

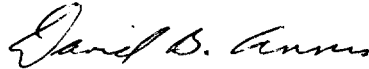
Informed Consent: An Analysis

An Honors Thesis (ID 499)

by

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## Informed Consent

"It is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie--Cobbs v. Grant (1972)," (18, P.750). The essence of self-determination lies within this statement. A person has the right to make basic medical decisions that affect him. These decisions are based on the patient's goals, fears, beliefs,.... To be a self-determining being when trying to decide on a medical treatment, information concerning the risks and expectations of the treatment is needed to make that decision.

The underlying goal of the doctrine of informed consent is to enable patients to have the information necessary to make decisions as self-determining beings. The doctrine places a duty on the physician to disclose the diagnosis, possible treatments, risks of treatment, and expected results concerning a patient's medical problem. How has the doctrine of informed consent evolved? What standards of disclosure must physicians adhere to? Why is this doctrine so important? Are there exceptions to the required standard of disclosure? How are these exceptions justified? Are these exceptions problematic? What does the future hold for the informed consent doctrine? Herein lies the answers to these questions.

In the 1914 case of *Schloendorff v. Society of New York Hospital*, Judge Cardozo stated, "every human being of adult years and mind has a right to determine what shall be done with his own body..." (11, P.976). The *Schloendorff* case was meant to apply only to cases of unauthorized treatment. The central issue dealt with the necessity of a patient's consent, not whether that consent was an informed decision. However, the basic premise of informed consent is found in the words of Judge Cardozo. This premise is that a patient has the right to exercise decision-making power over his own medical treatment.

The *Schloendorff* court provided the underlying premise of informed consent that latter courts used to expand the scope and meaning of the doctrine. The cases of *Salgo v. Leland Stanford Jr. University Board of Trustees* and *Nathanson v. Kline* expanded the doctrine to apply to cases in which the patient authorized treatment but was not informed of the treatment's risks. The plaintiff in the *Salgo* case suffered from leg cramps which caused an intermittent limp. To discover the extent of his problem, *Salgo* submitted to a test involving an injection of a material into his aorta. The injected material caused *Salgo* permanent paralysis from the waist down. *Salgo* was not informed

of this risk. The Salgo court held,

a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment (11, P.977).

This case dealt with more than mere consent to a treatment. This case, unlike *Schloendorff v. Society of New York Hospital*, stresses the importance of an informed consent. In fact, the phrase "informed consent" derives from the Salgo court.

The Salgo case was decided in 1957. Three years later the *Nathanson v. Kline* decision reaffirmed the Salgo court's holdings. In the *Nathanson* case, the plaintiff had cobalt irradiation treatment after surgery to remove cancer. The plaintiff was severely burned due to an excess of the irradiation. The patient never received a warning about the possible risks of burning. The court ruled that patients in *Nathanson's* situation should be fully informed of the risks involved in cobalt irradiation therapy.

According to the Salgo and *Nathanson* courts, physicians must disclose information about their patient's medical condition to that patient. What exactly must be disclosed to the patient? The Salgo court held that the content of what a physician must

disclose is based on professional medical judgment. This professional standard was clearly enunciated in *Karp v. Cooley*. The *Karp* court ruled that a physician must disclose facts which a medical practitioner in a similar community and of the same school of medical thought would disclose in the same situation. In those states which follow the *Karp* rule, a plaintiff must prove that the physician failed to disclose the nature or risks of the treatment in question. In addition, the plaintiff must establish what the physician should have disclosed based on the standards of disclosure of physicians in the same community. This can only be achieved through expert testimony. The experts would consist of other medical practitioners in the same community.

The expert testimony requirement was reaffirmed in *Woolley v. Henderson* and *Bly v. Rhoads*. The *Woolley* court reasoned that laymen with the benefit of hindsight would view the duty of disclosure based on the unfortunate result. The *Bly* court was concerned with the complicated and technical nature of many medical treatments. The *Bly* court contended that complex medical procedures and terminology should not be left for laymen to interpret.

Until the case of *Canterbury v. Spence*, the

professional standard prevailed throughout the United States. Canterbury established the reasonable person standard of disclosure. According to the Canterbury court, "The physician must disclose those risks which would be material to a reasonable person in the patient's position," (11, P.981). What is a material risk? The court held,

a risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy (5, P.787).

The Canterbury court discarded the professional standard because, "...respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves," (12, P.773). Thus, the court developed the reasonable person standard because the structure of the professional standard allowed doctors to choose whether they imposed an obligation to disclose upon themselves. Allowing the doctor to choose, showed no respect for a patient's right to self-determination.

Dunham v. Wright is another case in which the reasonable person standard was applied and defended.

Part of the Dunham court's reasoning for the reasonable person standard is that the patient must bear the pain and suffering as well as the cost of medical treatment or an injury resulting from medical treatment. Thus, the right to know all the material facts relating to a proposed treatment should not depend on the, "self-imposed standards of the medical profession," (11, P.982).

The professional standard was discarded by various courts because of the importance of patient autonomy. What is autonomy? Why is it so important? The etymology of the word autonomy is: autos = self; nomos = rule or law, (8, P.108). "Autonomy is tied up with the idea of being a subject, of being more than a passive spectator of one's desires and feelings," (8, P.107). To be autonomous is a, "distinctively human ability, that they are able to reflect upon and adopt attitudes towards their desires, intentions, life plans," (8, P.108). Thus, autonomy involves being actively involved in rationally thinking about one's desires, life plans,... and developing personal attitudes about these life intentions. Yet, autonomy involves more than simply thinking. Being an autonomous person includes,

1. Being capable of weighing choices rationally.
2. Being able to act on the basis of those rationally made choices (21, P.62). Autonomy involves rationality.

I think rationality is the foremost characteristic of being autonomous. Without it, there is no reflection upon desires or choices.

It appears that rationality is the first characteristic of being autonomous. Next an autonomous being is able to act upon the choices his rationality has produced. This ability to choose can be inhibited in two ways. First, is interfering with the freedom to exercise choice. This can be done by locking someone in a room. The person may chose to leave but is prevented from doing so. Second, is interfering with the choice-making process. This would involve limiting someone's choices. This is where the doctrine of informed consent comes into play. The contention is that when physicians do not disclose information on treatment alternatives, risks,... the patient's choices are limited.

Why is autonomy important? First of all, "Our self-respect is connected with whether we are recognized by others as having the capability of determining our own destiny," (8, P.112). Therefore, when a physician does not allow his patient to make an informed intelligent decision based on the patient's needs, goals,... then, the patient loses a part of his self-respect. The patient sees that the doctor does not believe that he is capable of making rationale decisions about his

(the patient) own future. Secondly, autonomy is important because, "being able to shape one's own choices and values makes it more likely that one's life will be satisfying than if others, even benevolent others, do the shaping," (8, P.111). Finally, "What is valuable about autonomy is that the commitments and promises a person makes be ones he views as his, as part of the person he wants to be, so that he defines himself via those commitments," (8, P.26). It makes sense that the importance of autonomy boils down to the fact that a particular patient has only one life to live. To make that life his own, he makes commitments based on his own views. A physician can not live his patient's life for him. The doctor must allow his patient to make his own decisions concerning medical treatment.

The professional standard of disclosure was discarded by various courts because it did not respect patient autonomy. Does the reasonable person standard respect patient autonomy? When compared to the professional standard it does appear to respect autonomy. The doctor is required to disclose that information which a reasonable person would deem material. The "reasonable person" is a composite of the members of the community. The values of a community are

incorporated to make up the values of the "reasonable person". This is an objective standard. To fully respect autonomy the standard needs to be subjective. The standard needs to move away from a hypothetical being and move toward the real person involved. "Judgments about what is beneficial to a particular patient will vary from patient to patient depending upon the particular norms and values of that person..." (8, P.102). The focus needs to be on the informational needs of individual patients.

The average reasonable person standard presently operative in law should be supplemented by a standard which takes account of the independent informational needs of actual reasonable persons in the process of making a difficult decision (2, P.7).

The present reasonable person standard is not totally without good aspects. These good aspects simply need to be added to.

Throughout the history of the informed consent doctrine, exceptions have been made to the requirement of disclosure. These exceptions have been justified by the principle of paternalism. Paternalism is "the interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests, or values of the person being coerced," (8, P.121). Physicians who are acting paternalistically believe that they are acting for the

good of the patient. Basically, paternalistic actions undercut autonomy. The patient is not permitted to make an informed choice.

Paternalism can be justified in some situations. "Paternalism is justified when autonomy is protected to a much greater degree than it would be if a non-paternalistic position were accepted," (21, P.65). For example, a woman has been seeing a psychiatrist for years. Due to her mental condition, bad news, such as her diagnosis of cancer, would drive her over the edge. She would never be able to function rationally again. Thus, her future autonomy is being protected by denying part of her present autonomy.

With the doctrine of paternalism in mind, the exceptions to informed consent must be examined. The exceptions to disclosure are as follows:

1. Emergencies
2. The patient is incompetent at the time.
3. The procedure is simple and the risks remote.
4. The patient requests that he not be informed, (a waiver).
5. According to the physician's judgment, it is not in the patient's best interest to know, (therapeutic privilege).

An emergency situation is one in which the patient is unable to receive information about or give consent

to a particular treatment. In an emergency, it would be impossible for the physician to wait until the patient was able to give consent. When a doctor treats a patient in an emergency he, "is acting to preserve the patient's possibility for future autonomous action," (8, P.116). The physician is infringing on the patient's right to make a decision. Perhaps the patient does not want a blood transfusion because of his religious convictions. Chances are that the doctor does not know this. He is simply trying to save the patient's life or limb. I think this exception is justified by the doctrine of paternalism.

The second exception is incompetence. In a situation where the patient is incompetent he can not rationally give consent. "The case of incompetency is one in which our autonomy has already been impaired, lost, or not developed so there is no denial of autonomy on the part of the doctor," (8. P.117). For example, an infant has not yet developed a sense of autonomy. The child can not give consent or even receive information. Yet, someone has to authorize treatment for an incompetent person. This is where the problems begin when dealing with the treatment of incompetent persons. Who gives consent for these individuals and what criteria should be used, needs to be determined by the medical and legal

communities. Parents and guardians are usually given the responsibility of authorizing treatment. However, who gives consent for the incompetent John Doe? These are perplexing problems.

It seems to be the norm that doctors do not have to disclose information to a patient when the medical procedure is simple and very low risk is involved. An example would be the routine blood tests given during regular check-ups. Yet, not being informed of the purpose of the test or even the smallest risk violates autonomy. A patient has the right to determine whether he is willing to take even the smallest risk. I personally do not know why the test is given. Should I know? I think so. Some doctors believe that informing patients of small risks could cause them to reject needed protection such as vaccinations (4, P.80). I do not think this is necessarily true. A patient in this situation is rational enough to weigh the risks and advantages of a blood test or a vaccination. The physician should respect the patient as an autonomous being. The patient has the right to make his own choice. I do not think that physicians should be allowed not to disclose the risks of a procedure no matter how small they are. Thus, this exception to disclosure is not a valid exception.

The next exception is that of a patient waivering his right to information. In this situation it is the patient's choice, not the physician's, to not be informed. "When a patient waives his right to be informed he is acting autonomously," (8, P.116). The patient, after rational consideration, decides to remain uninformed about his medical condition or risks and alternatives to a proposed treatment. The patient may feel it is in his own best interests to allow the doctor to have control over the situation. Perhaps the patient is protecting his own mental health. Whatever the reason is, the patient has the right to make that decision. The patient as an autonomous being has the right to waive his right to be informed. An attempt to force the patient to digest the information would be a violation of his autonomy (8, P.118). It has to be understood that a patient is acting autonomously when he waives the right to be informed. In order to fully respect patient autonomy this waiver exception must remain in use.

The final exception to disclosure is referred to as the therapeutic privilege. The therapeutic privilege exception allows a doctor to withhold information which could have adverse affects on the patient's mental or physical health, while still obtaining consent.

There are two situations in which this privilege is invoked. The first is when the disclosure of information has a, "direct harmful effect on the emotional state of the patient," (8, P.119). In this case, the principle of paternalism is used to justify the lack of disclosure. I think that physicians who honestly believe that their patient's mental state could be hurt by disclosing information are justified in acting. However, how can the doctor's beliefs about a patient be determined after the fact, in court for example. Perhaps the physician should be required to consult with a review board or other physicians. However, to do this the doctor would have to violate the patient's right to privacy, on top of undercutting his autonomy. There is another possible proposal. Instead of requiring patients, plaintiffs, to produce evidence that their physicians violated their autonomy without a good reason, the burden of proof could be shifted onto the physician. Thus, the doctor, plaintiff, would have to produce evidence that the patient would have suffered harm if the information in question was disclosed. This obviously would only come into play when the doctor was sued. In the end, medical practitioners will depend less on the therapeutic privilege exception.

The second situation in which the therapeutic exception is invoked is when, "The doctor believes that disclosure would lead the patient to choose a form of treatment that is not optimal..." (8, P.119). In essence, the doctor thinks the patient will make the wrong decision. To, "grant such authority to doctors must undermine the atmosphere of trust between doctor and patient, for the doctor could not for long simply remain silent but would have to mislead and, in many cases, lie," (8, P.119). This is a valid point. If a physician chooses not to inform his patient for fear that the patient will make the "wrong" decision, then what is keeping the doctor from lying to his patient to lead him to the right decision. Nothing! If doctors are allowed to use this reasoning for not disclosing, then the communications between doctor and patient will be constantly suspect by the patient (8, P.119). Withholding information with this reasoning violates autonomy and should not be allowed. The only way to remedy this problem is to shift the burden of proof onto the physician when patients sue. In addition to a remedy this can be a beneficial deterrent.

The therapeutic privilege obviously has advantages and disadvantages. Thus, the entire exception can not validly be banned from use. However, it does need to

be restricted. The legal and medical communities need to find a middle ground that will benefit the patient and not harm him. The patient is the most important element in the equation.

In concluding, it should be mentioned that the doctrine of informed consent is not the easiest to apply. Guidelines need to be set up so the doctor can help his patient understand instead of worrying whether his patient is going to sue him if he is unhappy. Physicians do not always understand why they must inform patients about the smallest of risks. Many physicians believe that patients do not want to hear bad news (4, P.78). The medical community needs to realize that most patients want and can handle bad news. They may deny the diagnosis at first however, this denial is a stage that will pass (4, P.78). Eventually, the patient will be able to work hand in hand with their doctor to make treatments more successful. In fact,

the damages associated with the disclosure of sad news or risks are rarer than physicians believe; and the benefits which result from being informed are more substantial... Pain is tolerated more easily, recovery from surgery is quicker, and cooperation with therapy is greatly improved (4, P.80).

Patients, physicians, and law-makers need to work together to eliminate the kinks in this doctrine.

This is the only way to protect and respect everyone, doctors, lawyers, and patients, as autonomous beings.

## Bibliography

<sup>1</sup> Appelbaum, Paul S., M.D.; Lidz, Charles W., Ph.D and Meisel, Alan, J.D.; Informed Consent- Legal Theory and Clinical Practice, Oxford University Press, New York and Oxford, 1987, P.18-31.

<sup>2</sup> Beauchamp, Tom L. and Childress, James F., "The Principle of Autonomy," in Natalie Abrams and Michael D. Buckner, eds., Medical Ethics, The MIT Press, Cambridge, Massachusetts and London, England, 1983, P.3-12.

<sup>3</sup> Berry, Steven J. and Wallach, D. Michael, "Informed Consent in Texas: a Proposal for Reasonableness and Predictability," St. Mary's Law Journal, Vol.18, Winter 1987, P.848-849.

<sup>4</sup> Bok, Sissela, "Lies to the Sick and Dying," in Thomas A. Mappes and Jane S. Zembaty, eds., Biomedical Ethics; Second Edition, McGraw-Hill Book Company, New York, 1986, P.75-83.

<sup>5</sup> Canterbury v. Spence, 646 F.2d 772 (1972).

<sup>6</sup> Christie, Ronald J. and Hoffmaster, C. Barry, Ethical Issues in Family Medicine, Oxford University Press, New York and Oxford, 1986.

<sup>7</sup> Dobson, Tracy, "Medical Malpractice in the Birthplace: Resolving the Physician-Patient Conflict through Informed Consent, Standard of Care, and Assumption of Risk," Nebraska Law Review, Vol.65, Fall 1986, P.672-677.

<sup>8</sup> Dworkin, Gerald, The Theory and Practice of Autonomy, Cambridge University Press, Cambridge and New York, 1988.

<sup>9</sup> Gert, Bernard and Culver, Charles M., "The Justification of Paternalism," in Natalie Abrams and Michael D. Buckner, eds., Medical Ethics, The MIT Press, Cambridge, Massachusetts and London, England, 1983, P.13-22.

<sup>10</sup> Goldman, Alan H., The Moral Foundations of Professional Ethics, Rowman and Littlefield, New Jersey, 1980.

<sup>11</sup>Griffith, Ladonna L., "Informed Consent: Patient's Right to Comprehend," Howard Law Journal, Vol.27, Summer 1984, P.975-993.

<sup>12</sup>Katz, Jay, "Informed Consent in the Therapeutic Relationship: Law and Ethics," Encyclopedia of Bioethics, Macmillan and Free Press, Georgetown University and New York, Vol.1, 2, P.770-778.

<sup>13</sup>Mappes, Thomas A. and Zembaty, Jane S., "Biomedical Ethics and Ethical Theory," Biomedical Ethics, Second Edition, McGraw-Hill Book Company, New York, 1986, P.1-46.

<sup>14</sup>President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Conclusions and Recommendations Regarding Informed Consent," in Thomas A. Mappes and Jane S. Zembaty, Biomedical Ethics, Second Edition, McGraw-Hill Book Company, New York, 1986, P.103-108.

<sup>15</sup>Robinson, Judge Spotswood W., "Opinion on Canterbury v. Spence," in Thomas A. Mappes and Jane S. Zembaty, Biomedical Ethics, Second Edition, McGraw-Hill Book Company, New York, 1986, P.90-94.

<sup>16</sup>Rosoff, Arnold J., Informed Consent- A Guide for Health Care Providers, An Aspen Publication, Rockville, Maryland and London, 1981, P.38-41.

<sup>17</sup>Teff, Harvey, "Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance?," The Law Quarterly Review, Vol.101, July 1985, P.436-442.

<sup>18</sup>Weisband, Alan J., "Informed consent: the Law's Uneasy Compromise with Ethical Theory," Nebraska Law Review, Vol.65, Fall 1986, P.750-767.

<sup>19</sup>Williams, Kevin, "Informed Consent or a Duty to Inform," Solicitors' Journal, Vol.129, March 22, 1985, P.195-198.

<sup>20</sup>Williams, Kevin, "Pre-operative Consent and Medical Negligence," Anglo-American Law Review, Vol.14, April-May 1985, P.169-180.

<sup>21</sup>Zembaty, Jane S., "A Limited Defense of Paternalism in Medicine," in Thomas A. Mappes and Jane S. Zembaty, Biomedical Ethics, Second Edition, McGraw-Hill Book Company, New York, 1986, P.60-75.