are always beneficial on balance, the nature of the deception itself, regardless of the consequences, is an independent justification for stringent restrictions of placebo use:

1) Persons have a *prima facie* duty of fidelity to one another, to be overridden in only the most extreme cases,
2) Our autonomy as individuals (and therefore our very humanness) is denigrated when we are deprived the opportunity to make individual moral choices.

THERAPY AND THE DUTY OF FIDELITY

Some actions carry special moral presumption by virtue of certain characteristics which tend to make them 'right' regardless of their consequences. One such right-making characteristic is truthfulness in communication: our ethical sensitivities place a very special value on honesty. Honesty merits special ethical status, not simply because of the results it produces, but because of a presumed 'inherent rightness' in telling the truth. Some moral philosophers have held that the duty to tell the truth is so strong as to be without exception. This is the thesis of Kant's essay 'On the Supposed Right to Lie for Altruistic Motives', where he claims:

> The duty of being truthful is unconditional.... Although in telling a certain lie I do not actually do a wrong, I formally, but not materially, violate the principle of right.... To be truthful (honest) in all declarations, therefore, is a sacred and absolutely commanding decree of reason, limited by no expediency.[26]

Placebo use necessitates deceptive practices which obscure the truth: it often misrepresents the patient's condition, and almost always misrepresents the nature of the 'cure'. When a patient places faith in a physician to disclose accurately what is wrong with him (to the best of the physician's knowledge), and what his treatment alternatives are (should treatment be necessary), the physician agrees to expectations that he can be counted on by the patient to behave in certain ways. The nature of the doctor-patient relationship is such that an implicit promise of lucidity and candor has been made. To deceive is to break an implicit promise to deal honestly with another human being. People have a right to demand honestly in their relationships, which gives rise to what Ross terms a '*prima facie* duty of fidelity'.

But, of course, physicians are faced with competing duties: the duty of fidelity and the duty to benefit the patient's health. Although both are strong moral claims, the nature of the implicit promise to deal honestly with another human being

is such that it would seem *more of a duty* to fulfil this promise (by avoiding deception) than to confer a benefit (by employing deceptive practices). Even if we discard Kant's notion that our duty to tell the truth is absolute, it is reasonable to maintain that disclosure of truth carries very great moral presumption. The only possible exception to the duty of fidelity, according to some versions of the formalist position, is when the benefits are extremely great, and the promise trivial, as Ross explains:

> . . . normally promise-keeping . . . should come before benevolence but when, *and only when*, the good to be produced by the benevolent act is very great and the promise comparatively trivial, the act of benevolence becomes our duty[27] (author's emphasis).

One of the most evident facts of our moral consciousness is the sanctity we give to telling the truth, which is not dependent on the good which disclosure might bring. The *inherent* rightness or wrongness of certain acts is recognised by Ramsey when he emphasises that:

> Medical ethics is not solely a benefit producing ethics, even in regard to the individual patient, since he should not always be helped without his will. . . . There must be a determination of the rightness and wrongness of the action, and not only of the good to be obtained in medical care or from medical investigation.[15]

Some have challenged my assumption that patients come to physicians expecting the truth regarding their condition and therapy, in addition to expecting a physical benefit. 'I've been dealing with patients for thirty years, and I know what they really want,' some physicians may say.

What patients actually do or do not want (benevolent deception or the truth) is a question which requires empirical verification. Unfortunately, empirical studies of patients' attitudes regarding benevolent deception as it involves placebo administration *per se* are not available. However, at least one area of benevolent deception (involving the disclosure or non-disclosure of a cancer diagnosis) present consistent evidence that patients prefer to be told the truth (88, 87, 89, 82 and 98·5 per cent in four independent studies) [28] whereas physicians believe it preferable to withhold the information for the patient's sake (only 12 per cent of the physicians usually tell their cancer patients of the diagnosis).[29] Although the psychology of the cancer patient and the candidate for a placebo undoubtedly differ, the pattern is remarkably distinct: patients prefer, at least in some situations, to have access to more information than physicians feel it in their best interest to divulge.

Although these data are not proof of all patients' desires in all situations, they do cast doubt on the ability of a physician accurately to predict decep-tions which the patient would approve. My only point here is that what the reasonable person would wish to know is not necessarily what the reasonable physician believes it best to disclose, nor even what the reasonable physician believes the reasonable person would wish to know. Moreover, such a substitution of the physician's judgement for autonomous informed consent may even be illegal, as the *Natanson* case itself indicates.

Some may argue that what patients say they want to be told (especially in response to a survey) differs drastically from what they *really* want; i.e., they may consider it a commendable show of independence, rationality, or strength of character to say they would prefer disclosures, while in actuality, they prefer to be treated paternalistically by their physician. Such an argument is not only insulting to the patient, it is downright dangerous: *it could justify any form of deception for any paternalistic purpose whatever*, since it claims to be working in the interest of the patient's 'true' (albeit submerged and inarticulate) self. Once a person assumes this view, he is in a position to impose his will on anyone at any time on his supposed behalf. There are no limits to paternalism if we accept this position.

There is no reason why the moral weight we give to truth-telling should deteriorate in a doctor-patient relationship, even in light of the competing duty to confer positive benefits wherever possible.

SELF-DETERMINATION IN THERAPY AND EXPERIMENTATION

Human medical care and experimentation, most will agree, are essentially different from procedures with animals. We have different moral and legal obligations towards each. We do not offer animals informed consent, because they would not know what to do with it if it were offered. Humans, on the other hand, are (thought to be) able to assemble the relevant data, consider all contingencies, and come up with a moral choice *for themselves*. This is the basis of the Kantian theory of autonomy: persons have unconditional value because they are capable of making rational choices and forming rational moral laws. This is the source of our dignity as human beings. When human beings exercise their ability to reason, they are acting autonomously.[30] Essential to the concept of individual autonomy is what Fried terms 'the intuitive notion of liberty: to dispose of one's self, one's person, one's body, mind, and capacities according to a plan and conception fully chosen for oneself.'[13]

When choosing among modes of therapy, the patient's condition and alternatives must be discussed honestly if his dignity is to be respected. The goal of health care has traditionally focused on the maintenance of bodily integrity; but the informed consent rrequirement calls for the protection of *human* integrity as well. To sacrifice the latter to enhance the former is an assault on the patient's

human dignity, as Berlin implies in a discussion of positive freedoms:

. . . to lie to men, or to deceive them, that is, to use them as means for my, not their own independently conceived ends, *even if it is for their own benefit*, is in effect, to treat them as subhuman, to behave as if their ends are less ultimate and sacred than my own.[31]

In the research situation, the patient-subject's autonomy is again at stake, but not for the sake of doing a procedure for his own good. To provide the patient-subject with all material information concerning the proposed use of his body is to respect his human dignity and enhance his autonomy; to violate his choice – through deception or withholding of useful information – is to treat him merely as a means to an end, and not as an end in himself. Deception of the volunteer in an experiment goes beyond denying him a 'human right', *it denies him a portion of what it means to be human.* Mead writes:

To fail to acquaint a subject of observation or experiment with what is happening – as fully as possible within the limits of the system of communication – is to that extent to denigrate him as a full human being and to reduce him to the category of dependency in which he is not permitted to judge for himself.[25]

AUTONOMY AS A BASIS OF INFORMED CONSENT

Although the rationale for informed consent varies from one jurisdiction to another, it has its roots in the principle of self-determination. Annas, *et al* cite statistics that 'of the approximately two hundred appellate decisions dealing with informed consent, fewer than forty-five cases mention the basis on which the court found or failed to find consent necessary. Of those that do give a basis, twenty-five rely on *the patient's right of self-determination*, thirteen citing *Schloendorff*,[47] where Justice Cardozo wrote in 1914:

. . . Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's informed consent commits an assault, for which he is liable in damages. . . . This is true except in cases of emergency where the patient is unconcious and where it is necessary to operate before consent can be obtained.[32]

In 1960, the principle of self-determination was applied not only to surgery, but to other medical treatment as well. Justice Schroeder argued:

Anglo-American law starts with the premise of thorough-going self-determination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of life-saving surgery or other medical treatment.[10]

The right to self-determination, as these cases imply, is a right independent of promoting benefits or minimising harm to the patient and/or society. If self-determination is a right, it is no less a right merely because benefits/risks to oneself are possible. Veatch writes: 'The principle of autonomy – the right to self-determination – provides an independent foundation for informed consent . . . necessary for all invasions of the body or even invasions of one's privacy.'[33] This is not to suggest that informed consent may not *also* do a lot of other nice things (e.g., avoid fraud and duress, encourage rational decision-making, and involve the public, as Katz suggests) [34] but rather that its *primary* purpose is to promote individual choice regarding one's body, not merely to promote consequentialist objectives mentioned above.

Conclusion and recommendations

Placebo administration necessitates the deception of patients and volunteer subjects by the medical profession. This deception tends to be unethical in light of the following considerations:

1) The negative consequences of this deception tends to outweigh any positive benefits on balance;
2) The very nature of a deceptive act tends to make it wrong, independent of its consequences;
3) Deceiving the patient or subject has serious implications on his right of self-determination, and therefore on his human dignity. On the basis of these considerations, I would make the following recommendations:

THERAPY

No substance should be administered to a patient deliberately to achieve a placebo effect unless they know the nature of both their 'disease' and the 'remedy'. If a placebo appears absolutely necessary (after the nature of the problem has been clearly disclosed and no other form of treatment is available and acceptable to the patient), the physician ought to make it clear that there is no chemical reason why the placebo might work, but that studies have shown that inert substances might psychologically benefit the patient. (At least one study by L C Park, *et al*, indicates that patients may benefit from placebos even though told of their nature)[23]. Such a disclosure should not be altered on the basis that the patient might refuse this mode of therapy or that the placebo's effectiveness might decrease somewhat. In other words, where the patient agrees to therapy *understanding* that the physiological benefit might be triggered by a psychological response, there is no deception. If treatment is necessary, a patient should always be given *bona fide* therapy (when it exists) rather than a placebo.

EXPERIMENTATION

Although some object that informing volunteers of

the presence of the placebo in the research design would ruin the research, no evidence has been presented by objectors to prove this argument. Mead discusses the possibility of general assent to deception prior to the experiment:

Many of the situations where concealment is genuinely necessary and the experiment cannot be performed in some other way can be handled by general assent from the subjects, *who know that they are agreeing to be deceived for the purpose of the experiment itself*[25] (author's emphasis).

Why not give the patient as much information as the researcher himself has in a double-blind situation? Leake discusses this possibility:

It is often claimed that the subject should not even know what the purpose of the experiment may be in order not to jeopardise the objectivity of the findings. In my opinion, this is not wise. Let the subject know just as much as the experimenter, even to the point of explaining that drugs may be interchanged. Such a method could control the possible subjective notions of the experimenter as well as the subject.[35]

By implication, the participants could also, without serious harm to the experiment, be told that drugs may be interchanged with placebos, or that there is a constant placebo group throughout the duration of the experiment. The following might be a feasible research design:

Group 1: Tell participants in this group that they will receive the active experimental drug, and administer that drug, as they have been informed;

Group 2: Tell them that they may get the experimental drug or a placebo; administer the experimental drug;

Group 3: Same information as Group 2, but administer the placebo.

Assuming that the participants agree to this arrangement prior to the experiment, this design would protect the subject's choice, while at the same time protecting the scientific effort, since comparisons of expectations could still be made.

What would be an appropriate course of action in the *hypothetical* situation in which informing the volunteer of the presence of a placebo in the experimental design would ruin the experiment?

First, there must be an *objective determination* that the expected results of the research are of immediate importance. It is not enough that researchers themselves feel their research would be important, given the biases inherent in the experimenter's attitude toward his own work. It might be desirable to include some competent lay persons to help determine the significance and immediacy of the expected findings. How important must the findings be? It is not enough that they be very interesting, or useful in some abstract future situation. Only an experiment that has a good chance of producing results of *life-saving significance* for large numbers of people ought to even be considered if deception is to be employed.

The obvious question to such a proposal is, why does a lot of benefit override formalist considerations of truth-telling and autonomy? To concede that great benefits alone merit such a trade-off would be to repudiate the inherent value of disclosing the truth and the absolute value of human beings as independent moral agents. A second criterion must be met to permit such research: there must be an objective determination that the subjects involved would consider the deception so trivial and the risks so miniscule that no compromise of their autonomy has been made. One way this might be done is to interview a very large number of potential volunteers, giving them all the facts of the procedure, including the disclosure of procedures which are deceptive. If those interviewed signify *overwhelmingly* that such a procedure would in no way offend them, then that is an indication that the proposed experiment, *in the opinion of the reasonable person*, makes no in-road into their autonomy. Wherever possible, subjects ought to be selected from the very population which indicated the deceptive research would not bother them. (I do not offer this plan as a *substitute* for existing requirements of informed consent outlined in the regulations of the Department of Health, Education, and Welfare, but as an *additional* safeguard in cases where it is impossible to disclose the presence of a placebo in an experiment.)

These standards of disclosure could protect both the integrity of the medical profession, and the dignity of the individual patient/subject, without seriously impeding therapeutic or scientific progress. Our society should reject any standard of disclosure which gains some physical benefit at the cost of human dignity.

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