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ABSTRACT

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Two aims of this dissertation are; (1) to describe the American experience of informed consent to the Japanese audience whose medical practice, despite its successes in health care, is feudal in terms of physician-patient interaction, and (2) to make an appraisal of informed consent as a part of the theory of participatory democracy.

Informed consent is a medical practice that requires a physician to disclose necessary information to a patient and obtain consent from the latter with regard to her proposal of a diagnostic or treatment procedure. Consent makes sense only when it is the result of understanding and voluntariness. So, the real message of informed consent is its democratic nature, namely patient's participation in medical decisionmaking against traditional medicine where a physician has been the sole decisionmaker.

In the first chapter I discuss Japanese medical practice that needs informed consent. The second chapter deals with the American history of informed consent and compares the legal doctrine and ethical idea of informed consent. The third chapter attempts a philosophical reconstruction of informed consent. It deals with the conversation model of informed consent suggested by Jay Katz and the spectrum of understanding from the informational level through the hermeneutical level to the shared decisionmaking stage. The legal doctrine concerns mainly informational understanding. Hermeneutical understanding attains ethical goal of commonality in the fusion of horizons (Gadamer). Democratic understanding is directed to the solution of problems by way of common understanding and shared decisionmaking (Habermas). Informed consent should mean shared decisionmaking realized only in the conversation model instead of indifferent medicine that informational understanding implies or of hermeneutical medicine where decisionmaking is still in the physician's hands. Consistent claims throughout the dissertation address the efficacy of language use in mutual communication and the idea of participation. The final chapter deals with participatory democracy in which social policies as well as ethical norms are placed in the open, the practice of informed consent being no exception. Our final discussion concerns social conditions that could make informed consent work. It includes proposals for public policy for informed consent.

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INTRODUCTION

The main topic of this thesis is informed consent. To thematize informed consent at this time may not be a very interesting project for contemporary issues in medical ethics and professional ethics in the United States. Informed consent has been discussed for more than three decades now. It is already eight years since the President's Commission's report on medical decisionmaking appeared. With so much literature available on this subject, there seems little more to say. Yet I want to undertake two tasks concerning this particular subject.

One is directed to the state of medical practice in my home country, Japan, where medical ethics has emerged only recently as a discipline. The physician-patient relationship in Japan is similar to what seems to have existed in the United States several decades ago. When I left my country eight years ago in 1982 I had left behind a series of unhappy encounters with physicians. One physician was simply mute, another smoked in front of me though I was an asthma patient, still another started arranging a tonsillectomy for my small son without consulting me. I was one of those birthing mothers to whom an episiotomy was administered without my knowledge, and this generated considerable silent resentment. I was also taken into the famous non-disclosure plot on terminal cancer cases. Looking back, I realize that I was a passive, dependent, ignorant, and unreflective patient. Most of the physicians I saw were not only unwilling to communicate with patients but also lacked awareness that they were dealing with persons. The study of informed consent in medical ethics here in the United States has taught me that the physician has a duty to inform and obtain consent from the patient and, more importantly, that the patient should and can be an autonomous decisionmaker. These were totally foreign things for the ongoing medical relationship in Japan until quite recently. As a sign of improvement there is now a new move to officially introduce the idea of informed consent. So, while the study of informed consent may be outmoded in the United States, a correct exposition of the idea is a needed and timely project for Japanese physicians and patients.

This study has also persuaded me that the most important message of informed consent is that it is a part of the theory of democracy, and that the physician's authoritarian posture and the patient's dependent attitude are inappropriate to citizens in any society where democracy is the declared way of life. The study of informed consent has relevance not only for medical practice in a Far-Eastern country but also for reflection on the overall scheme of democracy, which is the only option to take for a global community which we can envisage in the next century. Viewed in such a perspective, informed consent has yet to find a secure place in philosophical, ethical discussions of democracy. The relationship between physician and patient seems the last one to be democratized. The imbalance of knowledge and power between physicians and patients is too easily taken for granted. A medical relationship is the prime locus where paternalism is justified because of alleged incapacity, irrationality or immaturity of one party. Even in the United States the introduction of the idea of informed consent has not transformed every physician into a less authoritarian, open-minded care-provider, and every patient into a mature, independent decisionmaker. In the Western tradition individual selfhood may well be instilled in the socialization process. But when it comes to medical treatment, most people still want to take a child-like role in front of a physician. It seems that there is a need for establishing an autonomous self who can make a rational decision in a medical context. It is time to secure a place for informed consent in a theory of democracy, and present it in the curriculum for educating a democratic citizen.

So my second task in this treatise is to place the idea of informed consent in a proper place. I want to do it by seeking a linkage between the autonomous subject and communal orientation in the concept of understanding which finds its expression in communication with one another. To thematize understanding is also appropriate from the standpoint of the study of the elements involved in informed consent. For informed consent to be realized, it is said that at least two conditions have to be met, namely, understanding and voluntariness. Because voluntariness is (or should be) based on understanding, the discussion of understanding covers the issue of intentionality. It also has a strong connection with reflection and judgment.

My claims in this treatise are : (1) that a higher level understanding not only validates consent-giving but demands a truly democratic interaction without domination in a medical context; (2) that it is necessary and possible to make the physician-patient relationship as democratic as possible; and (3) that informed consent, when fully implemented, is the only institution to realize that sort of relationship. The following is the main scheme of this thesis on informed consent. In my discussion I owe much to medical ethics literature that appeared in the United States in recent years. I am indebted especially to Jay Katz's characterization of traditional medical practice as silent medicine and his proposal of the conversation model as the only feasible one to realize informed consent in an ideal manner. I have also found Jürgen Habermas enormously helpful for delineating the spectrum of understanding, thereby providing a new perspective on medical relationships. In the first chapter, I will discuss the problems of Japanese medical practice which lacks the idea of informed consent. Although Japan's public health care policy has greatly attained the goal of eliminating diseases, it attacked them without paying attention to the patients; silent, paternalistic medicine has long been operative. One origin of the present practice is traced to the official introduction of German medicine in the last century. German idealism was also instrumental in the formation of Japanese political ideology which supported and justified the pre-war authoritarian structure which is still an undercurrent of undemocratic relationships and basic social structure. I will then focus on how the medical establishment has approached the problems of medical ethics in recent years and discuss the problematics found in the new report of hearings of the Japanese Medical Association (JMA) on informed consent.

The second chapter concerns the theory and practice of informed consent that has been developed in the United States. The main focus is the contrast between the legal nature and the ethical requirement of informed consent. I will discuss the meaning and the limitation of the legal doctrine of informed consent, and touch upon the actual practice which falls far short of an ethical, democratic ideal. It will be shown that the ethical idea of informed consent is closely connected with hermeneutical understanding, but also with democratic understanding of self, others, community and objective knowledge.

In the third chapter the main focus is the conversation model and the concept of understanding in the context of informed consent. To understand information disclosed is the first step to be fulfilled in the procedure of informed consent. Understanding involves more than making sense of the given, objectively confirmable information within a certain context. Understanding is viewed in a certain spectrum. The most elementary type deals with objective knowledge. The second is hermeneutical. Since medical practice in identification and cure of a disease involves human beings as agents whose mental operation is the prime cause of actions, understanding should involve a hermeneutical approach which tries to derive meanings from the human actions. The hermeneutical approach counteracts the all-objectifying, physicalistic approach in medicine. However, the limitation of the approach lies in the tendency to keep the status quo intact, and not to reform the vertical relationship of physician and patient in a fundamental way. The third level has to do with democratic decisionmaking. The conversation model of informed consent proposed by Jay Katz incorporates the latter two phases of understanding. But there are variations of the conversation model. Hermeneutical conversation does not necessarily aim at democratic decisionmaking. A democratic conversation model encompasses features of all three levels, namely, objectivistic, hermeneutical and shared-decisional understanding. Habermas' communication theory will be evaluated as promising to endorse the democratic medical relationship that Katz's conversation model addressed.

In the final chapter I will discuss the basic understanding of the theory of participatory democracy in which informed consent will be placed. First, the legacy that Rousseau started will be reviewed. Then, the theory and practice of informed consent will be evaluated as something to be discussed and employed as binding in a democratic forum. It will be argued that the traditional authority of the medical profession should be exposed, demystified and reevaluated. To make medicine as democratic as possible, I will discuss a proposal for public education about the implementation of informed consent.

Some important features in medical care, such as the issues of gender difference and economic justice, have to be mostly left out of my consideration. The specific problematic in the medical relationship is here taken as gender-neutral. I also have to assume that there is no grave injustice about accessibility to medical care. But, since implementing informed consent in an ideal mode can be costly in a capitalist society, some economic consideration has to enter my discussion. Medicine should to a large extent be socialized. That means the right to medical care should be a part of subsistence rights which a democratic society is expected to guarantee. But even when distributive justice is realized, it is possible that a medical relationship remains gravely undemocratic. Socialized medicine could be concomitant with paternalism of the state, unless it is a product of truly democratic procedures. The discussion of informed consent will not lose its significance in a society where basic needs are taken care of.

CHAPTER I THE SILENT MEDICINE OF JAPAN

The theme of this chapter is medical practice in Japan, which is about to face the official introduction of informed consent. A correct conception of informed consent has never been more needed than now because of the growing interests of the general public in better medical practice and because of the responses of the medical establishment expressed in their reports and statements. In the first section I will mention issues of the physician-patient relationship and focus on a recent lawsuit and the judicial handling of the case. The description of the issues will present a contrast, or rather a serious contradiction, within an advanced capitalist and highly (although unbalancedly) technological society which, despite its outward democratic appearance, operates largely on traditional principles of social and human relationships that are clearly undemocratic. There is no serious shortage of medical care, but the lack of democratic interaction in medicine needs attention as it is the cause of much unspoken discontent and mistrust toward the medical profession. The second section will deal with the German legacy of Japanese medical practice and philosophical attempt to endorse this heritage which has hindered a full democratization of ways of life in society. I will discuss two representative theories of society and human relationships which can be contrasted with Western participatory democratic ideas. In the third section I will discuss the attitudes of the medical establishment toward the issue of democratizing medical practice in Japan. It will be suggested that although the concept of a patient's giving consent upon appropriate information may not be a difficult one for the Japanese to accept, the concept of a patient's participation in decisionmaking in medical matters would be too radical for both physicians and patients. If presented sugar-coated to suit the Japanese taste, however, informed consent will lose its liberating power as a democratic idea.

1. Conflictual medical relationship

On the external level Japan is on a par with other major industrial forces in the world equipped with the state apparatus of parliamentary democracy. The Japanese constitution is called the "Peace Constitution" because war is renounced forever and various individual rights are guaranteed. In public health care Japan is one of the most developed countries. Statistically, the Japanese enjoy the greatest longevity and the lowest infant mortality rates in the world. After the postwar introduction of American medicine, efforts were made to eliminate diseases such as tuberculosis and to deal with high infant mortality. The death rates per 100,000 population have decreased from 1,087 in 1950 to 615 in 1987. Japan was so quick to provide kidney dialysis machines that no serious problem of allocating limited resources has existed. A correspondent for *The New England Journal of Medicine* reports that "Japan has more CAT scanners per capita than the United States" (Iglehart, p.1166).

All the same there is much mistrust and dissatisfaction among patients with the medical profession. The charge of 'reckless medicine' is made against the practice of those who exploit medicine for their own personal interests. Physician overcharges (to the insurance agencies) for the reimbursements for their services, and large-scale tax evasion, have been social problems for quite a while. Patients are puzzled by the enormous amount of prescribed drugs which do not seem necessary. A close link between the physicians (who can both prescribe and dispense drugs) and the pharmaceutical companies seems to be immoral rather than just indiscreet. A visit to a physician's office is described in a popular saying, "Three hours' waiting, three minutes' consultation" which is actually routine, especially at an out-patient office of a large hospital. The author of a Japanese book titled *Reasons Why Doctors Are No Longer Respected* was himself a physician. He blames Japan's reimbursement system for physicians' unconcerned behaviors. He is not the only one who says that the system based on fee-for-service and universal insurance is an incentive for more patients to visit doctor's offices even for trifling reasons and for physicians to do only calculable services such as testings and dispensing of drugs (Nagai, p.27). Physicians justifiably claim that their effort to spend more time in the initial consultation is not duly rewarded. On the other hand it was the physicians who were mainly responsible for making medical practice very lucrative and expanding their power and authority through accumulated wealth. Physicians, who deplore that medicine has transformed itself from the art of *jen* (humanity), which used to be its ideal, to the art of arithmetic, where business or economics plays an important role, think that the solution to the problem will come from the recovery of medical practice which used to be operative on the basis of the age-old principle of *jen*. This was actually the suggestion made recently by the present president of the Japanese Medical Association (JMA) (Haneda). Advanced technology and changes in clinical management has transformed traditional medicine into a less humane, less personal one. Surely the nature of the relationships should be adjusted to a new medical practice which did not exist a few decades ago. But the solution for the problem is not found in the retrieval of an old ethic. Unlike those well-meaning physicians who suggest such a measure, one can justifiably point to a hitherto unheeded truism that patients can have a say about the treatment of their own problems. Further, instead of silent medicine, there seems to be something good about having a conversation between physician and patient and allowing the patient to transform from a passive, dependent beneficiary to an independent decisionmaker who can participate in medical decisionmaking. But such transformation would be impossible while physicians want to keep exercising their paternalistic authority, and reject patient's active participation. The idea of informed consent should pose a serious challenge to the traditional physician-patient relationship. On the other hand, it is also very likely that the idea will not be taken all that seriously in order for the relationship to change fundamentally. One may expect the judiciary, as the protector of constitutional rights, to acknowledge patients' right to self-determination. But it has not happened yet.

To illustrate this point I would like to cite one recent incident of a law suit filed by the family of a patient who had never been told by the physicians that she had a gall-bladder cancer. In this case *(Makino vs. The Second Nagoya Red Cross Hospital)*, even the family members were kept ignorant of the diagnosis. Initially her hospitalization had been urged in order to treat her gallstones. Apparently the patient thought she could ignore the gallstones, so she went ahead to make a scheduled sight-seeing trip abroad. The patient was a nurse at a different hospital, and her doctors at the Red Cross Hospital were not aware of that. She died a few months later from cancer. Japanese civil law (not medical law) dictates that when an invasive measure is going to be exercised there are duties to explain it and to seek consent from the person to whom the act is done (Kato, p.101ff). But since such a duty was not observed, the deceased patient's family sued the hospital for the failure to explain which caused the patient's misjudgment of her own problem and her decision to forgo the recommended treatment (which was not for her disease, however). The court rejected her husband's suit against the hospital for compensation (*Asahi Shimbun,* 5/29/89).

According to *Hanrei (*Case Law) *Times* (No. 699, 8/15/89), the Nagoya District Court gave the following justification for the verdict: (1) To disclose the exact name of the disease is a part of the physician's duties in the clinical contract, but it is within the discretion of the physician, who must consider the possible effect of the disclosure, to decide to whom and when the disclosure is to be made and what and how much should be disclosed while trying not to violate the patient's right to self-determination. (2) The patient's physician had not reached the final diagnosis of gallbladder cancer, therefore the plaintiff's charge, which was based on the assumption of such a diagnosis, was inappropriate. (3) It is not customary in our country to disclose cancer to the patient, and there is no duty to explain a possibility of cancer to the patient after the results of tests which were done only in the out-patient clinic. (4) The physician's explanation that it was a serious case of gallstones which had to be removed was appropriate as the method of trying to persuade the patient of the need for hospitalization. (5) In cases of cancer with poor prognosis, explanation to the family of the patient is necessary, but it was appropriate for the physician to intend to do so only after further examination. (6) The patient cancelled her own hospitalization and failed to visit the hospital again; therefore, the physician had no duty to take further measures.

The court makes reference to the patient's right to self-determination, without appearing to take this right seriously. No definition of the right is given, nor are any conditions for the implementation of the right specified. Apparently the court does not intend to commit itself to, or establish a legal precedent about, this specific right. The opinion betrays the court's ambivalence and involves a contradiction. If one takes the patient's right to self-determination seriously, one cannot give nearly absolute priority to a physician's discretion to withhold information without justifiable reasons. The patient was not incompetent by any means. By justifying the withholding of information which was crucially important to her decision about treatment, the court flatly denied the patient her right to self-determination. This case concerns the patient's refusal of treatment based on a false belief she formed upon the false or incomplete information given by the physician. It was the accomplishment of the American judiciary system and medical ethics to recognize that a decision made upon false or incomplete information is not authentic or legitimate. It implies that in this case causation could be established between the deceptive information and the patient's silent decision for no treatment. Accordingly, if damage resulted, the provision of inadequate information should be blameworthy. Clearly, in the United States, physicians in similar situations could well be held liable for deficient disclosure about the diagnosis and the nature of the proposed procedure. But such causation was not acknowledged by the Japanese court which apparently intended to protect the physician's interests instead of the patient's right to autonomous decisionmaking which would be possible only on appropriate information. The court's allusion to the patient's right contradicts its intention to give priority to physician discretion, which was acknowledged unconditionally. In this context there was no conflict between the value of patient autonomy and physician's commitment to health care. The former simply did not exist. Since the patient was abandoned to death in ignorance, the latter did not exist either. Silent medicine took a toll of a patient's life and the act was justified by the judiciary.

In the silent interaction many people simply do not realize that they are involved in morally questionable and irredeemable deceptions to themselves and others. The physician has a prima facie justification for remaining silent about the disclosure of a difficult case. They say that such a disclosure would discourage the patient and deprive her of the spirit to live. It is hard to disprove the validity of this assumption. There are actually cases where a patient, after finding out her grim prognosis, suddenly weakened and died. But it would be equally hard to disprove that the patient, once informed of her medical condition, might appreciate the information and try to spend the rest of life in her own unique manner. A good, caring physician would not allow his patient to fall into self-destruction in ignorance. In the above-cited lawsuit case, it cannot be said that the woman had a chance to survive with medical intervention; nonetheless it is evident that the physician deprived her of the right to know about her own demise and to prepare for that. We can argue that the Japanese people's constitutional right to choice should include their participation in medical decisionmaking as well. But so far the judiciary has not given such an interpretation. Another violation of patients' rights concerns treatment options which, even when they exist, are simply not explained to the patient. This happens often with breast cancer patients. Women who underwent a radical mastectomy used to agonize silently but begin to express their grudge bitterly after they hear that there were in many cases alternatives. But the practice of concealing diagnosis and treatment options still goes on. If the physician is ready to display treatment options including non-treatment, she would have to clarify the nature of the disease. That first-step is often omitted. If a case is an incurable cancer and no treatment is useful, the physician may still perform an operation, however useless or palliative it is, just to pretend that everything is fine and that the patient will get well after the operation only if she does not lose hope for recovery. In the good old days the patient could remain in blissful ignorance believing that she had an efficient, trustworthy physician who knew her physical condition better than anybody else, including herself. But those days are gone and what we have now is a setting in which it is hard for us to engender trustful relationships with each other. In the case at issue it is ironic that the patient was a nurse and her physician did not know that. Either the doctor was not interested in her life or she hid her occupation from him for some reason. It was not a relationship of trust from the outset. From her professional experiences and from what the doctor told her about the disease she apparently conjectured that her gallstones could be negligible at least for the time being. Failure to get correct information about diagnosis, even if it was tentative, was detrimental to her, and to great numbers of other patients. But it seems that both physicians and patients can have good relationships as morally equal persons if we consider what constitutes a conflictual interaction and what it takes to build a trustful, democratic relationship which is helpful for good care.

In the general public's impression Japanese physicians do not seem to care to speak to, or ask questions of, or listen to, patients' stories, or have a meaningful conversation with them. They seem to be very slow in realizing that in an ordinary clinical situation the silence of health-care professionals can lead to an ineffective treatment of the patient's problem. Patients are also very slow to realize that the fact that a patient is kept ignorant about herself and is treated like a small child is the cause of many unexpressed discontents. There are at least two sorts of physicians' silence. In a society, where not much attention is given to verbal communication, it is not easy to distinguish paternalistic silence from silence of a different nature which results from a physician's indifference to his professional duty and is especially prevalent in clinical situations between strangers.

Physicians' paternalistic silence and patients' acquiescence have a couple of explanations. One is the Japanese people's view of language use. Spoken Japanese sentences often omit pronouns of both subject and object, yet are taken to be understood by the listener. Speech acts are often incomplete, ambiguous and context-relative. Indirect metaphorical expressions are favored over direct realistic expressions. In the process of understanding, internal subjectification is more important than objectification as a means for intersubjective understanding. Accordingly language per se does not carry much significance as a way of mutual communication. The Japanese tend to think that they can unify different opinions simply because they can count on racial homogeneity that they believe to exist. Instead of attempting to arrive at agreement in an open argumentative form, they believe in the efficacy of symbolic gestures, back-stage dealings and 'belly' talks. Accordingly the Japanese people are often seen as poor in conversation and discussion at meetings and conferences. In medical relationships physicians are least expected to talk in terms of explaining what is going on. Lest they get cold shoulders from physicians who are unwilling to talk, the patients are scared to ask questions. We will find out later that both physicians and patients have to learn how to express themselves and communicate with each other efficiently from the belief that language was made for mutual communication.

Language use is one of various features that characterize human interactions in Japan. One predominant explanation for paternalistic silence is the hierarchical and authoritarian structure that the language use reflects in all phases of Japanese society. In medical relationships patients are treated like small children who are not supposed to claim rights to decisionmaking. They are taught to be obedient and thankful to whoever nurture them. Indebtedness to authority and duty to defer thereto have been main moral precepts since feudal ages. People often feel uneasy with rights-talk despite the assurances of the constitution, which was after all a gift from the United States. The idea of a patient's self-determination sounds repugnant to both patients and physicians. Moreover, patients feel they owe medical profession their overall state of medical well-being. When most of the citizens identify themselves as the members of the middle class (even though their standard of living is much lower than that of the people of other advanced countries), and when they feel that basic needs in terms of medical care are somehow taken care of, they think that they owe many of the medical benefits to the efforts of the medical profession and to public health policy. Surely the medical profession has done a remarkable job, but the lay people's unreflected indebtedness seems to perpetuate the inappropriate silent acquiescence to medical authority, and the lack of motivation to demand their due rights.

Moreover, one cannot ignore the role that one's family plays in medical care. Cultural anthropological studies tell how patients are indulged or spoiled in a close-knit traditional family system in which sickness or disease of an individual regarded as a family incident. One could even say medical paternalism may be only a part of the scheme of the family's dealing with a sick family member. Non-disclosure is a joint plot of the physician and family members. The number of nuclear families and single households is increasing so this description may not apply to all cases, but the weight of traditional family system can explain why most patients still want to be totally dependent on the family-centered care system so that even an otherwise intellectual person may refuse to know her own disease and leave everything to others without realizing that to be treated like an infant is not what a mature person should want.

Recently there have emerged many symposiums and publications on medical ethics (Kajikawa). This phenomenon has apparently been the result of influence by information and literature flowing from the United States. It has called people's attention to a great discrepancy between contemporary medical practice and traditional mentality in Japan. Concerned citizens begin to realize the serious gap between ethos and advanced technology that perpetuates problematic medical relationships. We may be facing a promising transformation of medical relationship, but it is also the case in Japan that things foreign are readily introduced but rarely taken seriously enough to change people's fundamental mindset. Democracy is not yet rooted in the Japanese soil. In the following section I will discuss the modern history of medical education and the system of ethics that endorsed the practice in which patients have been excluded from decisionmaking process.

2. The German legacy

Medicine practiced in contemporary Japan is not very different from that in the United States. Mainstream medicine is Western-style, but the structure of the medical establishment, of the medical educational system, and the mode of physician-patient interaction is to an important extent the product of the model of German medicine that was adopted by the government after the breakdown of feudalism in the late 19th century.

During the opening years of the Meiji Era (1868 - 1911), the mainstream of Western medicine in Japan was British medicine. William Willis, the physician to the British Minister to Japan, impressed the new Japanese government officials with the excellence of British medicine while being actively engaged in practicing surgery and teaching at the newly founded medical school in Tokyo (Sugaya, p.27). British influence gave way to Prussian because the two individuals who were in charge of planning a new medical reform policy determined that German medicine was superior to all others. Their reasoning was as follows: (1) Dutch medicine was only the translation of German and French medicines; (2) luxurious French medicine did not suit the financial state of new Japan; (3) British medicine was inadequate because of the British contempt for Japanese people, and (4) American medicine was too new and offered nothing for Japanese to learn from. Whatever their official justification of the rejection of other possibilities, their decision seemed inevitable. The Meiji government leaders already had a great liking for the Prussian system of constitutional monarchy. They had also found German military, economic, legal and educational systems suitable for emulation. Thus the Meiji Government officially invited physicians from Prussia to teach at the national medical schools, thereby starting an influential tradition of German-style medicine in Japan. Significantly, Erwin Bälz, one of the early German medical professors hired by the Japanese Government, cautioned in his diary against the influx of the American ideas of democracy and freedom (Bälz, p.92).

An important consequence of the introduction of German medicine was the strengthening of the authoritarian structure in medical education and in the over-all medical institution of the country. The overpowering status of the 'ordentlicher' professor, especially in medicine, had its model in German medical education. Each department, with a chairperson who exercised absolute power at its top, built a high wall around it and its inner tight-knit hierarchical structure. As a consequence there was, and still persists, a lack of cooperation among different clinical divisions in hospitals and medical schools.

German medical terms are still used in the Japanese clinical world. Words such as 'Karute'(<die Karte=chart), 'Kuranke'(<der Kranke=patient), Pulusu'(<der Puls=pulse) and 'Mesu'(<Messer=scalpel) are only a few of them. Patient charts were written in German until recently. The practice of medical paternalism and secrecy was enhanced by this German-writing in the clinical context and symbolized non-accessibility from the patient. Patients have taken for granted the non-disclosure of information in diagnosis and

prognosis of their diseases. Nowadays charts are often written in English and even Japanese but they are still inaccessible to ordinary Japanese patients. Even if the patient understands the foreign language used in the chart, physicians protect secrecy by using technical terms which are unintelligible even to intellectuals. Communication through the use of an easily understood language has never been attempted. Physicians simply have not been taught in medical school to communicate meaningfully with patients. They are easily annoyed by patients who want to ask them questions.

The social status of an ordinary physician was formally established in 1906 by the enforcement of the Medical Practitioner's Law which recognized only the graduates of medical schools as physicians (Sugaya, p.77). This meant that only the practitioners of Western medicine and not doctors of *Kampo* (traditional, oriental medicine) were allowed to remain in the mainstream of Japanese medicine. Only those who are educated at the now 80 Western-style medical schools are entitled to take medical license examinations. *Kampo* is still widely practiced, but only a few percent of physicians employ the method together with scientific medicine which has been blamed for its excessive use of tests and chemicals. An organization of private practice physicians was gradually formed and came to be called the Japan Medical Association in 1923. It became an enormous power center and has often been involved in conflicts with other social powers.

German influence is still perceivable and often dominant. After all, German ideas were accepted because they were in harmony with the traditional political ideologies based on Neo-Confucianism and Shintoism which justified the authoritarian rule with the emperor at the top. Against American individualism the Japanese mental system operates on collectivism due partly to its own political and intellectual tradition and also partly to the German influence. Under such a mindset people are born not as individuals but instead into the relationships of the family only as members of a communal unit. In feudal days Neo-Confucianism served as the ideology of the individual having a fixed role and relationship within a family or community. Democratic principles dictate that individuals jointly decide on their own future project. By contrast, in the Orient the concept of self has rarely been given due consideration. "Annihilate your self to serve to the public (country, corporate body, feudal lord, emperor)" has been one of the most important slogans demanded of the people throughout the recent centuries. The private self was posited opposite to, and only to be subsumed by, the public which was the transcendent authority posited by the mandate of heaven, according to the tradition handed over from the ancient Chinese tradition.

Two most influential modern Japanese thinkers, Kitaro Nishida (1870 -1945) and Tetsuro Watsuji (1889 - 1960) expounded systems of thought which endorsed and supported the above-mentioned traditional political ideology. Nishida was a professor of philosophy at the University of Kyoto while Watsuji was a professor of ethics at the University of Tokyo. As pioneers in medicine, technology and social, humanistic sciences with a number of influential scholars, both universities have been the academic centers of Japan. In his most famous *A Study of Good*, while referring to James, Berkeley and Hegel, Nishida develops a heavily idealistic philosophical system in which the ultimate reality is realized in the intellectual intuition where there is no distinction between subject and object, intellect and will. The experience of this reality is something that you have to attain yourself and that cannot be expressed in language. Consciousness, reason, spirit are all features of this ultimate, subjective, unchanging unity which can be called God, who is in turn the basis of other-love in an ethical context. A good action is the realization of the individual self which is actually a part of the commonality which is in turn the universe. Our real self is identified with the substance of the universe. Individuality is "the self-determination of the general" that is God. There is no absolute evil because the ultimate reality is Good. Evil arises only from contradictions within the system of reality.

This eclectic system of Hegelian, Judaeo-Christian, Zen Buddhist and Neo-Confucianist thought was popular among those who had been exposed to German idealism. For many young philosophers, Nishida synthesized those thoughts to form a 'uniquely' Japanese system of epistemology, metaphysics, and ethics. But as ethics this only exhorted meditation in order for one to be unified with the essence of the universe or at most religious fellowship with others. Nishida's "self-determination" was by no means a principle for autonomous action. It was Watsuji who propounded the system of ultimate reality which was political and which took the form of the state in which alone individuals could realize themselves.

Watsuji studied in Germany and incorporated Hegelian ideas into his grandiose system of ethical thought. His ethics was based on the idea that ethics (*rinri*) means studies of *rin* (=relationship). In his influential book *Ethics as the Study of Ningen* (=human being) he noticed the term *ningen* (*nin*=human, *gen*=inbetween, relation) refers exactly to the relation between humans rather than to an individual human in Western thinking. *Ningen* is rendered as man, human or *anthropos* in the Western languages which, according to Watsuji, means no more than an atomistic being and does not reveal the true meaning of being human. Humans can by no means subsist without having relations with other humans, so the nature of this being is unable to be represented in the way it is rendered in a Western language. For Watsuji ethics is not a study of subjective, individual moral sense or the like, but the study of the social order of human relationship. He uses Hegelian and Buddhist language in characterizing humans as the self-negation of the Absolute Negation, or the community as the living totality in which alone individuals can have meaningful existence. He emphasizes that usual relationships are by no means complete unless subsumed in the real totality which could be found only in certain higher-order organization. The state is the ultimate organic totality in which alone individual freedom can subsist. The nation is prior to its individual members (the opposite idea of Rousseauan democracy) and is itself the ethical totality. The most ideal polity would be absolute monarchy. From this standpoint Watsuji defended the cause of Japan's nationalism and supported its war efforts for imperialist expansionism. Even in the postwar years Watsuji remained at the top of the scholarly hierarchy in the study of ethics, and some of his disciples were strong advocates of emperor worship and imperial tradition.

One can readily see that this sort of philosophical orientation was in opposition to the democratic constitution which was to be implanted in the postwar days. Individual autonomy or self-determination was something which did not belong to this way of looking at human relationship. This basic intellectual, political orientation has not changed drastically since the prewar days. This is one reason why the same political party has remained in power and has established conservative national policies in every division of society, especially in education. It is true that private institutions are less authoritarian and more democratic than public institutions, but that is not always true. The president of the JMA from 1957 to 1982 was a graduate of Keio Medical School which was founded by an egalitarian pioneer educator of the early Meiji Period. A man of anti-establishment vein Dr. Takemi was always involved in confrontation with the bureaucrats of the Ministry of Health and Welfare (MHW). On the other hand he displayed quite an authoritarian, anti-democratic personality by monopolizing all the decisionmaking powers in the institution. During his reign nothing was done to rectify the physician-patient relationship or help promote patient autonomy. He did virtually nothing to respond to the revised Helsinki Declaration although the revision was made in the World Medical Association's Tokyo Conference in 1975 over which he presided. What he did was to strengthen the authority of the medical profession against the state power and the resistance from lay people. The JMA lacked motivation to reconsider its own morality and reconstruct medical relationships on democratic ethical principles.

3. Responses to informed consent

For a long time in history Japanese physicians have believed that the ethic of *jen* sufficed to keep medical art in good shape. But with regard to the quality of medical art, members of the medical community have been uncritical to each other's work; as an American observer remarked, there "are no formal mechanisms for reviewing the quality of medical care in any setting" (Iglehart, Part Two, p.1168). The Medical Morality Council of the MHW is mainly concerned with tax fraud or other types of criminal conduct by physicians. Immoral doctors are suspended or deprived of licenses in accordance with the findings of the council. But our real concern is to democratize medical practice so as to put an end to the tradition of medical silence and get the patient involved in decisionmaking. Having a reasonable code of professional ethics would be a first step to self-improvement. However, the Japanese medical profession does not have a code comparable to the code of ethics of the American Medical Association (AMA) which has been revised a number of times over a long period. In an effort to consider medical ethics, the JMA set up in 1965 a task force within its organization. This, however, was dissolved two years later after sponsoring a series of lectures given by prominent scholars (Fuse, p.205).

On the part of the state administration, the Health Policy Bureau of the MHW organized a study group on bioethics which brought together prominent figures from various fields such as law, medicine, philosophy and business. This study group has met several times since April, 1983. In 1985 they issued a report titled *Considering Life and Ethics* which deals with the physician-patient relationship, particularly the issue of informed consent. The participants do admit the importance of the idea of a patient's rights to self-determination but at the same time they express scepticism toward the actual implementation of the principle of informed consent. Their justification for this scepticism is based upon their view that an average patient is unable to understand or judge the state of his illness and treatment. Apparently they do not realize that disclosure is vital to the principle of informed consent. These intellectual dignitaries believe in the integrity of medical profession, but not in the integrity of each patient, and still advocate the benevolence model of the physician-patient relationship. In this report there is no reference to a need for drawing an ethical code based on patient autonomy. They seem to think that physician's benevolence and patient autonomy are inherently contradictory.

By now most of the nation's 80 medical schools have ethics committees (*Asahi Shimbun,* 12/30/86). Their main agenda focuses on the definition of brain death and the regulation of organ transplantation. It is characteristic of these committees that their membership includes high executives of the medical schools who are also physicians and that they do not recruit many people from outside the campus or from other disciplines. All but one are closed to public or media (Saito). Secrecy and exclusiveness are still their common denominators.

These situations reflect the general atmosphere surrounding the Japanese medical establishment, which is far from open and democratic. The Japan Bar Association, on the other hand, held a symposium on brain death and organ transplantation in 1986 at its Annual Convention for Human Rights. From their report it is evident that their position is to enlighten the public and to call for the development of a consensus among the people on these issues. In their 1980 declaration about experimentation on human subjects, they asserted the importance of a principle comparable to informed consent. In 1984, a nation-wide lawyers' group issued a "Patients' Bill of Rights" which stressed the patient's right to information. However, it is not known how seriously this statement has been taken. In the United States the "Patient's Bill of Rights" was declared by the American Hospital Association in 1972 so that we are always reminded of our rights as patients entering a hospital, but there has been no such move in Japan.

From the physicians' world there has been some move to improve the situation. In early 1988 a new initiative was taken by the National Federation of Insurance Physicians Organizations to which less than a quarter of Japanese physicians belong (Okamoto, p.68). They issued a manifesto of their basic posture about medical care. According to the reported draft of the manifesto, they were determined: (1) to make an effort to develop a humane relationship between physicians and patients, paying attention to the care of a total person; (2) to strive for better coordination among physicians and among different divisions of medicine; (3) to play a more positive role in community health care; (4) to work harder in continuing education so that patients can have access to the most advanced medical expertise; (5) to promote dialogue with patients in order to know better the patients' wishes and to offer what is needed to help them realize their way of life; (6) to keep the medical record strictly confidential except for therapeutic needs or medical development; (7) to avoid unethical conduct; (8) to be alert to dangers of advanced technology; (9) to promote social welfare; (10) to learn from history, to oppose all peace-threatening moves and to acknowledge that it is a physician's responsibility to prevent nuclear war and eliminate nuclear weapons.

This is a great advance over their traditional paternalistic posture. Not only do they realize the importance of dealing with a patient as a total person, they also admit the need for a meaningful conversation. From my point of view, however, this manifesto still falls short of being aware of the importance of the value of patient autonomy which is vital to good medical care. Also it fails to attend to the need of reforming the insurance system itself. Some physicians oppose the implementation of informed consent mainly because it is simply impracticable under the present system of insurance reimbursement. The health insurance system does not pay for the physician's consultation session with the patient. However much effort is expended for the conversation it is not rewarded monetarily. One plausible remedy, then, is to reform the insurance system and to acknowledge the physician's effort to implement informed consent. For that purpose, however, informed consent has to be officially introduced. I cite a case of one recent exemplary physician who withdrew from the insurance system and started a private practice in which he hoped he could spend enough time with each patient (Mizuno). In that manner, however, he was able to see no more than five patients each day and had a hard time making both ends meet every month. If the Japanese people, both lay and professional, decide that medical decisionmaking is mutual, it will be necessary to reshuffle the whole system to accommodate the idea of informed consent, and to reform the reimbursement system. Informed consent is something which enlightened patients should demand of their physicians. In that sense the future of informed consent depends on the education of both patients and medical students.

Finally, let us take a look at the recent statement made by the JMA Council with regard to informed consent. Since 1985 the JMA held meetings on bioethics with experts from different fields in its Bioethics Council but they focused on brain death and organ transplantation on which they issued a final report in January, 1988 (*Asahi Shimbun,* 1/13/88). Critics pointed out that the JMA had never disclosed to the public the actual processes of their deliberations on these issues. What they did was to try to legalize organ transplantation without any ethical code. After working on the issue of brain death, the Council then took up informed consent and issued a report early this year (*Journal of the JMA,* February 15, 1990). This time the record of the procedure has been made public.

In this report informed consent is translated as *setsumei to dooi* which means "explanation and consent". There is so far no fixed standard translation for the English term 'informed consent' which is neatly concise in its own right. It is indeed a difficult one to translate into an equally concise phrase. An attempted translation can end up long and explanatory, spelling out something like "consent made upon being informed". One suggested translation, *nattoku dooi,* in much shorter wording means something like "understood consent" but it is not very appropriate because *dooi* means consent, while *nattoku* is something that should be a part of consent so that it sounds redundant and cannot represent the important content of the original version, namely, "voluntary consent given only upon the understanding of the appropriate information provided". The JMA version is not appropriate either, because it dichotomizes the agents and the actions and thereby lessens the poignant implication of the patient's decision-making. Informed consent surely involves two parties but this translation suggests two separate unilateral actions which may not adequately interact with each other.

The JMA Council report gives a long-overdue credit to informed consent. It acknowledges that the idea of informed consent needs to be introduced to improve the quality of medical care and physician-patient relationship. It calls for physician's awareness of the duty to explain and obtain patient's consent. It also calls for physician's new approaches to 'Mundtherapie' which, according to the writer of the report, was operative in traditional medicine. The report says the Mundtherapie should go hand in hand with consent-obtaining effort. It also advises physician's openness, which would open up the patient's heart "to talk everything". It goes further to call for reform in the insurance system to facilitate longer consultation session.

It was indeed an epoch-making event that the JMA's council issued a report which recommended the introduction of informed consent into Japanese medical practice. However, we also must note that the report wants to stress that the American model of informed consent cannot be imported as it is into Japanese medical practice because of the latter's historical background and the different ways of human interaction in both countries. So the writer emphasizes that physician and patient are in no way equal in terms of knowledge, and the former should exercise leadership in persuading patients to the physician's choice even if there are alternative treatments. A patient is reminded that she can express her wishes, but cannot give positive instructions to the physician. Apparently patient's waiver and physician's discretion are considered as rules, instead of exceptions. After all, the report does not address a general audience, but only physicians. It tends to underscore physician discretion and naturally to be inattentive to patients' needs to be informed and participate in decisionmaking process. The translation 'explanation and consent' does not successfully send a message about the need and importance of real consent-giving, and of having appropriate information before decision-making as a recogniton of concerned citizens in a democratic society.

The report also endorses the thesis that since there is neither an explicit legal precedent nor a judicial tendency to introduce the idea of informed consent, a formal introduction may be made as an ethical imperative which can also have valid claim of constitutionality, rather than as a legal doctrine as was the case in the United States. Surely it does not seem likely that in Japan informed consent will first get employed by the judges, but rather by legal scholars and philosophers, and then physicians and hospital associations. However, having heard that said by the medical profession, I have a misgiving about the practicality of the suggestion. I am especially concerned about the silence of the JMA to the courts, especially the Supreme Court, which have often failed to play the role of the protector of rights guaranteed by the Constitution. In this report the JMA council almost endorses the two Supreme Court rulings in 1981 and 1988 that limited physician's duty of explanation. Patient's autonomy and right to self-determination in this context seem to be no more than a gift bestowed with a paternalistic largess. As in the judiciary opinion cited in the first section, autonomy or the right to self-determination is only cursorily mentioned. With this in mind it does not seem to me that Japanese medicine is going to be democratized in a near future unless there is legal protection of patients' rights.

In this chapter I have discussed the conflictual relationship between physician and patient in a society equipped with parliamentary democracy and capitalist market economy. I have pointed out the deficient relationship between the physician and patient as the result of the vertical structure that the medical profession has constructed in the modern age with the use of German idealism and philosophical endorsement. A partial remedy can come from the introduction of informed consent. The idea of informed consent can point out to the people the fact that their self-indulgently passive, child-like role as patients has partially contributed to their plight, and can also direct their attention to their unnecessarily subservient relationship to the physicians. Although a suggestion that informed consent should be introduced in Japanese medical practice as an ethical imperative is plausible, the importance of having a legal endorsement cannot be ignored. So there is a good reason to turn to the American experience. I am now going to study the theory and the actual practice of informed consent in the United States where the idea was legally formed and ethically developed.

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CHAPTER II INFORMED CONSENT: THEORY AND PRACTICE

The theme of this chapter is informed consent as it has been legally introduced, ethically supported, and medically practiced in the United States. The history of informed consent will tell us that the path it has so far trod is far from a smooth, easy or clear-cut one, even from its start on the judiciary scene. But the study of the history and the American experience of informed consent is necessary for those who want to turn to it for guidance, whatever the experience is, since informed consent based on the way of life in a democratic society is the only viable alternative to a traditional medical relationship. Another reason for this chapter was indicated in the end of the first chapter. The legal birth of informed consent in the United States will be reevaluated. In this chapter, the history, theory and practice of informed consent in the United States will be examined. After that, the elements involved in informed consent will be reviewed. All through the discussion I will pay attention to the difference between the legal doctrine and the ethical idea of informed consent, as that distinction has a bearing on the medical practice which faces the introduction of informed consent.

1. American history of informed consent

Informed consent first appeared in the American jurisdiction with regard to medical malpractice suits. Ethical, philosophical and legal discussions followed it during the past thirty years largely to endorse and promote the initiative that the courts took. Thus, although informed consent should be regarded as an ethical principle where there is no established law, its origin in common law and later development in courts and legislature deserves careful attention and reappraisal.

The idea of informed consent in its present form had not been recognized until the American courts pondered on it and made a series of memorable judgments on compensation for the plight of patients who suffered from harm done by physicians. A great credit should be given to the judiciary of this society for initiating the movement for informed consent and stimulating heated discussion in legal, philosophical, and ethical circles. To turn our eyes back to the Oriental country we featured in the first chapter, we find that a newly published Japanese book with the title *Infoomudo Konsento (*Informed Consent, Mizuno) ignores this origin and maintains that the origin of informed consent dates back to the Nürnberg Code of 1946 and more recently to the Helsinki Declaration of 1964 (later revised in 1975 and 1983). However, these codes were primarily meant to regulate clinical experimentation involving human subjects administered for biomedical, clinicalresearch. The motivation was of course attributed to the Nazi atrocity. I am not sure how the author can explain the origin of informed consent in therapeutical context without reference to what happened in the American courts. The judges could have had the Nazi's inhumane deeds in mind, and therefore regarded the Nürnberg Code as a guiding principle, but the Helsinki Declaration did not play the role of a precedent because the appearance of the idea of informed consent in 1957 came chronologically prior to the Helsinki Declaration. As stated before, a similarly negligent stance is taken by the report of the JMA Council on informed consent. It does mention the legal origin of informed consent in the United States, but unduly dismisses the importance of its birth and place in common law and indicates that the only option to be taken in Japan would be in the use of an ethical doctrine in an uniquely Japanese way. However, I think their stance is wrong because belittling the origin means the denial of the significance of democratic values to be reflected in medical relationships. The historical origin of the idea of informed consent can go back to the birth of democracy in modern Western history which, as many Japanese intellectuals seem to think, is incompatible with the 'unique' Japanese way of thinking. I hope that all the advocates of informed consent will realize that this idea is a part of the theory of democracy, and democratic values have to be either protected by the constitution or common law.

Before I start I would like to acknowledge the following books as my main references. The initials in the parenthesis indicate the symbols used in this and subsequent chapters for the citation of the sources, namely, (P) for President's Commission's *Making Health Care Decisions (*1982); (K) for Jay Katz's *The Silent World of Doctor and Patient* (1984); (L) for Charles W. Lidz et al's *Informed Consent (*1984)*;* (F) for Ruth R. Faden & Tom L. Beauchamp's *A History and Theory of Informed Consent (*1986)*;* (A) for Paul S. Appelbaum et al's *Informed Consent -- Legal Theory and Clinical Practice* (1987). Some of them cite empirical studies which find out how well, or rather how poorly, informed consent has been practiced in the actual medical interactions between physicians and patients. But these books are similar to each other in the motivation of writing, namely, to endorse and propagate the cause of informed consent in medicine. They all intend to show that informed consent is an ethical imperative which arose from the advocacy of patient autonomy and to give moral support to the legal doctrine. I have not drawn from unsympathetic views of informed consent because they typically base their arguments on the inadequate practice of the idea when, in fact, necessary conditions for its implementation are far from being satisfied.

The legal doctrine of informed consent can be expressed in terms of legal requirements imposed on physicians, namely, "the dual obligations to inform patients and to obtain their consent" (K, xiv). The doctrine is derived "from the common law and includes the entire body of law dealing with the general obligation to obtain informed consent, specific requirements by which to meet these obligations, and the exceptions to both" (F, p.25). To put it in another way, "It is from the collected opinions of appellate courts that the legal requirements for informed consent are derived, and from which the legal *doctrine* of informed consent has been developed by scholars, as an embodiment of the *idea* of informed consent" (A, p.15). The distinction of the legal doctrine from the idea of informed consent is attributed to Katz. My thesis also accepts the distinction which presumes that some of the discussions developed in a legal context could not have arisen in a strictly ethical consideration. The reason is, the legal doctrine arose in malpractice lawsuits filed by the patients who had been harmed or wronged by physicians. Common law and statutes of informed consent were formulated either to protect patients or physicians. Physicians may also suffer from some egocentric patients who want to take advantage of the former's unintended, unavoidable mistakes. Thus, some of the laws were made by the legislators urged by those physicians. But the original intent of the legal doctrine of informed consent was intended for the rescue of patients. Patients' suffering was far greater than the physicians' and could not have been stopped without legal help. So the discussion of the legal doctrine focuses on the identity of the medical damage caused by medical intervention.

On the other hand, the ethical theory which was developed to endorse the legal doctrine apparently has one objective, namely, to make it eventually possible to eliminate the necessity of such lawsuits, that means, both parties take responsibility for what they do. Thus, if the ethical theory had been introduced first and practiced well, then the lively legal discussions in the United States courts and law journals would have been mostly irrelevant. After all, the ethical theory of informed consent arose only after the incentive was given by prominent legal opinions, although the judges' sense of justice is owed to the democratic theory of modern ethics which emphasized autonomy or self-determination of rational subjects. The American judges have made tremendous contributions to the ethical awareness of patient autonomy or right to self-determination in medical decisionmaking process. But the difference between the legal doctrine and the ethical ideas lies mainly in that the former takes note of the objective, external conditions for medical decisionmaking when damages occur, while the latter pays attention to the significance of individual, autonomous subject's rationally making her own decision. Material causation is a key word in the legal doctrine, while understanding is one important concept in the ethical idea of informed consent.

In the legal doctrine, informed consent refers to the physician's duties to disclose to, and to obtain consent, from the patient about a proposed treatment. The focus is on the physician's duties and responsibilities and not directly on the patient's need for autonomous decisionmaking. The courts and physicians could have kept paternalistic medicine and patient's status intact. But in the United States the democratic principle at work in the history of political decisionmaking was invoked, if not fully, in questioning the traditionally vertical relationship. The courts which deliberated on the causation of a patient's plight apparently identified as the ultimate cause or reason the inferior status of the patient whose own health was at issue, yet who had no say about the treatment of her medical problem. In an actual legal inquiry, the causation of materialized harm is sought in whether and how much disclosure was made. Consent might have been sought cursorily without information about the procedure. It was a medical custom in the West even prior to this century to seek consent of the patient before surgery took place (A, p.36). But uninformed consent had no substantial value.

Consent became informed more than three decades ago in 1957 when the term informed consent was first used in the court ruling in the case of *Salgo v. Leland Stanford Jr. University Board of Trustees.* "Justice Bray of the California Court of Appeals introduced it in a brief paragraph at the end of his opinion..."(K, p.60). In the forehistory to the 1957 introduction of informed consent, the consent requirement in common law could somehow protect "patients from unwanted interferences with their bodily integrity" (A, p.44). In *Pratt v. Davis (*1905) the physician with the intention to cure epilepsy removed the patient's uterus and ovaries without telling her about the nature of the operation. The court rejected the defendant's claim that the patient was not worthy of explanation, and acknowledged the patient's right to refuse, namely, the physician was prohibited from violating "the bodily integrity of his patient" without permission. What was blamed here was the physician's failure of informing and of obtaining consent from the patient. But since the physician was afraid of the patient's refusal and the fear was somehow taken as justifiable, the violation of consent requirement was the main issue. The *Schloendorff v. The Society of New York Hospital (*1914) case is remembered for Justice Cardozo's famous statement: "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 consent commits an assault, for which he is liable in damages-" (K, p.51). Mrs. Schloendorff's surgeon had removed her fibroid tumor despite her explicit refusal of any operation. She had only permitted an examination under ether. It was not a case of "negligence" but the one of "assault" or "trespass". But this remarkable verdict provided out no specification about one of the most important conditions to implement self-determination, namely, the necessity of having necessary and sufficient information before making a right decision. Katz writes, "Courts tended to be as oblivious as physicians to the idea that inadequate disclosure made meaningful consent impossible and thus constituted an interference with patients' liberty" (K, p.52). The idea that disclosure and consent should come hand in hand was to be realized much later. Even in mid-1950 an auto mechanic who had lost the ability to move his fingers due to a faulty operation which might have been unnecessary lost his case because he had given consent, but the consent had apparently been based on a deceitful information (K, p.53). Risks and alternatives of treatment (at least no surgery, in this case) were not disclosed. Few realized that consent-giving was only nominal if made on faulty information without reference to risks and alternatives, and such an act had little to do with a free, conscious act of self-determination presumably permitted to the patient. Katz suggests that if there was no genuine consent due to misinformation or misrepresentation, then the laws of fraud and battery could or should have protected the wronged patients. It took years for people to recognize the necessary connection between disclosure and consent, understanding and decision-making, existence of options and the act of choice.

After a transthoracic aotography, Martin Salgo suffered paralysis of the legs (A, 39). In his lawsuit for redress of the injury he claimed that "the physicians negligently had failed to warn him of the risks of paralysis inherent in the procedure" (K, p.61). According to Katz the term informed consent which was used in *Salgo* in 1957 for the first time was not Justice Bray's invention. Katz discovered that it had been taken from the *amicus curiae* brief submitted by the American College of Surgeons to the California Court of Appeals (K, p.60). The pivotal passage that contains the introduction of this doctrine goes as follows.

> "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, and physician may not minimize knowing dangers in order to induce his patient's consent; but patient's mental and emotional condition is important, and discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent" (317 P. 2d 170).

The passage epitomizes the ongoing dilemma that the opinion generated. In the first part we see the unmistakable acknowledgment of the requirement of disseminating necessary information to the patient. The underlying idea is that only an informed person could make a free decision. The opinion even says that a physician is liable if he withholds "any facts". In the second part, which Katz says is "a most ambiguous sentence," where the term informed consent appears for the first time in the history of medical jurisprudence, we see already the curtailment of the application of the doctrine. The extent of disclosure is within the physician's 'discretion' with regard to the disclosure of risks. One can tell instantly that the ideas of full-scale disclosure and professional discretion easily conflict with each other.

Indeed they are "reconcilable only in the kingdom of dreams" (K, p.63).

Nonetheless, "*Salgo* initiated a process that eventually could force medicine to abandon its feudal practices" (K, p.65), because it brought in for the first time the combination of information and consent into the medical decisionmaking. It marked "the transition from simple to informed consent" (A, p.38). And that meant also the change in the meaning of consent. Simple consent could be given mechanically without adequate information, understanding, deliberation, or conscious act of choice. It could even be given under duress, coercion or anesthesia. Informed consent is totally different in spirit from simple consent. It presupposes rational understanding of information and competency to deliberate and make autonomous choice. On the one hand, it was evaluated as the response to the decisionmaking need and ability of the patient. On the other, the new physician's duty to disclose was, according to Katz, due to the recognition of the age of technological interventions which could result in grave, unremediable damage and which, therefore, required a new arrangement such as informed consent. But the doctrine of informed consent was going to be applied to conventional treatment procedures as well, so the significance of the transition, namely from simple to informed consent, was enormous. Unfortunately it was not the case that all later courts followed suit with regard to the physician's duty of disclosure. "One court even imposed liability upon a physician for mental anguish caused by information that he disclosed to the patient about her condition and its proper treatment" (A, p.39) and that happened in 1958. From the outset the history of informed consent was to be a difficult one.

The next important case, *Natanson v. Kline* (1960, 350 P. 2d 1093) in the Kansas Supreme Court, was seminal in the sense that "Justice Schroeder's opinion established the law on disclosure and consent for the next 12 years in almost all jurisdictions that considered the matter" (K, p.65). Mrs. Natanson received severe injuries from cobalt radiation therapy administered after a mastectomy. She had given consent to the treatment but had not been advised as to the possible harms that such a therapy might incur. She sued her radiologist for negligence and failure to give necessary information. Justice Schroeder's opinion expresses the basic orientation of Anglo-American law that is based on 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" (1104). Justice Schroeder further says: "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 judgment for that of the patient by any form of artifice or deception" (ibid). This seems to be a statement powerfully endorsing patient autonomy and the patient's right to refusal of a treatment or procedure proposed by the doctor. It is stated that the physician's "own judgment" should not override the patient's decision about treatment. For that purpose the doctor is not allowed to mislead or deceive the patient by giving insufficient information. As far as we read this passage the physician who misguides the patient is subject to legal liability. Furthermore *Natanson* required disclosure not only of risks but "of the nature of the ailment, the nature of the proposed treatment, the probability of success, or of alternatives and perhaps the risks of unfortunate results and unforeseen conditions within the body" (1106). "These requirements ...are now the bedrock elements of the information that the informed consent cases and statutes require physicians to provide to patients" (A, p.41).

As to the extent of disclosure the judge invoked "the professional standard of care and the therapeutic privilege to withhold information" stating that the "duty of the physician to disclose ... is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances" (1106). A reasonable physician is expected to abide by "the standard of what is customary and usual in the profession" (A, p.41). The consequence of imposing the professional standard was, however, the placing of a new burden on the patient who had to prove against what was customary and usual within the medical profession. Katz and other advocates of patient autonomy think that under this requirement a patient would have difficulty finding physicians who would be willing to speak against their colleagues, especially on possible risks and treatment options.

This case was an example of a negligence case instead of a battery case. It was assumed that, after all, the physician would not try to intentionally harm the patient and Mrs. Natanson had consented to the proposed therapy. That her consent was given was taken as an evidence for the physician's freedom from liability to a battery charge. That insufficient or deficient information does not constitute a valid consent or that consent given upon faulty information should be void did not come up in the lower court deliberation, simply because it was presented as a negligence case. What negligence is depends upon a definition. A physician could be negligent in performing a medical procedure and harm a patient. She could also be negligent in recognizing informed consent and fail to give necessary and sufficient information to patient. In this case the physicians thought negligence was "defined as a violation of the duty to use due and proper care" (1098). But the plaintiff took it as violation of "a duty to advise" of the fact that the proposed treatment involved risk or danger (1099). Thus the defendants were not termed liable for negligence in the lower court. The physician's withholding of information could be taken as acting out of good intentions to place the best interests of the patient first and out of the consideration that the disclosure might direct the patient to refuse the necessary treatment. But if there was no valid consent, then the case should have been one of battery.

The Kansas Supreme Court ordered a retrial, but it was also balancing physician discretion and the requirement of full disclosure. The court was reasoning that it was permissible to withhold some information if the patient had the possibility to refuse the treatment proposal. Katz says that the choice of negligence over battery "places additional burdens on patients by requiring proof that they would have refused the proposed treatment if they had been fully informed" (K, p.69). The application "of the negligence theory of liability, with this causation requirement, has the potential to limit severely the patient's recovery of damages-..." (F, p.131). However, if we take Katz's real intention to be the application of battery law which would award dignitary injury or "insult to the personhood of the patient" (A, p.133), it may not yield much compensation in terms of monetary amount when patient'autonomy is valued less than it deserves.

At any rate the *Natanson* court became the legal precedent of requiring disclosure with the professional practice standard in the negligence theory of liability. The discussions of the legal doctrine of informed consent started to center around the standard of disclosure and the causation between the nature of disclosure and the patient's consent or refusal of treatment. These are the legal discussions. They talk of the causation between the consent or refusal which 'materialized' the actual damage. Legally, especially in the negligence case, the physician's mismanagement or unskillfulness is not exactly the issue. The logical consequence of the argument was to find out whether the damage was 'caused' by the patient's consent. But prior consent could not really refer to the adverse consequence which was to be caused by the physician's mismanagement rather than by the patient's consent given on faulty information. Such a legal argument sounds far-fetched from our common-sensical approach and surely does not belong to the ethical theory of informed consent. Ethically speaking, regardless of the actual damage (that means, even if a harm was not materialized), the withholding of adequate information is questionable in itself, unless a specific situation dictates that physician's discretion or therapeutic privilege is justifiable. In other words, physician's unreflected exercise of 'discretion' or authority should be questioned regardless of its consequence. In ethical theory, it is simply the case that consent can be validated only by sufficient disclosure of knowledge, its understanding, and voluntariness in the action of choice. In the legal causation theory this sort of consideration is simply missing, and the act of consent tends to receive an inappropriate status only connected with the consequence of the act. Justice Schroeder's justification of physician discretion went so far as to endorse the non-disclosure of cancer to the patient. He wrote: "There is probably a privilege, on therapeutic grounds, to withhold the specific diagnosis where the disclosure of cancer or some other dreaded disease would seriously jeopardize the recovery of an unstable, temperamental or severely depressed patient" (1103). Such a legal endorsement could help preserve a custom which is ethically problematic, because it is hard to determine the psychological state of the patient and also a deception of this sort could lead to a series of deceptions, or preclude a treatment procedure proposed on reasonable grounds. One cannot propose a treatment unless one discloses its nature and purpose. But as for the cancer disclosure, a recent survey shows that the majority of physicians disclose and the majority of patients appreciate the disclosure. Despite some of these conservative features, however, the Natanson court should be remembered for its emphasis of the importance of informed consent.

The *Canterbury v. Spence* case of 1972 (464 F. 2d 772) was "the next and last landmark informed consent decision" (K, p.71). The plaintiff sued his surgeon for his failure to tell him the (one percent) risk of paralysis after a laminectomy. The following is a passage from Judge Robinson's opinion which advocated the physician's duty of disclosure for informed consent:

> "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible" (780).

Judge Robinson makes it clear that possible risks and treatment alternatives should be disclosed so that the information is material for making a specific treatment decision. He says, "The topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated" (787).

With regard to the extent of disclosure, Judge Robinson brought in the standard of a reasonable patient instead of a physician's professional standard. The transition from the older standard to the new one was a "bold move" (K, p.74). The judge specified that the permissible extent would be decided by considering what a reasonable person would want. It was called a patient-oriented standard. It was also called a legal standard because it was to be set by law (785) or "imposed by courts rather than by medical custom" (A, p.44). According to this rule, "the physician is required to disclose all information about a proposed treatment that a reasonable person in the patient's circumstances would find material to a decision either to undergo or forego treatment" (A, p.45). In this sense it was an objective standard (787). The patient-oriented standard of disclosure had been formulated by Waltz and Scheuneman in a legal journal in 1970. This standard seemingly freed the plaintiff from finding an expert witness to speak against the defendant-physician and the defended custom of medical practice. Justice Robinson stated, "Experts are unnecessary..." (792). He stressed patient's informational needs again and again.

However, as an objective standard Justice Robinson's patient-oriented standard made no reference to the specific individual plaintiff-patient and her values and needs. Although the opinion advocated the patient's self-determination, the objective standard did not address the principle which is based on the assumption that each individual is significantly different, with different needs and wishes. Thus this court advocated both a reasonable-person-as-patient standard and therapeutic privilege which could easily conflict with each other. Patient's real wishes and physician's discretionary considerations can remain parallel phenomena not easily to be reconciled without an appropriate medium of mutual communication.

Katz wishes that the court would have addressed the need for physician to initiate interaction in the form of conversation so that both parties could understand each other to make guess-games unnecessary. Needless to say, this is an advice made from an ethical point of view. Medical jurisprudence apparently has serious limits to the implementation of the idea of informed consent, even though courts such as *Canterbury* took seriously the different standards of disclosure. Unfortunately, the court's adoption of the reasonable person standard did not help much the promotion of patient autonomy. Nonetheless, "about half the courts" adopted the objective patient-oriented standard between 1972 and 1978, but the tendency has declined gradually and moved in the opposite direction (A, p.45). In the retrial *Canterbury* was reversed (K, p.80).

A subjective patient-oriented standard was presented in *McPherson v. Ellis* in 1982 (287 S.E. 2nd 892) but the case was later overturned. Justice Mitchell of Supreme Court of North Carolina wrote that a particular individual's "supposedly inviolable right to decide for himself what is to be done with his body is made subject to a standard set by others" if an objective standard is employed. Indeed a subjective standard is most appropriate for the ethical idea of informed consent and most feasible when physicians actively engage in conversation with a particular patient. Still the courts should not reject it in the legal doctrine, since in a world of strangers it is the patient and not her physician who knows better that an untoward outcome might befall on her because of her own past history which may not be known to her physician without an active interaction. This applies especially to a surgeon, radiologist or anaesthesiologist. Discussion with the patient should include even a remote possibility of a serious harm. But since the courts have not been sympathetic to the subjective standard, it is clear that what is called the conversation model of informed consent remains only an ethical requirement without legal endorsement. There have been no remarkable major court rulings since *Canterbury* and a couple of other important cases in 1972. One notable case was *Truman v. Thomas* (1980) in which the court reaffirmed that the risks of no treatment should have been included in the disclosure of risks, even against the patient's wishes. This means that the right to treatment refusal should also be informed (F, p.138).

To compare the early history of informed consent in the United States with that in Japan where the courts have not taken the initiative in acknowledging a patient's right to self-determination, one has to say that, although the U. S. courts were ambivalent about the conflict between patient autonomy and physician discretion, they have been far advanced in taking the patient's right seriously. The judicial initiative was followed by legislative move to incorporate informed consent into statutory law. I would like now to take a look how informed consent was treated by law-makers.

2. Informed consent legislation

Although the legal doctrine of informed consent has never been formulated in a uniform way, it is commonly thought that informed consent refers to the physician's duties (1) to make disclosure to, and (2) to obtain consent from, the patient. From the reverse point of view it refers to the patient's right to self-determination, however limited it is. It was stated earlier that there had already existed a consent principle before the age of informed consent. With the advent of the legal doctrine of informed consent, the element of making disclosure became the pivotal point in the physician-patient relationship. Legislative effort following the judicial presentation of informed consent focused on the issues of disclosure.

However, the statutory approach to informed consent was mainly concerned with limiting the physician's duty rather than expanding patient's right. Meisel and Kabnick's research in 1980 (hereafter, M&K) on legislation of informed consent tells that, although prior to 1974 "informed consent developed entirely within the domain of the judiciary", between 1975 and 1977, twenty-four states enacted informed consent legislation of some kind. The number rose to 30 by 1982 (F, p.139). Their study compares the enacted statutes with common law precedents in the jurisdiction, if any. They write that this sudden move had to do with the "medical malpractice crisis" of 1974-76 which was strongly felt by physicians. The legislative move was to respond to their outcries and to deal with the crisis. Thus the legislators tended to be motivated by the desire to curtail patient's recovery in their lawsuits and protect physicians's privileges rather than patient's rights. This fact still gives an impression to the rest of the world that informed consent in the United States was developed mainly to protect physicians instead of patients. Many of the states cited in the research report have both statutory law and case law that do not exactly correspond to each other with regard to the requirement of standard and content of disclosure, and so on. Incidentally, Michigan has only common law regulating informed consent cases, and therefore is not included in the study.

With regard to the standard of disclosure which is "the standard by which the adequacy of the physician's disclosure is measured" (M&K, p.421), fourteen jurisdictions out of twenty-four adopted professional standard. Two states (Pennsylvania and Washington) employed patient-oriented standard. Eight were silent. At common law, eleven states had professional standard, while seven had lay standard and six had no standard. From common law to statutory law there was an increase of three state statutes employing the professional standard and a decrease of five using lay standard. That means, five states dropped the patient-oriented standard which their common law had established.

The professional standard has two kinds, those with and those without a "locality rule". The standard with a locality rule refers to the custom established or advocated by the local medical community. This means the extent to which a reasonably prudent physician would disclose by the professional custom in the community. As we saw in case law, this poses hardship to the suing patient because she would have difficulty finding supporters and witnesses among the local medical community. Out of the fourteen statutes which employ professional standard, only five are without locality rule, while the locality rule proviso had only two advocates at common law. In the two states where they employ a patient standard, the physician was required to disclose the amount of information that a reasonable person "would consider material to the decision whether or not to undergo treatment or diagnosis" (M&K, p.423). As a whole the researchers do not think there was a great change in consequence of the legislation. The legislative intention was to make plaintiff's recovery more difficult. Meisel and Kabnick comment: "what changes were made in standards of disclosure have, on balance, been mildly favorable to physicians"(M&K, p.426).

With regard to the content of information disclosed, there is no discussion of the adequacy of information about the nature of the disease or the exact diagnosis. Presumably, the disclosure of that sort is taken for granted. The focus is rather on the nature of a particular treatment or procedure proposed by the physician. Since the legislation concerns the civil litigation calling for compensation for an injury incurred from the procedure, the disclosure should first be whether the procedure is diagnostic or therapeutic, invasive or not, whether anesthesia is necessary, how long it would take, and so on. Fourteen statutes require this disclosure while ten are silent. At common law twelve required it, so there is an increase of two statutes about the requirement of disclosure of the nature of the procedure at issue.

"The disclosure of the risks of the proposed procedure is one of the two most important elements of disclosure" with the information of treatment alternatives being the other (M&K, p.429). Twenty-two states out of the twenty-four included the requirement of risk disclosure. Some statutes had specified lists of risks to be disclosed. The report cites the cases of Texas and Hawaii where they had detailed lists of risks to which, however, M&K comment: "...we view such a statutory scheme, which the extent of the required disclosure depends upon a predetermined list of procedures and their risks, as implicitly characterizing the doctor-patient relationship as mechanical rather than human" (M&K, p.430). The authors claim that this move would pave the way to a computer's taking over the intermediary role in the relationship with the job of disclosing the risks as well as diagnosing. Meisel later reiterates the same fear in A, p. 53. When there are no predetermined lists, then standard of disclosure, professional or lay, is invoked. It is taken for granted that common, remote, minor risks do not have to be disclosed. The disclosure of alternative treatment, if any, is a requirement only in the eleven statutes, although as M&K say it is indispensable, and should be, together with no treatment, one of the important topics in the physician-patient conversation. "Failure to require disclosure of alternatives shows either that the legislatures were unaware of its importance to informed consent theory or that their goal was, in fact, to make recovery more difficult" (M&K, p.435).

Far less states, namely only four, require the disclosure of benefits of the proposed procedure. But this requirement may be equally important as the risk disclosure requirement, especially when the procedure is diagnostic rather than therapeutic. If Japan had a statute or case law requiring the disclosure of diagnostic or therapeutic benefits, then the physician's failure to meet the requirement in *Makino vs. Second Nagoya Red Cross Hospital* would have been a basis for a judgment for the patient.

Another element which has some impact on this Japanese case is the consideration of causation. There are two kinds of causation cases: injury causation and decision causation. The first is a case to establish the necessary connection between the physician's treatment and the actual injury the patient incurred. The above case falls under the decision causation. The plaintiffs claimed that the physician's failure to disclose the nature of disease gave the patient a false belief that she could forego the proposed treatment or diagnostic procedure, and this guided her to make a fatal decision to refuse the physician's recommendation. In other cases patients could claim that if properly informed they would have refused the proposed treatment and could have avoided unfortunate consequence. To prove decision causation there is an objective test and a subjective test. Nine statutes employ the objective test "under which 'a reasonably prudent person in the patient's position would not have undergone the treatment or diagnosis if he had been fully informed....'" (M&K, p.440). Two statutes adopt a subjective test "under which 'the plaintiff must prove that if he had been informed of the material risk, *he* would not have consented to the procedure...'" (ibid). At common law five adopted objective test and five subjective test. The objective test tended to be favorable to physicians and detrimental to patient autonomy, while the subjective test was considered unfavorable to physicians and just the opposite to patients. M&K propose an alternative test which they call "a material-factor test" under which the patient would have to demonstrate that the information withheld was material to the decision-making process" (M&K, p.441). In this approach the patient does not have to answer a hypothetical question to prove she would have made a different decision if the disclosure were complete. At any rate the message is that any physician should take seriously the causation between the information she imparts, or fails to convey, and the response of the patient.

There are four exceptions to the requirement of obtaining informed consent, namely, emergency, incompetency, waiver and therapeutic privilege. Among them the last one is most problematic. At common law, fifteen states recognized therapeutic privilege, while nine statutes did that. Therapeutic privilege is understood to be exercised when there is a fear that certain disclosure might harm the patient so that the physician refrains from giving the unfavorable news. The fear is taken to be a justifiable reason for non-disclosure under paternalistic considerations. But ethically speaking, if there is no substantial disclosure, then there should be no valid consent. By giving false information, the physician could still obtain consent to her proposed procedure and avoid legal liability, so the exception by therapeutic privilege is not necessarily concerned about consent-seeking duty. Rather, it is exercised from the paternalistic reason not to psychologically harm the patient. The authors of this article conclude that the legislative efforts to make patient's recovery more difficult did not attain their purpose greatly, because the therapeutic privilege did not increase the recognition on the statutory level. On the other hand, it seems that physicians could use the incompetency exception and claim that the failure to inform was due to presumable lack of capacity to understand, which may not easy to prove.

Assessments of the statutory law of informed consent by the writers of the books cited so far tend to be understandably negative. They lament that the doctrine has not effectively overturned the long-time tradition of paternalistic practice. One of them writes: "The legal doctrine of informed consent and the much-trumpeted legal right of self-determination have not had and are not likely ever to have a direct and deep impact on the daily routines of the physician-patient relationship" (F, p.141). They base their judgment on the judicial setback and empirical studies of physician-patient interactions in various clinical settings. I would now like to take a look at a couple of these field works.

3. Practice of informed consent

Despite the above-mentioned limitations, judicial and legislative statements have somehow directed our attention to the right of patients which had long been ignored or suppressed. Once a wrong is done, perhaps there is no other remedy for the damage than judicially or legislatively declaring that it was a grave violation of the patient's right to information and choice. I have to repeat my assertion that the U. S. courts have made a tremendous contribution to advancing patient autonomy by trying to rectify the inferior status of patient. However, for our need to know or understand our rights as citizens of a democratic society, the courts' enlightening posture did not attract enough attention, as the judges' opinions were not easily accessible to the general public. We need to have our rights and responsibilities clearly defined and spelled out in the form of a bill of rights or a professional moral code. In that sense the Patient's Bill of Rights published by the American Hospital Association in 1973 was phenomenal. It may be the case that the declaration was more compelling for the physicians than case law decisions established at a remote courthouse. Faden et al comment: "For perhaps the first time in any influential document of medical ethics, the physician was compelled, by claim of right, to incorporate patients in the decisionmaking process and to recognize their right to make the final authoritative decision" (F, p.94).

As for a professional ethical code, the first code of the American Medical Association (AMA) was made in 1847 (more than a hundred fifty years ago) and was to be revised four times until the most recent revision in 1980. It was largely based on paternalistic principles. Nonetheless, it was better than nothing, as there was something to be revised or restructured or reconsidered. The 1980 "AMA Principles of Medical Ethics" is very short (250 words) and does not reflect much of the recent development of medical ethics except for stating, "A physician shall respect the rights of patients..." and "A physician shall make relevant information available to patients..." (K, p.23). However, the principle of informed consent was addressed in the "Current Opinions of the Judicial Council" of the AMA issued in 1981.

In the following, I would like to cite some of the empirical research done on the clinical scene with regard to the practice of informed consent. In the report of research done in an abdominal surgery clinic and a cardiovascular clinic of a university hospital (where the physicians were all residents and interns), Lidz and Meisel present the legal model of informed consent (it is, however, an ethical model): a patient is informed, understands the information, makes a decision about the proposed treatment and then gives a voluntary consent to the procedure (P, Vol.2, p.317ff). In actuality, however, it was rare to see such an ideal model realized, instead they found that "informed consent is largely absent from the clinic; it is almost exclusively a creature of law" (p.320). For most of the physicians informed consent is "synonymous with having the patient sign a consent form" (p.328). In the hospital policy, it was officially stated that informed consent was required for "all invasive surgery, any procedure using an anesthetic, experimental procedures, and any 'non-surgical procedures which the chief of the department has determined involve more than a slight risk of harm'" (p.328). On the surgery ward, major diagnostic tests such as cardiac catheterizations, exercise stress tests, and 'electrophysiological studies' needed to get informed consent. They involved more or less risk so there were some refusals from patients but they ended up being persuaded into going through the proposed procedures anyway. In some cases a fiduciary relationship was formed so the patients left the final decision to the physicians. Minor diagnostic procedures which included "X-rays, CAT scans, blood tests, urine tests, ultra-sound tests, EEGs, EKGs, etc." (p.333) were regarded as routine and thought to require no patient consent. Also, medication decisions were exclusively made by physicians. However, the researchers point out that medication decisions and also the 'routine' procedures might involve serious harms that the patients should not ignore.

The survey shows that most substantial decisions were made by physicians. Consent forms were often signed mechanically regardless of patient understanding so that the physician's immunity from legal liability was guaranteed. As for autonomy and understanding, their studies showed that "outpatients were more autonomous and understood and participated more than inpatients did" (p.343). The inpatients tended to feel helpless and subdued in their sick role. In other words "passive dependency" was "the normatively expected behavior pattern" of the inpatients (p.347). Another variable that made a difference to the degree of participation in decisionmaking was the nature of the disorder, namely chronic vs. acute diseases. Patients on renal dialysis were found most knowledgeable and active participants in decisional interactions. On the other hand, acute patients with acute diseases were only concerned with quick removal of their problems, and tended to be passive to doctors' instructions without questioning about any alternative diagnoses or treatment procedures, if any. Often not enough information was given. One extreme case was reported in which the physician was doing everything to obtain consent from an apparently incompetent patient (p.375). The researchers commented that the doctor's act of "obtaining consent might have compromised the quality of care". Perhaps the physician was too mindful of his risk of legal liability to pursue his primary responsibility to attend to the needs of the patient. This is a case in which the requirement of informed consent went against its own purpose.

In this report on mostly cardiac and surgical cases, we find one similar behavior which may be a sign of deep concern but also of a false belief on the part of the family members. A cardiac patient's daughter refused the researcher's interview request because she did not want her father to know of his heart attack history which might upset him badly; the observer's own impression was otherwise. At least in the report there is no case where a physician intentionally withheld information lest it harm the patient.

Another belief that controls the physician-patient interaction has to do with the uncertainty of medical knowledge. The report writers address this issue. The type of information that physicians feel uneasy to convey to the patients is that a particular diagnosis, prognosis or treatment procedure is not absolutely certain. And according to the reporters, this is the information that should be imparted because it has to do with decisionmaking about treatment (p.377). But in this case again, what is required is the patient's maturity to know and think about treatment options with different uncertainties and to choose one on her own or make a joint decisionmaking with her physician.

As stated before, routine care and medications are given often without explanation or patient consent. Surgical procedures are explained but usually one particular "medically preferable treatment" is presented or recommended so the patient does not really have a choice. Most likely the procedures recommended have been determined already by the medical establishment and tested by individual physicians. The decision then usually concerns as to whether one accepts it or not. The research shows that most patients are simply acquiescent to the doctor's recommendations.

The report refers to the role of the consent form. As elsewhere nurses are assigned to get the consent form signed. In most of the cases the prepared forms do not give any detailed explanation about the treatment procedure for which consent is sought. So there sometimes could occur a good deal of conversation between the nurse and the patient. But this situation does not strictly comply with the spirit of the idea of informed consent. Informed consent assumes that explanation and disclosure precedes the act of decisionmaking. Serious conversation taking place right before the signing implies that either prior explanation was not satisfactory or the patient did not understand the content conveyed, although a bit of conversation is better than nothing when there was no prior mutual understanding between physician and patient. A consent form could be signed without any understanding in an extreme case. Even an incompetent person can write his name on a form. One might do it as well when coerced or forced, or just to please the physicians and nurses. The findings by Litz et al. show that most physicians regarded the act of obtaining a signed consent form as a cumbersome rituality. For them the permission form that patients sign at the time of admission to a clinic entrusts the physician to proceed with her decisions, and to which she can expect cooperation from the patient. In this sense the practice of obtaining informed consent does not live up to the original intent of the legal doctrine much less to the ethical principles that the doctrine invoked. In the conclusion of their report Litz et al. remark:

> (1) "Disclosure" does not typically occur. Rather patients learn various bits of information, some relevant to decisionmaking, some not, from doctors' and nurses' efforts to obtain compliance and from "situational etiquette".
> (2) "Decisions" are not made by patients. "Recommendations" are made by doctors to patients.
> (3) "Consent" does not exist. Instead what we find is "acquiescence," the absence of "objection," or occasionally a "veto" (p.401).

So the researchers claim that no meaningful decisionmaking takes place in an actual clinical context. Other research done at psychiatric clinics and a research ward testifies a similar conclusion (in L).

This is a discouraging picture for those who want to learn from the American experience. Nonetheless, such experience cannot spoil the significance of the introduction of informed concept in the recent history of medical practice. The plausible reason for the apparent failure of the implementation of informed consent in the actual practice is simply that neither physicians nor patients are aware of, or ready to accept, the full significance of this institution in its legal and ethical senses. They are simply not prepared to exercise the practice which was introduced in the last three decades. In the final section of this chapter I would like to review the elements that are involved in the ethical principle of informed consent which both physicians and patients should recognize and adhere to.

4. From the legal doctrine to ethical principle

The legal doctrine as such is not an ideal form to be presented as an ethical principle to citizens in a democratic society. If informed consent is practiced poorly, it is because physicians only concern themselves with pro-forma satisfaction of the legal requirement. In this section I would like to summarize the major difference between the legal doctrine and the ethical principle of informed consent. This discussion will lead to the next chapter dealing with an ideal human interaction to which the one between physician and patient should not be an exception.

As has been shown in the previous part of this chapter, informed consent was legally invoked to save patients who had suffered from damages caused by medical intervention. The courts which upheld the importance of informed consent recognized the patient's status as a consent-giver. Judges such as Justice Robinson of the *Canterbury* case stressed patient's informational needs. But the doctrine centers around physician's duties to inform and obtain consent from the patient in order for the physician to be free from legal liability when damage is done to the patient, and not exactly on the enhancement of patient autonomy, much less on the need for shared decisionmaking.

The major elements of the legal doctrine of informed consent are information, explanation or disclosure given by physician on the one hand, and consent or refusal by patient to the physician's proposal on the other. The judge's task is to evaluate the existence and the nature of disclosure upon which the patient was supposed to give consent to the proposed procedure. A common formulation of the standards of disclosure of the legal doctrine includes four elements, namely, (1) nature of the procedure, (2) risks, (3) alternatives or options, (4) benefits (A, pp.41-57). Deficient disclosure as such is not legally culpable if no harm is done. These items are weighed in accordance with either the objective professional standard (with or without locality proviso) or objective reasonable patient standard. We saw that a subjective, individual patient standard was not acceptable as a legal standard. Disclosure of treatment options may be neglected in law most problematically from the standpoint of an ethical view. ‘No treatment’ is a viable alternative which the patient may not be aware of unless informed, and if informed consent should be exercised ethically optimally the patient needs to be informed of any other treatment alternatives which would satisfy her specific needs. There may be safer, less costlier procedures elsewhere, but often professional custom, pressure of time, and ignorance on both sides determine a treatment option. Disclosure of possible benefits of the recommended procedure may look self-evident and unimportant, but in some cases its failure may invite the patient’s refusal of the proposed procedure for no good reason. In many case laws and statutes, these are the things which should be disclosed, but they are not always dealt with as necessary items in disclosure. The problem is that they cannot be adequately presented in a uniform, objective manner that a hypothetical, reasonable person would want. After all, the different standards specified in the doctrine are "derived from the requirements of the litigation process. They are devised not to aid physicians in performing their legal duty to inform patients, but to instruct juries in deciding in retrospect whether or not a particular defendant-physician had adequately informed the patient-plaintiff" (A, 49).

Exceptions to the requirement of informed consent also belongs to the legal consideration. They are often uniformly specified under the conditions of emergency, incompetency, waiver and therapeutic privilege. These are the conditions that can free the physicians from legal liability. So the consideration of the exceptions is also for protecting physicians. As has been already stated, the most problematic is the last condition. The first three can have standards to test their objectivity, but the last one is often based on the physician's subjective paternalistic justification which could be quite irrational. Physicians can exercise paternalism when they somehow judge the effort to seek informed consent as not in the interest of the patient. Perhaps this proviso is legitimate and necessary as long as most patients are still in the stage of being dependent, non-decisionmakers, but it is subject to abuse and manipulation. In order for the patient to be exempted from the exercise of the physician's therapeutic privilege, she has to learn how to be treated as a responsible, independent adult who can claim an equal share in medical decisionmaking. Perhaps she has to know first the value of being an autonomous decisionmaker.

The legal requirement is a retrospective consideration, and in the consideration of preventing harm or liability, the doctrine is indifferent to the proper status of patients, and to the mode of physician and patient interaction. The legal doctrine of informed consent centers around the physicians' duties. Corresponding to the duties are the patients' rights. The courts which gave birth to and supported the legal doctrine of informed consent did acknowledge the patients' rights of autonomous decisionmaking. What is radically different about the legal requirement of informed consent from the traditional style of medical interaction is the newly acknowledged status of the patient as the informed consent-giver. But consent-giving is all that the patient's right is about according to the legal doctrine. What exists between physician and patient may be a one-way traffic in terms of communication. The patient can be only a receiver of information, and a formal consent-giver. The legal doctrine cannot give justice to a fully autonomous person as a patient. It is indifferent on whether the patient deliberates, understands, or voluntarily gives consent to the physician's proposal. It is indifferent to what good can be done when a person is regarded as capable of considering, making judgments about, and consenting to, the treatment proposed by the physician. Regarding the patient as an autonomous, rational decisionmaker should enhance the self-respect of the patient who may otherwise feel overly helpless and depressed by her illness. It is better to be treated as an independent, mature person whose needs and desires are given due attention rather than as an ignorant, dependent invalid who needs care but not respect, or even as a mere consent-giver. The legal doctrine does not concern this sort of thing.

Even if informed consent presupposes the acknowledgment of the patient as an autonomous person whose illness is at issue, neither courts nor legislatures pay attention to whether the person as the recipient of information understands and deliberates on what is informed. Justice Robinson writes: "In duty-to-disclose cases, the focus of attention is more properly upon the nature and content of the physician's divulgence than the patient's understanding or consent" (464 F.2d 772, 780, n.15). Since understanding involves a lot of things, as we will see in the next chapter, and it may be hard to measure the level and quality of understanding, it is understandable that the legal section wants to avoid requiring understanding of the patient, even at its most rudimentary level. Nonetheless, understanding should be a crucial concept in the transformation of informed consent from the legal doctrine to an ethical requirement, because this is the mental operation directly connected to making a rational judgment and a conscious decision. I do not know how one can make sense of giving consent unless one presupposes understanding in the act of giving consent. One should remember that consent forms can be signed under duress or without understanding. Therefore, consent-giving can be substantial only when understanding in its proper mode takes place. You cannot expect instant understanding by anybody from a brief encounter as a stranger to the other party. So understanding necessitates the existence of conversation.

The elements that the field researchers cited in the previous section had in mind at the start of their study were as follows: 1. Disclosure of information concerning the treatment. 2. Competency of the patient whose consent is solicited. 3. Understanding of what is disclosed. 4. Voluntariness in decisionmaking without coercion. 5. Decision made either to accept or refuse (L, p.22). These are in fact the items that are to be enumerated in an ethical theory of informed consent, and not found in the legal doctrine. The original motivation for the doctrine was the acknowledgment of patient autonomy, but the subsequent legal discussions tended to compromise it in favor of more physician discretion. Thus, when the above-mentioned conditions were enumerated, the researchers were hastily expecting to see the realization of the ethical requirements. That means, failure to meet one or two of the items is not legally liable. Rather they should have said that the failure of any one of them was ethically questionable. To meet just the legal requirement is simply different from the ethical considerations. And the researchers should have realized that neither physicians nor patients were ready to realize the spirit of informed consent. They had not been adequately educated to experience a democratic encounter with each other. I think of not just education at medical school or, in case of patients, education at lower levels of school. We learn things through experiences. Both parties observed in the research lacked experiences. Just to be reminded of the existence of patient's rights before one enters hospital is simply not enough to act as an independent decisionmaker. Democratic experience takes time, but we have to start somewhere.

In the book written by Appelbaum et al an important distinction is made, namely, between the event model and the process model. In a legal setting informed consent is represented as the event model because it is in a most superficial respect the matter of actual, temporal happening of signing an informed consent form. The event model is applicable when informed consent is dealt with formally, and in a legally dictated way. The event of signing a consent form and the act of authorizing can take place only as a matter of formality. In Faden et al's book there is a clear claim that concerns the characterization of the nature of informed consent as "an autonomous authorization by a patient" (F, p.3). Authorization could mean that it is a temporary act and the matter of unilateral decision without the existence of mutual interaction. Legally there is no real requirement or guarantee to break the silence that characterized traditional medicine. The event model which focuses only on the aspect of authorization or consent-giving does not reflect the participatory process of decisionmaking which takes place over time during a series of interactions between two parties. So if one conceives the act of authorization as an event as in (F), then it can be placed under the event model, to which the authors may object because they also discuss physician-patient communication extensively. The representation of informed consent simply as authorization is not appropriate. Conversely, the process model represents the ethical ideal of informed consent which can be realized during a series of interactions, explanations, questions and answers, where modifications of previous beliefs and needs, and the development of new ideas, may take place.

The ethical idea of informed consent is an ideal which can be realized only when understanding takes place on a higher level than just the level of understanding in a simple mode. Real understanding which is related to decisionmaking can be attained only in conversation. In conversation it is likely that the topic of standards of disclosure does not arise in the physician's mind. An ethically plausible standard has to take account of specific needs, values and desires of each individual participant in a democratic interaction. It would be irrelevant to talk about a professional standard or a reasonable person standard when the specific person's needs and desires are known through conversation, except when external social pressure dictates that both parties have to employ a less than satisfactory option. But that kind of compromise should be made clear after the effort for mutual discussion is explored. In the ideal model where autonomy and care nicely interact, there would be no need for therapeutic privilege and physician discretion. There is an ethical imperative for the physician to respect the patient's wishes and desires, and for the patient to be aware of her own capacity and right to be an independent, decisionmaker, responsive to the physician's care-giving effort. So physician's duties to disclose and obtain consent are not all that informed consent is about. Informed consent is expected to promote and encourage the values of autonomy and health, or a la Katz, liberty and custody. From the standpoint of a physician, these values mean the requirements of respect for the patient as a person (from a deontological reason) and effective cure of illness (from a utilitarian reason). Traditional medicine was solely concerned with the latter value whereas the extreme form which puts exclusive value on patient autonomy is feared to be medicine without care. So the two requirements have to be well balanced. Nobody wants a purely paternalistic medicine or atomistic, contractarian, computerized medicine. We want to strike the balance, namely, we want both autonomy and humane care. This is very demanding for physicians, and also for patients who cannot anymore rest contented with their dependent, childlike role. The goal may be attained through the exercise of informed consent in an ethically appropriate way.

However, it may be another story to demand that a patient be a participant in the medical decisionmaking process. This last qualification, namely, the patient as a shared decisionmaker (shared, because the image of an absolutely autonomous, solitary decisionmaker is irrelevant to the patient) is not always embraced by all informed consent advocates. It is an ethically developed theory of informed consent which not only pays attention to the enhanced status of patient as a consent-giver, but wants to make informed consent a joint project between physician and patient. There is a big gap from the stage of a passive consent-giver to the one of a shared decisionmaker. For informed consent to be implemented in a democratic society requires more than meeting only legal requirements, or even ethical requirements, for separate decisionmaking. Shared decisionmaking imposes further tasks for physicians and patients. Physicians should understand themselves before they can understand patients. In fact, understanding oneself and each other will be a vital condition for democratic interaction. Above all patients should appreciate the value of participation in medical decisionmaking.

We have traced in this chapter the history, theory and practice of informed consent in the United States. That informed consent was born in the judiciary in the United States should not be taken lightly. In many cases the courts have proved to be the protector of the rights of patients. We have also noticed the significant difference between the legal doctrine and the ethical theory of informed consent. Some of the elements in the legal doctrine do not show up in the ethical requirement of informed consent. The legal doctrine cannot deal with understanding, patient autonomy or democratic decisionmaking. Ethically speaking, consent given negligently or involuntarily does not make sense. Courts and legislatures seem just to focus on the appropriateness of disclosure. But correct disclosure is meaningless when not understood correctly. Only in conversation can physicians come up with a right prognosis and treatment proposal, and then a possible misunderstanding can be rectified. Conversation can enhance mutual understanding. The logical consequence of our discussion is in the next chapter's concentration on conversation and understanding.

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CHAPTER III UNDERSTANDING

This chapter concerns the conversation model of informed consent which is evaluated against three kinds of understanding. Understanding refers not just to the patient understanding of the disclosed information but more importantly also to the physician's and patient's self and mutual understanding. A patient's understanding of disclosure as such belongs to the first type. Understanding, when directed to objective knowledge, requires only making sense of cognitively confirmable information operative in inductive or deductive logic. Information flow takes place in one way. Understanding is not satisfied with that kind of information when it is directed to things pertaining to human volition, consciousness, desires, and needs. Enter hermeneutics which indicates that a dialogical or conversational mode is the only appropriate approach in such an inquiry. Gadamer will show us how it works. Participants in conversation are engaged in reciprocal interchange of ideas which would be indispensable for good physician-patient relationship. Purely pursued, this kind of interaction may yield no decisionmaking result, that means; it may not be able to have a decisive bearing on informed consent if this latter refers specifically to physician-patient joint decisionmaking. Democratically reflective understanding is invoked in the operation of informed consent. A democratic institution presupposes the existence of both autonomous individuals and their dialogical, conversational relationships. Since informed consent has to do also with objective understanding, it encompasses all three phases of understanding. Understanding on the second and third phases reminds us of the need for the conversation model. Conversation which the physician initiates would enable the patient to understand the situation he is in and participate in the joint decisionmaking process. Understanding and conversation are mutually complementary. Katz is an advocate of the conversation model which aims at shared decisionmaking. Gadamer champions hermeneutic insights in human interaction. Habermas is concerned with a decision-oriented modality of communal relationships. My discussion will center around the works of these people.

1. The conversation model of informed consent

Jay Katz in his seminal *The Silent World of Doctor and Patient* (1984) documents the history of silence of the medical interaction between physician and patient. Katz characterizes the long tradition of medical practice as that of silence in terms of information and decisionmaking. Physicians tend to be silent all the way through the medical interaction. Needless to say silence has little to do with inefficiency.

Silent medicine can do a remarkable job. Also, there are physicians who are by nature taciturn but very skillful and devoted. Silence has also exceptions. Some physicians are friendly and skillful in initiating conversation in a positive way. They listen well and can get a good diagnosis. But traditionally, physicians most typically never invited patients into conversations pertaining to treatment decisions. They took the sole burden of decisionmaking. Overall, physicians have been silent, and have not even asked many questions. Katz points out that nowhere in the Hippocratic Oath are physicians advised to talk about diagnosis or prognosis with the patients. The need for having a conversation with their patients rarely came into the mind of physicians. The main and sole purpose of medical practice has been the effective healing of sickness. Katz reveals that medical history is scant in documenting physicians' willingness to talk with patients.

There is a traditional justification for silent medicine. The tradition was made in the early days of medical history that characterizes physicians as those who by divine blessing receive special, esoteric knowledge which is not to be shared by the general public. The Hippocratic Oath (to the Greek gods of medicine) starts with the physician's expression of appreciation for the teachers who imparted the exclusive knowledge; he then promises to transmit it to his own sons and those of his teachers and some disciples "but to none others".

People outside of the selected group are left ignorant of medical knowledge. Indeed it is amazing to realize how ignorant we still are about our own body and illnesses. At school we never learn anything substantial about physiology or etiology. We recall from our discussion in the first chapter that physicians in Japan recorded diagnoses and prognoses in German (nowadays often in English) so that patients can never find out truth about their cases. Our ignorance seems as if it were systematically planned, imposed and controlled. Physicians' silence perpetuates our ignorance. Both physicians and patients lack a common language for communication. Medical terminology is too complicated and recondite. Physicians can anytime 'persuade' or 'outwit' patients by the magic of technical terms. When frustrated by professional medicine, some people start their own search for truth looking over books and documents, and finally get fairly well informed about medicine as well as how it is actually practiced. But otherwise patients remain as ignorant and powerless as ever in contrast to medical professionals' outstanding expertise and authority. If medicine wants to preserve its privileged tradition, silence will remain as its trademark. Physicians decide everything and patients just obey their 'orders'.

In individual cases against the demand for more open medicine, physicians are ready with a paternalistic reason to be silent. Silence is exercised in cases of grim prognosis, placebo-giving, treatment alternatives, detailed information about proposed treatment, and treatment against the patient's expressed wishes. One paradox here is even when patients are formally granted rights to know and to exercise autonomy, they are left ignorant like children not knowing how to exercise their rights. According to Katz, also at work is the complex phenomena of 'transference' and 'countertransference' between physician and patient. Patients bring in "an over-evaluation of the physician as an omnipotent healer" while physicians bring an "under-evaluation of the patient as a competent adult" (Katz, p.142). And unconsciously physicians blame patients for causing reactions in them. Physicians' countertransference is deeply ingrained in their professional attitudes which, Katz says, "...include the need to appear authoritative, the importance of hiding uncertainties from patients, the need to view patients as incompetent to participate in decision making, and the belief that patients' welfare depends on patient's trusting doctors' capacities to know what is in patients' best interests" (p.150).

Katz's prescription against the phenomena is active conversation between physicians and patients. He also believes that some general principles could be spelled out "based on an understanding of the psychology of physicians and patients and on notions about proper professional conduct with respect to decision making" (p.153). Without conversation, physicians' promise of benefitting patients upon a belief that they know best not only patients' physical needs but also their values and wishes will be largely unfulfilled. But in conversation, "misconceptions, confusion, fears, and ignorance can be clarified" (p.162). Further, conversations will enable both parties to clarify false transference, reduce irrationality, and understand each other's needs and assumptions. The ultimate goal of Katz's conversation model is a shared decisionmaking about treatment options. One of the reasons why medical decisions should not be placed solely on physicians' shoulders and has to be shared by physician and patient, is because of the uncertainty of medical knowledge, the stochastic nature of the consequence of technological application, and the fallibility of medical authority. Since there is no absolute certainty about medical science, the physician needs to talk about it and share the decisional authority about treatment options, and the responsibility to accept the consequences, unless it is caused by the physician's lack of skills. Katz says conversation "unites physicians and patients in common vulnerabilities" (p.121).

If the conversation model as it is proposed by Katz were followed, then there would be no need to consider of exceptions to informed consent requirements of the legal doctrine that we discussed in the second chapter. Indeed, Katz's scenario is not to posit two different types of people or groups of people apart from each other in adversarial position and give the one party a chance to exclude the other from entering into a conversational relationship for whatever reasons. Instead, he sees to it that mutual trust can be engendered in having meaningful conversation which physician starts and which results in shared rational decisionmaking about good care. Unlike so many other physicians Katz is a staunch advocate of patient autonomy as well as of shared decisionmaking. He thinks consent-giving should be part of a shared enterprise of arriving at a mutually favorable agreement. He proposes this model as the only viable condition to bring about the situation where informed consent can meaningfully take place. Katz's model is clearly an example of the process model against the event model, and no other modality can be relevant and placed under this category.

Nonetheless, this proposal can sound unpractical. There is a clear limitation of time. In a three-minute consultation session, the physician may do no more than confirm his nurse's record of the patient's complaints. To make good of the situation, a compromise has to be made. Howard Brody points out that in a primary care unit the physician cannot spend enough time with one patient to carry out the conversation model to the satisfaction of both parties (Brody, p.5). As a compromise for mainly accommodating the legal requirement, Brody suggests that in presenting risks and benefits of treatment options, a reasonable patient standard should be employed instead of the physician's community or professional standard. He calls it the transparency standard because the physician tries to make her thinking about her treatment proposal transparent to the patient. The transparency standard requires some time to apply itself, so it can be employed when a three-minute consultation period is expanded to more than several minutes. This approach is based on the premise of near impossibility of conversation or personal interaction between physician and patient. A more idealistic standard, namely, an individual patient standard is only attainable on the premise of the existence of extensive conversation. So the transparency approach does not aim at the objective of patient participation in shared decision-making and perhaps is not very different from just informational, objectivist approach in the sense that informational flow is one-sided and patients are not required to be transparent. However, the approach can be applicable to two other phases of understanding and modes of interaction, since its advocacy of open-mindedness of physicians is treasured by all conversationalists, either hermeneutical or communal decision-oriented. To clarify my point, I would like to turn my focus on the spectrum of understanding and the modality of interaction.

Understanding is one of the features in the ethical idea of informed consent which does not have an adequate place in the legal doctrine. Physicians are not legally required to make sure that the patient has understood the disclosed information. Understanding is one aspect of the physician-patient conversation which the ethical theory of informed consent would mandate. Whether a patient understands what her physician tells her affects her decisionmaking, so that understanding is not only an epistemological issue but an ethical issue as well. Lack of understanding could make both information and consent meaningless. One cannot possibly make a right judgment and decision on faulty information or poor understanding of correct information. As we saw in the previous chapter, consent can be given without understanding, but a valid consent should not just be informed but understood.

Our ethical assumption is clearly that consent or authorization or decisionmaking can be validated only by understanding and voluntariness. So even in cases where understanding is not legally required, it is still necessary to confirm that understanding takes place. "Patients' common reluctance to ask questions or admit of confusion means that physicians must take the initiative in exploring patients' understanding" (A, p.170). "It is evident that an adequate decisionmaking process must include continual monitoring of patients' understanding" (A, p.171). When understanding has to be weighed, the only plausible solution would be to employ the conversation mode of interaction where the existence of or lack of understanding routinely gets surfaced, monitored and rectified. However, patient's understanding of what is disclosed may be more complex than we think. My claim is that what is called patient's understanding of disclosure already should presuppose adequate self-understanding and understanding of the meaning of medical treatment, practice and relationship. Medical understanding involves many things including physician's and patient's self-understanding, their mutual understanding, physician's understanding of patient' stories and patient's understanding of physician's explanation. One may even say that a patient's genuine understanding of disclosed information can take place in light of understanding in all these contexts. If an agreement, or joint decisionmaking is involved, understanding will be related to practical judgment and actions. So there is a spectrum of understanding, each phase of which has a corresponding mode of interaction. I call the simple mode of understanding of objective knowledge, "informational understanding". The second level is hermeneutical, because the object of understanding is now values, desires, and meanings of human actions that scientific inquiry cannot handle. The third one is communal, action-oriented understanding which I could call democratic understanding. The categorization of understanding in this way is owed to hermeneutics and critical theory of social science. First of all, I will focus on the simplest form of understanding which faces information objectively acquired, handled and transmitted. Understanding in the legal doctrine, and in usual discussions of informed consent, does not extend much beyond this level.

2. Informational understanding

In the most rudimentary usage, understanding is equivalent to comprehending the content of disclosed information, and something that can be certified by objective method, by testing or experimenting with the help of logico-mathematical inferences. This usage of the word understanding in the modern times is explicated by Kant in his critique of pure reason. For Kant, understanding is primarily the epistemological faculty which "enables us to *think* the object of sensible intuition" (Kant, p.93). Only through sensibility (intuition) and the understanding we can know anything *a posteriori*. In the understanding we think the sensibly given object by means of concepts, both *a priori* and *a posteriori*. Understanding is also an act that the faculty of the understanding exercises. We can understand and know something when its manifold sensible data, what Kant calls its representations, are synthesized in a concept. "Knowledge is ÄessentiallyÜ a whole in which representations stand compared and connected" (Kant, p.130). Causation is one of the pure concepts of understanding (categories) which enable us to make sense of our experience of a physical object and legitimately derive general rules working in nature. The act of understanding is directed to the world of phenomena, the world ruled by laws of nature. This world of sensible objects is intelligible through the faculty of understanding. With this thesis of understanding

Kant claimed that he endorsed the foundation of legitimate scientific knowledge. Empiricists utilized his thesis and attributed the basis of their scientific inference to this faculty of understanding. Logical empiricists of our century derived their verification principle from this tradition. In this context understanding understands the causal network of nature utilizing inductive and deductive inferences. The basic principle of modern science, namely, "to explain, predict and control" is rooted in this foundation. Nowadays explanation, instead of understanding, is the term used to describe a natural scientist's primary objective with regard to the physical constitution, event, and phenomenon of the object according to the logical empiricist's philosophy of science. Thus, in this stage, understanding means the act of scientific and intellectual grasping of the object, and phenomenon, expressed in causal terms. It has to do with mental operations which take place in epistemological acquisition and transmission of objective knowledge. Theories of objective knowledge can be value-laden, and some sort of interpretation (even to the point of arbitrariness) can be involved, but the objectivist scientists tend to believe that intersubjectivity among scientists can be obtained by the understanding of objective knowledge about physical nature.

This may seem too theoretical to have anything to do with a patient's understanding and comprehension of medical information. But there is an analogy between scientific understanding and patient's understanding of disclosed information. In the legal doctrine of informed consent, one of the judges' main concerns was to find a connection between objectively determined standard of disclosure about risks, benefits and options on one hand, and the patient's consent or refusal on the other. When a physician informs and obtains consent on the premise that information is understood, the information concerns factual, objective truth about a specific medical problem. In acquiring objective knowledge about a certain illness, physician may use various methods to find out what bothers the patient, what would be an effective treatment for the problem, and so forth. In the attempt to understand the nature of the specific illness, scientific medicine concerns mainly physiological causation. If a physician believes that medicine is exhausted in finding out a causal connection between certain physiological cause and a confirmed event, and in hitting upon a most effective treatment of the problem, the whole procedure may be done in a detached manner. A radiologist who believes in diagnostic efficacy of a high-tech machine often administers a procedure which may be unnecessary and involve considerable risks in such a detached manner. She seems to think that a sheet of paper describing the risks will suffice to meet the requirement of explanation. To her a patient's questioning of the procedure is a great nuisance and a hindrance to a scientific, technological success. In explaining scientific findings, the physician may use only scientific terms which are not intended for patient understanding, or may not even attempt to explain, because it is useless to address a non-comprehending patient. Understanding on the part of the patient requires intelligence to grasp and handle that sort of information, which may be given in difficult language beyond comprehension.

Objectivity of scientific findings and their disclosure can be valued and shared by common medical expertise and by knowledgeable patients as well. In the event that democratic medicine in a global, democratic community is realized, knowledge and technology should be made commensurable with the understanding of all competent laypersons and their relevance to human life should be discussed by all the concerned citizens. What is suspect in the ongoing practice of medicine is the idea that objective, scientific knowledge can accord physicians new expertise and authority with the result of mystifying its possessors and distancing them even further from lay people.

In the context of informed consent, in order for this practice to make sense, the first step is to make sure that the patient understands disclosed information. For the patient to understand the information the physician should be aware of the patient's degree of intellectual understanding. It would be legitimate and desirable for the physician to expect the patient to have some prior basic knowledge about medical science so that the latter can have better undertanding of the disclosure and relieve the physician of the burden of explaining everything from scratch. If the physician is caring enough to take patient's understanding seriously, he can identify the state of understanding by asking the patient factual questions about the information disclosed which require not just yes or no answers. To elicit understanding, however, the physician should be careful not to use technical terms that the patient would encounter for the first time in his life. If physicians find difficulty paraphrasing the information in accessible terms, then the medical profession should start thinking seriously of educating not only physicians to be more efficient in communication, but also patients or future patients when they are still in secondary schools.

Now this is the most rudimentary level of understanding which is directed to objective knowledge. What is to be understood here is a certain object whose truth is objectively, cognitively obtained and confirmable. One may notice that the information flows only one way and that there is no substantial interaction to discuss the information between the parties involved. So the knowledge disclosed does not grow, get modified or corrected in the unilateral flow. In a medical interaction, patients contribute little in the process. Objectivist medicine heavily relies on tests and instruments. By contrast, a good physician would make an effort to find out about the patient's problem by soliciting information from the patient in order to make a right diagnosis and prognosis.

In addition to this informational understanding, Faden et al suggest that it is important that the patient understands what he is doing, namely, that he is authorizing something. (Recall it is what consent-giving means according to (F)). There is a difference between the statement that the patient understands what he has heard and the one that he understands that what he is going to do is the act of authorization. While the first refers to human cognition of the object (objective knowledge) just described, the latter refers to an activity which reflects over its own activity. There is a clear transition from the first to the next stage. When one talks of understanding which should validate both information and consent, it could not be just the shared objective knowledge that the rudimentary stage of understanding refers to. Rather understanding is used when our interest or concern is directed to something deeper than the appearance an observable object displays. When I say I understand someone or something, I do not just mean that I place the person or the thing in a causal network so that I grasp the object in causal terms like how the object came to exist or appeals to our senses, or the like. Instead the object is placed in a meaning network in which, in the case of a person, intangible relationships between my and his inner structure loom large, such as value orientations, wishes, and desires. To make sense of what I am doing is an operation of such an activity. So when Faden et al claim that it is that kind of activity which is supposed to validate or legitimize information and consent, they mean understanding in this elevated sense. Patient's understanding is not just for the explanations of physiological, etiological, therapeutical findings, but also for the meanings of the proposal, the patient's role and mutual relationship with the physician. In case of medical inquiry, such an intellectual operation is important when the physician approaches the patient and listens carefully to her story. A physician's understanding no less than a patient's understanding should be relevant in order to make sense of the physician-patient interaction and their joint decisionmaking.

Perhaps a physician's understanding is what precedes his effort to attain patient understanding. Physician understanding is not just the understanding of causation of disease which is verified by his scientific background knowledge and methodology. Physician understanding is required when he is concerned to give individualized medical care to a specific individual person. Medical care should not be an assembly-line process much less a temporary impersonal event. The physician has to understand himself and the patient in the elevated sense of the term. It is the task that a logico-analytical, scientific approach is not helpful to fulfill. The discipline of hermeneutics has provided a different approach to understanding human actions and stories.

3. Hermeneutical understanding

Hermeneutics offers insights on the necessary connection between conversation and understanding. The approach attempts to look for the theory of truth about human existence and interaction by focusing on dialogues among rational participants. It offers a new perspective on illness phenomena in a profound way which scientific medicine has not attained. It requires conversation between physician and patient so that medical inquiry into illness and understanding of it gets substantial support from disclosed truth that conversation uncovers. Its main expositor of this century is Hans-Georg Gadamer (1900-) who offers an important theory of interpretative understanding.

Hermeneutics was developed in the area of understanding and interpreting art works and theological or legal texts. Their main concern was not to explain the object in causal terms but to dig out the hidden meanings of the object to be interpreted. Gadamer in *Truth and Method* examines the history of hermaneutics in the nineteenth century and contrasts his method with the British empiricists' way of approaching physical nature and human nature. He suggests that gaining objective knowledge is not all there is about understanding anything at all. Such an approach, termed as natural scientific or positivistic, may be applicable only to the purely physical event or process. As we have seen, to look into the physical causation of a thing suffices for understanding it in its simplest mode. Epistemologically, however, the Kantian understanding delimits the scope of the knowable or understandable object. The knowledge of illness causation is limited in the sense that a satisfactory result cannot be obtained by replicable, testable methods alone despite scientific medicine's promises. Hermeneutics directs our attention to the fact that human events and conditions including illness symptoms are not totally explainable in scientific terms. The application of natural scientific method, namely, the subsumption of an instance under a generic occurrence seems perfectly legitimate in natural science but becomes problematic in the field of human sciences, because they involve consciousness, intentionality, and other psychological states which occur not in predictable, observable way. In a medical context perhaps a stamping-out of an epidemic can be done in an objective, scientific way regardless of an individual patient's background or intention which may be at work in an individual sickening and healing process. Otherwise, a physician can fail to 'understand' her patient and still succeed in curing her physically and emotionally only in a lucky case.

Gadamer calls our attention to the fact that it was Martin Heidegger (1889 - 1976), his mentor, who made a significant turn in his *Being and Time* on the problem of understanding by showing that understanding is not just an act of the human subject but rather it is "the mode of being" of human existence (Gadamer, xviii) in which it is now ontologically rooted. Heidegger shows that understanding is a primordial feature of a human person to whom truth appears when he is in a concernful circumspection toward environmental totality, and in a solicitude toward other persons, instead of a natural scientific interest and exercise of logical inference. Understanding concerns what a human person does, not as a physiological being but as an intentional existence.

The method of understanding for Gadamer is a circular and reciprocal movement which goes back and forth between subject and object, between part and whole. One cannot understand the object only taken as a separate being without the context it is placed in. Contrariwise, the whole cannot be grasped without looking into individual parts that constitute it. In this respect Heidegger pointed out earlier that a human existence cannot be grasped unless by comprehending the totality of the world in which he lives in terms of time and space. Heidegger distinguishes an authentic understanding which is circular from a common understanding which is used in scientific or everyday context in which information flows unilaterally. He would not apply the concept of authentic understanding to the understanding of a partial event or state separated from the whole. For him to understand something authentically is to place that thing in the entire perspective and to derive the meaning of that being in relation to the totality of beings. Heidegger's *Dasein* is not something such as the combination of soul and body, or as a political, rational, risible animal or the like. Instead existence is the person's essence. He is thrown in existence (regardless of his will) into this world and is only grasped as someone in progress, not as a total, whole being. A person exists, understands, wills, acts, projects oneself over possibilities, and so on, in his unique way when he is situated in the life world. This approach can be contrasted to the physician's understanding of physical causation of disease or to the patient's understanding of objective truth that is disclosed. Instead, one may want to inquire into the possibility of the physician's and the patient's self and mutual understanding and of placing things in a proper perspective. And that should make a difference to the purpose of their interaction. This existence is hardly atomic, though it has to experience its beginning and end all by itself. It is historical, partly repeating the past experiences of the past people. Yet it is also as if one carves one's own future in one's own way. So there are two moments in the existence. We are conditioned by the past history of human existence. We are historical beings. Yet we understand and can plan our own course of existence. Heidegger's authentic understanding understands that a human being is characterized both by historicity and freedom.

A difference of Heidegger's person from Gadamer's is that the former is an individual existence whose initial interaction is not with other persons but with things in the network of usability. For Gadamer an individual is not so much a person who projects oneself in the future as the one who brings in one's unique past into the interaction with other persons. In Gadamer's words the cycle of the parts and the whole "is constantly expanding, in that the concept of the whole is relative, and when it is placed in ever larger contexts the understanding of the individual element is always affected" (Gadamer, p.167). The hermeneutical approach expects understanding to grow, expand and transform.

Heidegger and Gadamer are in accord with each other as to the importance of language and conversation in the act of understanding associated with the definition of truth. For Heidegger truth is something which can be talked about, manifested, unhidden or disclosed through discourse (Heidegger, p.56). Truth is uncoveredness and also the state of uncovering. Being false "amounts to deceiving in the sense of *covering up ÄverdeckenÜ*" (p.57). When he is under the spell of influences of others, public opinions or hearsays, the person is in untruth. Things can be disclosed, and it is simply good to be placed in the open. Discourse is 'equiprimordial' with understanding (p.203), which means, discourse is also a fundamental constituent of being a human person. In other words, understanding takes place in discourse in which interactions between different persons is done in language. "Dasein has language" (p.208). Silence could also be part of the discourse, because a person could express himself by being silent. Yet silence is not a genuine characteristic of a person. "Man shows himself as the entity which talks" (p.208).

For Gadamer language gets an even more important bearing as the medium of hermeneutical experience. "Language is the middle ground in which understanding and agreement concerning the object takes place between two people" (Gadamer, p.345). Understanding is attained through the process of questions and answers in conversation. Good questions can achieve openness and insight. For Gadamer, not only the medium of understanding is linguistic. The characteristic of the hermeneutical object is in fact linguistic. It is not just that everything can be expressible in language, but that human thought process and the ontological order of the world itself are all embedded in linguistic activity. A commentator writes that for Gadamer "language goes its own way because it answers the immediate needs of its speakers and expresses what they find most important..." (Weinsheimer, p.241). The hermeneutical emphasis of conversation through the use of language which reveals hidden needs and desires of speakers has great relevance to our discussion of the conversation model of informed consent.

For Gadamer and unlike for Heidegger the act of understanding takes place most importantly between two persons. "Understanding is primarily agreement or harmony with another person. Men generally understand each other directly, ie they are in dialogue until they reach agreement" (Gadamer, p.158). Gadamer does not say that people can after all perfectly understand each other. His goal of communication is more modest than radical mutual penetration of each other. Instead, understanding is "always understanding about something". So mutual understanding "means understanding each other on a topic or the like". But we still say two persons understand each other; then that "means that they understand each other not only in this or that respect, but in all the essential things that unite human beings". He also says, "Understanding becomes a special task only when this natural life in which each means and understands the same thing, is disturbed" (*Ibid*). When there is an apparent misunderstanding, an effort to reach mutual understanding is made. In conversation, in the exchange of questions and answers, people will realize the uniqueness or individuality of each other (p.159).

What happens in such an encounter is a "fusion of horizons" that each participant has brought in. The fusion is a condition of experience and to have a horizon (one's own clearly defined worldview or perspective) is a characteristic of being a human person. One who has no horizon "does not see far enough and hence overvalues what is nearest to him" (p.269). And "...to have a horizon means not to be limited to what is nearest, but to be able to see beyond it" (ibid.). Conversation is to discover each other's place of existence and horizon, what the other thinks, wishes, needs, aspires. Good conversation starts with openness and listening and asking question. Asking questions means we admit the knowledge of not knowing (Socratic method). In referring to the Socratic dialogue Gadamer makes a distinction between genuine and false discourse. Genuine discourse obtains between the persons who want to know, understand and get insight from the other. Whoever thinks he knows better does not even ask the right questions. Whoever wants to prove her rightness, instead of willingness to know, does not elaborate on what should be asked. Indeed, asking the right kind of questions is an index of the quality of conversation out of which something positive comes. Discourse that is intended to reveal something requires that that thing be opened up by the question. Gadamer observes that in this context of question and answer, truth and knowledge come to the fore. The things that come to the fore are essentially undetermined. That is why they are brought into the open. But the initial question decides what is to be opened, discussed and decided. A false question does not open up what is to be settled. "Knowledge is dialectical from the ground up. Only a person who has questions can have knowledge" (p.328). But we cannot spell out in advance what should be questioned. Only the awareness of lack of knowledge induces one to ask questions, but it is hard to know what we do not know. It "is so hard to obtain an admission of ignorance" (p.329).

Gadamer's theory uncovers features of conversation in which Katz is interested as a model for informed consent. The general principles which Katz suggested for initiating physicians' conversation with patients should include "Know your ignorance. Be open. Ask good questions." These are most basic, but abstract, guidelines applicable not only to physician-patient relationship but also to any kind of dialogical relationship. The principles should depend on how you want your relationship to be. One ideal mode of medical interaction is existential against the intellectual type of Platonic dialogical relationship. Physician-patient interaction is not just a salesman-customer, or a colleague-colleague relationship. On the contrary, both physician and patient encounter each other on the deepest level of our existence; namely, in the experiences of bodily pains, of life and death, where we get truly desperate, need support, and can be deeply sympathetic. Here on this level we can be reflective on the meaning of mutual existence. One reflection might lead to the awareness that physicians and we the ordinary people are both beings who happen to live in the same period of history and to share same or similar cultural tradition and social experiences. From a wider perspective of history the awareness of contemporaneous existence could arouse care for the co-travelers, feelings of sympathy and solidarity. Thus the physician-patient interaction could be regarded as an existential encounter which is allowed only to us as contemporaries. Concern and care are extended in the others' mode of existence through the mediation of the presence of illnesses, fears and anxieties. The meaning of illness experience is one thing that should be seriously talked out in the dialogue between physician and patient. Both parties cannot be resigned to their mutually fixed roles, but should experience the fusion of horizons, that is, share the mutual perspectives. But for this purpose both parties should be mature, informative and understanding. Narrative medicine and holistic approach can both be kins of hermeneutical medicine, which is not just a possibility but rather a necessary requirement of good health care. Indeed a therapeutic merit can be accorded to hermeneutic medicine. A medical doctor testifies that recent research has shown that "when patients feel heard, they are not only more satisfied but healthier" (*The New York Times,* 3/29/87).

I now turn to the ethical implication of Gadamer's hermeneutics. Heidegger did not talk too much of a tradition (at least in his major work) but Gadamer wants to say that to understand the other is to understand her from her cultural heritage which might be alien to other people. In the human interaction what happens is not just the fusion of different horizons, but a birth of a new, common horizon. The fusion of horizons is necessary because we are all different and the difference has to come up to the surface once. But it is necessary for another reason. That is, an ethical objective of our interaction. After all, Heidegger's main interest was ontological whereas Gadamer specifically addresses one ethical question, that is, the application of moral knowledge to make a right judgment in a particular, concrete situation. For Gadamer, application is part of understanding. Medical insight has no meaning except in application and this ultimately cannot be understood in purely technical terms. If you somehow gain moral knowledge, for example, that informed consent is an ethical requirement, the knowledge is meaningless unless it can be applied to an actual medical relationship. A moral person is not an objective observer but a mature, rational decisionmaker who lets her moral knowledge about a right conduct control her action. Unlike accumulation of technical skills, experience is not "sufficient for making right moral decisions" (p.282). It is not impersonal, objective knowledge. Development of moral consciousness may be done by education and custom to some extent, but we have to remember that each concrete situation demands a different application of the knowledge. In our context mechanical application of the idea of informed consent does not work. The terms "informed" and "consent" can be meaningful only when the disclosed information and the act of consent-giving are truly understood in the process of discussion and agreement.

What is required of a physician as the initiator of meaningful conversation is to be ready to utilize his moral intuition and tries to 'see' what should be done immediately. What should be done would be to ask the patient right questions, understand the patient's hidden wishes, and to get her involved in a conversation for making a right decision. In such a situation, understanding shows itself in the form of an 'understanding' attitude. Understanding "appears in the fact of concern, not about myself, but about the other person. Thus it is a mode of moral judgment" (p.288). An understanding physician "united by a specific bond with" the patient, "thinks with the other and undergoes the situation with him" (ibid.). Physician and patient encounter to make a rational decision about treating a health problem. What is intended in a dialogue between a physician and a patient is not the complete and direct understanding of each other which is neither possible nor necessary. Instead the goal is an agreement between both parties about a specific topic, most often about choosing a method of cure among alternatives.

The fusion of horizons that Gadamer emphasizes is an insightful observation of an interaction of the persons with different backgrounds and views of life. Unfortunately, however, Gadamer regards the physician-patient conversation as something different from usual relationship to which his model can be applied. In Gadamer's view the medical relationship consists only in knowing the other party's horizon and not in generating a new horizon or "seeking agreement concerning an object" (p.270). Implicit in his observation is that the physician-patient relationship is such a vertical one that no equal mutual interaction is relevant, that the disease to be cured is something that the physician should be concerned with and the patient has no say about, and that coming to agreement does not seem to be the goal of this relationship. Gadamer says, "Where a person is concerned with the other as individuality, eg in a therapeutical conversation or the examination of a man accused of a crime, this is not really a situation in which two people are trying to understand one another" (p.347). After all, the above extrapolation of Gadamer's understanding model to a medical relationship was mine. I suspect that Gadamer may still belong to the old German mentality as far as the medical relationship is concerned, in which the physician is depicted as the sole decisionmaker and the patient just obeys his instructions. But if we can claim that the physician-patient relationship should be a hermeneutical one, then Gadamer's scenario should also be applied to the medical relationship as well, because the real issue is how to conceive a fusion of horizons among those who are not only different but unequal in their resources in an important respect.

Indeed hermeneutical medicine should be medicine's immediate goal if it tries to get out of an impersonal, objectifying orientation. This orientation is one in which conversation does not take place. What is lost therein is not only ethical but therapeutical. Hermeneutics has taught us the importance of medicine dealing with a uniquely different individual having different problems, needs and expectations. However, Gadamer's emphasis on tradition is both his strong and weak points. He does suggest an important point with regard to what it means to understand each other when each comes from different tradition. People from different cultural background often have different points of view about health, sickness, care of the sick, death and the dead. Even if the physician speaks the language of the alien patient, she may not hit at the most appropriate cure for the patient unless the physician gains some knowledge of their taboos, customs and views, however peculiar they are. Gadamer asserts that there is nothing wrong about having prejudices (namely, unique views) about morality and way of life insofar as they are rooted in one's legitimate tradition. Indeed some prejudices are true and legitimate. For him prejudice is a precondition for understanding. In our context we might want to say that the awareness of one's own bias and openness to the cultural tradition of the other is one of the important requirements of culturally conscientious physicians who practice in a democratic society. Presumably medical anthropology was born to respond to this requirement. This means each tradition is taken more or less as authentic and respectable unless it greatly hinders the physician's way of dealing with the patient. This approach is commendable when there is no particular reason to reject or ignore the tradition, and there is some reason to believe that the patient's belief in the tradition may help the healing process. Faith in the supremacy of modern science and technology tends to keep us from listening to the wisdom that we have inherited from our ancestors. So hermeneutic medicine directs our attention to the existence of alternative approaches which have been historically tested and verified. It can make suspect scientific physicians' rejection of traditional medicine as unscientific and worthless without scientifically checking into the merits and demerits of the cultural tradition. Scientism can become very dogmatic in rejecting anything which belongs to the past and is seemingly based on something other than scientific causation and reasoning. One serious problem with hermeneutic medicine, however, would be that physicians may be taken in by the patient's cultural tradition uncritically. One extreme of traditionalism claims that anything that has endured historical vicissitudes is right and worth preserving. One claim out of this approach is the thesis of incommensurability of different cultural traditions. And a cultural-anthropologically conscientious physician may concern herself too much with understanding the patient's cultural heritage and meeting the demands from the heritage bearer. A possible consequence of this approach would be that what the physician deals with is not the patient but the tradition that the patient bears.

From the ethical point of view such cultural relativism only helps endorse passive acceptance of a tradition simply because it has been historically transmitted, when it may be ethically problematic in ignoring personhood, autonomy, care for others and other democratic values that have a bearing on all the members of a future global community. A tradition often could preserve serious discrimination as to sex, age, race, education, walk of life, and so forth which can hinder participants in a democratic interaction from conversing in common, free, equal terms.

The greatest contribution of hermeneutical approach to informed consent was to point out that understanding, not only of disclosed information but also of the meanings of the participants' mutual roles and actions, has to precede the act of consent-giving, that such understanding takes place only in mutual conversation which the physician starts from her concern in the patient, that in such a conversation something like a fusion of perspectives takes place, and that only such understanding as application can make mutual agreement attained in the conversation meaningful. In the end, however, Gadamer's ethical stance in the matter of application became suspect. What he has in mind may be age-old moral principles which might not be democratic at all. Or we could also say that the dogmatic use of such principles might fit quite comfortably into conversation as Gadamer reconstructs it. So, even when hermeneutical medicine is successful in obtaining right diagnosis and prognosis, if tradition and authority should be preserved intact, decisionmaking would still remain solely in the hands of physicians. When hermeneutical medicine is influenced only by tradition and authority, it is not critical, free, and creative. The promised dialectical development of dialogue may not meet the expectations and needs of those involved. This sort of limitation of hermeneutical understanding is pointed out by understanding of a higher level which is possible in the presence of participants with equal status and communicative ability for shared, democratic decisionmaking.

4. Democratic understanding

Thus, although we get good insights from Gadamer about the conversation model of the physician-patient relationship, we still are not quite satisfied with his approach. It is Jürgen Habermas who thinks of mutual understanding and the conditions to attain that goal in terms of free and equal participation. It is not just the patient's understanding of physiological, therapeutical information disclosed, nor just the patient's understanding of physician's transparent thinking, nor just the physician's understanding of the patient's stories that make up the process of genuine understanding of a participant in a democratic decisionmaking process. The attempted understanding is to take place in both ways on the same topic at the same time for a clear purpose of attaining agreement between the two parties. Habermas writes:

> "The goal of coming to an understanding...is to bring about an agreement...that terminates in the intersubjective mutuality of reciprocal understanding, shared knowledge, mutual trust, and accord with one another" (Habermas, p.3).

The goal of communication is mutual understanding about something. This much is not different from hermeneutical understanding. For Gadamer the goal of understanding is agreement and harmony. For Habermas, agreement and consensus. Both seem to say the same thing about obtaining practical truth through conversation. But there is a difference as to what agreement is. Gadamer's agreement seems to concern what have already existed as horizons, prejudices, views of life. Habermas is concerned rather with what should be done on the premise of existing needs, conditions, and possibilities. The basis of his argument is the critique of ideologies that may constitute Gadamarian prejudices and traditions. Gadamer does not address the feature of shared decisionmaking which is the vital concern for both parties in terms of life and death questions.

Habermas wants to show the efficacy of communicative actions, and ultimately the possibility of gaining action and decision-oriented understanding by proving the communicative capacity within speech acts that rational decisionmakers exercise. Habermas refers to the theories of ordinary language philosophers concerning speech acts. His main concern does not lie in linguistic analysis such as syntax, semantics or empirical pragmatics of sentences of a language. Instead Habermas tries to show what actually constitutes a communication act which leads to a mutual understanding between two parties and which happens in any language of the world.

Habermas' schema of universal pragmatics may be applied to the physician-patient communication as follows. There are three important elements in the structure of speech acts that take place in a person-to-person relationship. The first concerns the cognitive aspect of a proposition that happens in the conversation. For example, the statements such as "I have a headache" and "Your X-ray shows that there is a tumor in the stomach" have to be understood as true or corresponding with reality in order to get the conversation going. The second element of the speech act structure is the expression of the speaker's truthfulness. Implicitly or explicitly expressed portions in the utterance of a sentence such as "I sincerely think..." betray the speaker's inner subjectivity, his truthfulness, transparency of his inner thought. Finally there is the element of rightness in the speaker's assertion that fits for the communicative relationship. Sentences and propositions are uttered often with illocutionary additions such as "I have to tell you...", "I declare...", "I prescribe...", "I advise you...", and "I promise you...". We may note that Habermas does not deal with erotetic forms of language, the way to ask questions, and imperatives, the way to express commands. The three elements, namely, truth of transmitted cognitive content, truthfulness of the speaker's intention, and rightness of speech act with regard to the particular intersubjective relation are the basic conditions for successful communication that leads to mutual understanding. In the intersubjective relationship what is expressed is that a conversing person is involved in three worlds, his inner subjective world, his outer objective world and his intersubjective world with other persons. Habermas presupposes human capability to start an intersubjective relationship and that language can bear the role of mediation to connect up the three worlds. The triad represents three different values that correspond with the spectrum of understanding, namely objectivity, truthfulness and commonality. Habermas's understanding covers all three dimensions. In the context of informed consent, understanding understands objectivity of information exchanged and expanded in conversation between truthful participants for sharing decision and responsibility.

Habermas' universal pragmatics is the analysis of a set of speech acts that can result in a successful mutual understanding. There are a number of things in his thesis that are suggestive for our discussion. First, speech acts are the fundamental components for the act of attaining understanding. Silence, gestures, facial expression, or sign language could sometimes substitute linguistic expressions but they are all only derivative and fall short of the effectiveness of speech acts. With Habermas, one can be somewhat optimistic about the efficacy of language use that can more or less represent the objective state of the world and subjective intentionality. In our context there may be doubt as to whether the same pain language can be shared by both physician and patient, if the physician has no experience of sickness herself. But if there is to be mutual understanding, then the existence of shared language has to be presupposed. Conversely if there is no such thing as common language, then ultimate understanding cannot be attained. One should be confident of one's communicative competence as a participant in conversation and as a psychologically and intellectually mature patient or physician. This competence is also something that has to be cultivated and trained. Thus, education for physicians and possible patients are equally important. Habermas' scheme is intended for all the members who make up a democratic society. Sharing the same language, effective language use, and belief in the efficacy of the language seem to be the first requirements for acquiring the competence. Secondly, speech acts should or can be honest and transparent of the inner psychological states of the speaker. Trustworthiness of the speakers is indispensable for good conversation and one of the requirements in communicative competence. Understanding of each other's inner state is not the goal of conversation, but the speaker's readiness to be transparent is the *sine qua non* for generating trustworthiness. Recall Brody's transparency standard of the legal doctrine of informed consent. Here, however, transparency is required of both parties in the conversation. Deception, self-deception and any other cover-up of the speaker's inner state are meant to be the giving up of the effort to attain mutual understanding. Thirdly, Habermas' communication theory presupposes the existence of communicative participants in conversation with equal status and ability to communicate. Equality and care for others are fundamental qualifications for participants in intersubjective communication.

Given the conclusion about each person's conversational capacity, what makes most sense is to converse with each other and find out the other's thought process and hopefully arrive at an agreement which would satisfy each other's needs and aspirations. What should be shared in the medical interaction are not only information on the nature, diagnosis, and prognosis of the disease, risks and benefits of the treatment, and possible alternatives, but also the image and understanding of the state of medical knowledge and technique, especially of medical uncertainties, and acceptability of considering one's own values and desires in decisionmaking. If there is an agreement, then the process is called shared decisionmaking instead of solitary decisionmaking on either side which may otherwise go parallel without interacting with each other. The authorization model cited earlier is surely an improvement over paternalism because it attends to the patient' decisionmaking right, but as such it may perpetuate patient's passive status, namely, of only accepting or refusing the physician's proposal. The conversation model which goes beyond hermeneutical understanding calls for patient's contribution in the decisionmaking process on top of physician's honest disclosure of all needed information gained through the interaction. The model therefore suggests something very radical and innovative. It imposes new duties both on the physician and the patient. The physician's duties do not just concern disclosure and consent but the duty to initiate conversation becomes the most important one. The patient is equally obligated to respond to the physician's invitation and to be prepared to understand the physician's role and willingness to cooperate. Silence is no longer a virtue. If you talk with, and understand, each other well, and arrive at an agreement on a treatment option, then there will be little room for resentment after the treatment is done, unless the physician displays considerably poor quality of care.

Habermas discusses an ideal interactive situation in order to show that it is at least possible that such a thing could hold if appropriate conditions are met. The conditions are spelled out in the form of the communicative competency of each participant. But even when competencies are latent in them, still the ideal situation may not occur. That is when Habermas comes up with consideration of the things that place constraints on the realization of the situation. So the discussion of the ideal interactive situation is helpful to contrast it with the situation where conversation is constrained and no genuine understanding is achieved, which is actually close to the case in our world.

For Habermas what has to be overcome is "systematically distorted communication" (Habermas, p.120) in which deception or manipulation of one party over the other by way of illusory information takes place to generate "false consensus" or agreement. This observation has a clear relevance to our discussion of uninformed or misinformed consent. Also the following are possible constraints placed on physician-patient conversation. The first is stereotypical mutual images. There is an age-old notion that the patient cannot be rational in thinking so that she is not entitled to a rational conversation. To label any patient irrational may be wrong. Pain, fear and deprivation of mobility may be upsetting the patient but not necessarily limiting totally her capacity for rational thinking and decisionmaking.

On this matter, Katz makes an interesting observation. He says that the basis for possible mutual understanding is not mutual rational competence but something opposite may be the case (K, p.120). Katz distinguishes between autonomy as decisionmaking right and psychological autonomy as the capacity to make decisions. Instead of trying to prove the validity of psychological autonomy which could in turn validate the patient's claim to have decisionmaking right, he embarks on a discussion from Freudian psychoanalysis of the influence of unconscious and irrational motivations. But he does not apply these motivations to form a deterministic principle of psychological law. Rather he tries to show that not only patients but also physicians are affected by these processes. The result of this finding is that you no longer can claim that physicians' belief, especially of benefitting the patient, which is used for justifying the control over the patient, is more rational than a patient's alleged irrational mindset under the influence of illness or injury. Instead of proving the patient' capacity to make rational decisions Katz disproves the rational-irrational distinction and the physician's alleged monopoly of rationality. Reflection and choice both work in the decisionmaking, and the process is not necessarily rational or conscious. A physician's judgment is not necessarily predominantly rational, while patient's judgement is not necessarily predominantly irrational. Patients could be on a par with physicians in terms of irrationality. A physician's proposal or recommendation of one particular treatment option is often influenced by her subjective inclination, belief, or value preference when there are so many uncertainties about medical science and there is no definitive consensus about the treatment, one example being breast cancer treatment.

How could one make sense of these opposite suggestions? Habermas seems to suggest that both physicians and patients are on a par with each other in terms of rationality whereas Katz says it is the case in terms of irrationality. I do not think these two thinkers present a difficulty for each other by making seemingly opposite observations. Katz says that both could be irrational not in qualitatively different ways. Habermas would not disagree with Katz's thesis because that seems to be the case with the *status quo* of the physician-patient interaction when in fact some physicians claim that rationality is only with them and not with their patients. On the other hand, Habermas talks of an ideal situation when mutual understanding can take place, when both parties can engage on perfectly rational terms. Katz wants to say that the seeming lack of rationality with the patient cannot be an excuse for the physician to refuse conversation. Both could be irrational in a similar degree, but it is required of the physician to initiate the conversation which may clarify the problems and find a solution. It is Katz's strategy to discourage physicians from withdrawing from their conversational responsibility. Katz wants to say they should be pressed to modify their self-understanding. But after all, it is evident that Katz also believes in communicative competence of all participants.

Since physicians have been historically the only decisionmakers in medical affairs, they are the ones to realize that patients have both informational and decisional needs. The belief that a self-determination right does not belong to patients is a great obstacle for mutual understanding. Actually, those physicians who hold on to it would not admit the need for mutual understanding or conversation. Conversely negative attitude such as fear, blind trust, dependence, and acquiescence make patients silent and vulnerable to coercion, manipulation and imposition of a physical, psychological trauma by physicians. It sometimes happens that an unfortunate encounter with a physician motivates the patient to be self-reliant. But such a consequence cannot justify the damage done. It is better that the damage did not happen at all. If the lack of informed consent was responsible for it, then the damage was definitely avoidable. Patients should be transformed self-consciously to an independent decisionmaker so that they can urge the reluctant physicians to be involved in lively conversation. Another constraint is related to the above two, that is the belief that patient are incapable of conversation and understanding anyway because of inequality of intellectual competence. In order to remove misunderstanding, a patient has to be mentally prepared to have a meaningful encounter with a physician. Education is again needed to remove this obstacle.

However, the great obstacle for a good encounter would be a socio-cultural environment in which both physician and patient find themselves and which does not allow them to engage in free discussions. The whole structure of the medical profession tends to be hierarchical, authoritarian and undemocratic. So the existing health care and insurance systems may be the greatest hindrances for democratic interaction. Also, hermeneutical understanding in Gadamer's sense fails to take a critical stance to the ongoing practice. The communal decision-oriented understanding urges the participants in the conversation to critically discuss the situation. Surely these are not actual topics to be discussed between physician and patient in the present practice. But the passive stance on both sides encourages the image of medicine as a power center in capitalism instead of taking the role of liberator of human suffering. Together with these, the status and authority of the medical profession and the validity of informed consent are the topics that will be dealt with in the next chapter, as something to be discussed in what Habermas calls discursive will-formation in a democratic society.

In the rest of this chapter, I will summarize what is gained from the above discussions of understanding. In the medical relationship understanding is something that does not limit itself to the area where the patient understands the information disclosed. Both physician and patient could share the basic understanding of the meanings of disease and death which lie at the basis of human existence common to the peoples in East and West. The common denominator of a disease is something which encroaches your body and hinders you from pursuing your everyday activities, or from attaining a goal, or from fulfilling your social responsibilities. Fever, pain, loss of energy make you feel resentful, exasperated, and desperate. The role of the physician is to help the patient restore her physical and mental ability to function in society. A physician is educated to tender a wound or sickness of a fellow human who is unable to take care of oneself properly. Sickness is not usually an isolated phenomenon. Knowledge and understanding of the background of a sickness should be important to find an appropriate cure. The superior knowledge, however uncertain, that the physician possesses about human biology and psychology should be used for freeing human bondage from misunderstanding and misconception that generate unnecessary fear and despair. Appropriate understanding should take place on the part of the physician about his own role and the "organic nature and the complexity of medical practice" (P, Vol.2, p.401). This requirement goes further to the understanding of the historical, social, economic situation of their mutual positions. What is requested of a physician is a vision and mission to keep enlightening the general public without taking advantage of their ignorance. If there occurs a panic in the area of a sudden epidemic or an incident of irrational ostracism against those who suffer from socially induced diseases, it is the physicians who can enlighten the ignorant folks. Physicians can be paternalistic in the face of such ignorance and irrational beliefs. Indeed a physician's proper understanding of his own role is required before embarking on the project of obtaining informed consent. However, the most important part of a physician's role is to recognize the patient's informational and decisional needs, and initiate conversation to share decisionmaking and informational authority. Moreover, what is important for both physicians and patients is their belief in the effective use of language. Successful communication and coming to understanding is guaranteed by the language structure, if the speakers realize what they are doing. Both parties are expected to have awareness of communicative competence. The realization of communicative competence is the matter of education and training. In this regard the way the Japanese people approach their language is wrong and inappropriate for a democratic interaction. Openness and truthfulness should and can be attained through conscious speech acts. Without the awareness of these features of successful communication informed consent will not be realized in an ethically relevant way.

In this chapter, I have discussed the conversation model of informed consent proposed by Jay Katz. It was shown that the conversation model belonged to the process model against the event model in which informed consent was supposed to occur at a discrete moment. The process model on which informed consent is considered as taking place in a certain duration of time is an ethical requirement. Genuine understanding may not take place on the event model in which informed consent can be only nominal. Understanding was discussed in terms of a spectrum. Informational understanding is used in natural scientific inquiry as well as in everyday situations where natural causation or logical (both inductive and deductive) inference is at issue. Hermeneutical understanding is at work when one wants to interpret the phenomena or derive meanings from human activities. We learned from the hermeneutical approach that human illness and its healing process are not purely physical phenomena. Gadamer offered insightful observations about an understanding relationship but it turned out that he was too reliant on, and uncritical of, tradition, so we turned to Habermas to gain better understanding of our present situation and mutual understanding to work together to solve medical problems. We saw Katz and Habermas endorsing the conversation model which has joint decisionmaking as the goal of interaction. Understanding is connected with arriving at a good medical judgment and joint decisionmaking. Understanding per se may not lead to a necessary action at all, while a sound judgment should be the result of a sound understanding. The ethical theory of informed consent requires that understanding precede decisionmaking. However, the physician-patient relationship is not an isolated phenomenon from the main structure of society. If the relationship is hierarchical, it is a mirror of the society which has a hierarchical structure. But even when the overall social structure is democratic, the physician-patient relationship could remain vertical because of the traditional authoritarian practice of the medical profession. Informed consent requires that the participants in clinical decision-making process keep equal status as decisionmakers at least in matters that directly concern the patient's value system, even though both parties are unequal in expertise and social influence. In the next chapter informed consent will be examined as a part of a participatory democratic institution.

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CHAPTER IV DEMOCRACY, AUTHORITY, PUBLIC POLICY

In this chapter I would like to deal with informed consent from a broader perspective, namely, as a part of the theory of participatory democracy. A democratic theory concerns a social structure that operates according to democratic principles. The democratic principles include the idea of participation in decisionmaking process to realize communal values. Medical decisionmaking between physician and patient should not be an exception. I will go on to examine the issue of democratic justification of a social institution such as informed consent as was suggested by Habermas. Along this line of thought, authority of the medical profession and the range of physician discretion will also be discussed. I will also continue to discuss various constraints that obstruct a democratic interaction. Finally some proposals will be made on how informed consent can best be incorporated in the mindset of the people and practiced in the physician-patient relationship in an ongoing quasi-democratic society.

1. Participatory democracy

Informed consent as treated so far is a practice proper to a democratic society. More specifically, it embodies the values proper to participatory democracy. To understand both some of the implications of informed consent and some of its pre-conditions, it will be helpful to spell out the corresponding notion of democracy. There are two reasons to connect democracy and informed consent, ethical and therapeutic. First, autonomous or shared decisionmaking as democratic practice should not be limited to political arena. Medical relationship should also be democratic. Second, autonomy or independence makes the patient stronger and more committed to her own health. The first claim can be logical and necessary conclusion from any proposition about participatory democracy. There is no reason to exclude medical relationship from such consideration. The second claim is neither logically derived nor empirically conclusively verified. However, in the sense that health can be one of the things that an enlightened person can control, the second reason can also be the logical conclusion from the analysis of the change of a person from a dependent individual to an autonomous, democratic member of society. The change is expected to take place in the self-image of the profession and in the consciousness of the lay people. Then, democratic medicine most likely fares better than feudal medicine and also better than hermeneutic medicine we discussed earlier in terms of healing the patient as a whole person. Democratic medicine respects the patient as a person who has or is going to have communicative competence, rational decisionmaking ability, and readiness to take responsibility for decisions made. Democratic medicine will enhance her self-respect, personal dignity, independence, and determination to carve her own future in her own way. The first two chapters of this thesis recounted what has happened in feudal or paternalistic medicine. For both ethical and therapeutical reasons, patients deserve a democratic treatment if they are in a democratic society, however formal it is. The undemocratic status of patients reflects undemocratic self-image of the medical profession and the professionals' privileges in the medical decisionmaking process when the matter at issue directly concerns the patients. So the most plausible thing we can demand of the medical profession is that it reconsider its own image and try to approximate itself to a democratic institution as much as possible, while we laypersons try to learn to be better participants in decisionmaking in as many phases of life as possible. What we need to do now is to get a boost from theories of democracy in order to deal with the implementation of an institution which is appropriate for a democratic society.

Among the theories of democracy, only the one of participatory democracy has direct bearing on our inquiry because of its respect for wishes and needs of each participant in a decisionmaking arena. Democracy is an arrangement in which equal, free, and rational agents assemble to discuss and decide freely and openly things which are important for them. We want to reject the idea that democracy starts and ends with exercising voting rights to elect our representatives to offices on local and national levels. Participation belongs to the core idea of democratic theory. It is no doubt that the ancient Athenian democracy was democracy as far as the participating members were concerned. From our eyes it was not a real democracy because the membership was limited to certain strata of society. Their principle of discrimination contradicts what we can call democratic values. However, in the Athenian democracy we can find one salient feature that is necessary for democracy, namely, the principle of direct participation in a political decisionmaking process. Participation itself may be a neutral concept as to the values that are to be realized. We should say that direct participation to decide and realize the values that have universal application is the only modality appropriate for autonomous citizens. Participatory democracy pertains not only to the decisionmaking procedure but also to the values to be realized.

In *The Social Contract* Rousseau discusses two spheres in which participation is decisive, namely, at the time of making a contract of association to form a society and also at the time of actual political decisionmaking. Rousseau thinks that a society is formed because people want to get out of the state of nature and decide to join together and cooperate to found a community to protect themselves and solve various problems of life. This act may be only hypothetical, but

Rousseau thinks that it should be the main idea of the relation of society to its members. Unlike the feudal idea of social constitution in a traditional society like Japan, the Rousseauan theory tells that we are not just born in a fixed form of society and supposed to passively accept our fixed roles in it. Instead, society is something we mold by ourselves and can change, if necessary. It is a truly radical and revolutionary idea that we can form or change the society which is usually thought to be given and unchangeable. The idea of contract and the justification of revolution can be traced to Hobbes and Locke, but it was Rousseau who was the coherent advocate of participatory democracy. According to Carole Pateman who wrote *Participation and Democratic Theory* in 1970, Rousseau was the first powerful theorist of participatory democracy, as "his entire political theory hinges on the individual participation of each citizen in political decisionmaking" (Pateman, p.22). The agents in that situation are presumed to be politically conscious and active. They are ready to debate and make decisions on the matters that concern their own life. They are the legislators of their own laws and rules.

One of the strongest merits Pateman sees in Rousseau's theory is its educating effect on the part of the participants. The agents are not perfectly autonomous persons from the beginning who know what to do and what to choose to live a good life in a society. Rather each individual is expected to learn to be democratic by participating in democratic procedures of various decisionmaking arenas in society. Instead of being a rational, moral person from the outset, the agent as a product of social, historical conditions becomes a full-fledged citizen by learning what is required of her and what she can do in terms of needs and desires in the specific social context. The person eventually will realize the limitation and possibility for self and mutual development while actively taking part in communal affairs. Participation is preeminently a learning process for the participants. The individual involved in the process will learn to be a socially responsible person. Pateman maintains: "Once the participatory system is established, and this is a point of major importance, it becomes self-sustaining because the very qualities that are required of individual citizens if the system is to work successfully are those that the process of participation itself develops and fosters; the more the individual citizen participates the better able he is to do so. The human results that accrue through the participatory process provide an important justification for a participatory system" (p.25).

We can then talk about something called democratic personality which is expected to be born out of each participant in such processes. Openness, truthfulness and social concern seem to constitute such a personality. Democratic personality-building takes place gradually in the process of taking part in the intersubjective interaction. On the level of each participant's mental orientation, to be democratic means to treat others as being equally capable of making communal decisions and of acting responsibly according to the decisions thus attained.

Rousseau does not suggest that any guiding principles should be chosen in the original situation, but rather presupposes that there are a couple of principles on which society is to be constructed. They are the principles of liberty and equality which are "the greatest good of all" (Rousseau, p.55) and not incompatible with each other. Liberty does not exist without equality. By equality he does not just think of political equality, but of economic equality as well. To be economically stable and independent is an indispensable condition to becoming a full-fledged citizen of a society. According to Pateman, J. S. Mill was another participatory democracy theorist who advocated the significance of participation at a local government level and also in industry (Pateman, p.33). Mill seems to have been sympathetic to socialist causes except in the case of its centralizing tendency. In our days there are people who believe that perfect democracy will exist only in socialism (Cunningham). Since informed consent is greatly constrained by the economic structure of society, it will be best realized in a democratic society where economic equality is also attained. The existing disparity in expertise and wealth between physicians and patients poses a greatest challenge to the democratization of the physician-patient relationship.

However, we may also pay attention to those advocates of direct participatory democracy who want to dismiss the need to establish basic principles such as equality and freedom in the beginning. They also tend to ignore the meaning of the original contract situation. Instead they want to emphasize the process that participants undergo in gathering, talking, debating and deciding. For Barber, who drew largely from John Dewey and wrote *Strong Democracy -- Participatory Politics for a New Age* (1984), there is no political truth in the beginning. Rather in the due course of participation people learn and recognize their needs and their solutions. They come together to form political consciousness, and to be able to make political judgments through political discourse and activity. Barber admits that not to have initial principles is rather an uncertain business, but insists that political discourse generates political truth about what should be done communally. He confirms this anti-foundationalist thesis in his most recent book *The Conquest of Politics (*1988). Indeed, the discussion of an original contractual situation, or the confirmation of the basic principles of justice in the beginning, may not be so important as the idea that we make up a society in which we can have a say in the matters that directly concerns us. On this view, participation will generate the values to be realized. And this idea does not contradict the Rousseauan view of participatory democracy as is observed by Pateman. Still, one may say that Barber's type of democratic interaction also implicitly presupposes the communicative competence of participants, and the three value orientations arising from the analysis of speech acts that Habermas spells out. In a medical context the value and meaning of healing a wound will be recognized and realized in the participatory process of both physician and patient. Underlying beliefs are the participants' competence to truthfully communicate, attain some sort of agreement and to fulfill the agreed-upon agenda responsibly.

There is another important feature in participatory democratic theory, namely, the idea that the people's voluntary agreement or consensus is the only legitimating, justifying or binding power to a contract, law or other social arrangement. The legitimacy or justification of the foundation of a society or a social rule is derived ultimately from the unanimous agreement of the participating agents. In the theory of Rousseau there is a thesis that people are somewhat "forced" into the participation. Everybody is lured into the society to become freely active in a communal life. This is the only time when a paternalistic principle works and makes sense. The basic task of society remains to guarantee the citizens' political freedom as much as possible. It is the society where in principle people can freely get out or enter. So their decisionmaking is uncoerced and free. It is this freely-made agreement or consensus that makes an authority legitimate and binding. Other sources of power or authority are illegitimate and void as far as the decisions about the social arrangements are concerned. Rousseau says: "...since force is not the source of right, conventions (=the original contracts) remain as the basis of all lawful authority among men" (Rousseau, p.11). Pateman does not specifically refer to the question of legitimation or justification that participation ensures, but only notes that a collectively agreed-upon decision is more easily accepted and realized by individuals. We will come back later to the issue of legitimation of a social arrangement such as the practice of informed consent, but this discussion of legitimation or justification has an important bearing on the meaning of a consent-giving activity. A well-understood, uncoerced, freely-given consent is a product of participatory process of medical decision-making. Only such an activity can be responsible and meaningful.

What we learn from these discussions is that, if democracy is to be worth its name, participation has to take place in as many levels of society as possible in order that both society and people become gradually democratic. The character or virtue of being democratic gains importance not only in the talk of institutions but also of individual agents. Further, the idea to assemble for intersubjective discourses is motivated not only by self-interests but concern about others.

Democracy admits no fundamentally hierarchical structures in human relationship, and a democratic person is sensitive and compassionate to the needs of the others, especially to those who are underprivileged as the result of injustice imposed in the past. The antithesis of democracy would be not simply unjust power, but political apathy or indifference when the world is still full of oppressive, negative elements for mutual development. The antithesis of democratic interaction is not simply hierarchical relationship, but unreasonable relegation of decisionmaking power when one can be more autonomous and independent.

For democracy to be alive, nothing is more important than having regular meetings where people can assemble for political discussions. Democracy as a social apparatus can be maintained by these meetings where anybody can participate and can be heard. It is important to keep conversation going in the political arena, and no less important on other levels of human interactions. Through verbal interchange people's desires and needs are known and taken care of. Only openly discussed and agreed-upon matters may have a legitimating power. For all participatory theorists, democracy is a process. It is through democratic process that both personal self-realization and the search for political truth is attempted and attained. Although a complete participatory system may be impossible or at least not in view right now, the virtue of being democratic is not something unattainable.

However, it is Rousseau himself who said in *The Social Contract*, "Taking the term in its strict sense, there never has existed, and never will exist, any true democracy" (p.70), and "If there were a nation of gods, it would be governed democratically. So perfect a government is unsuited to men" (p.71). Rousseau was referring to constant "civil wars and agitations" that could haunt the democratic state. It is not the case that democracy can proceed automatically once its formal procedure is established. It will encounter anti-democratic wills or forces among the people. There are always people who want to monopolize political, economic, and any other decisional power of society. For some people domination over other people never ceases to be the origin of the greatest joy. There could also be other elements to break down democracy. For Rousseau democracy presupposes "many things difficult to combine", namely, first, a very small state where people assemble and know each other easily; secondly, a simple tradition without complicated procedure to get consensus; thirdly, over-all equality of status and property of the people, and lastly "little or no luxury for...it corrupts both the rich and the poor..." (p.70). As in Thomas More's 'utopia', there is much caution against the accumulation of wealth, because it is a strong factor to divide the minds of the people. In our days there are other goods the distribution of which is the vital concern of the people, namely, medicine, education and work opportunities. If there is no way to arrive at an agreement, democracy will break down, but if we are patient, there are ways to find breakthrough by way of negotiation and compromise (Benjamin). Surely perfect democracy has never existed, but it may be too early to give up before we have ever seriously tried. After all, 'worldwide perfect democracy' (Cunningham) may not be impossible, and if democracy is a process, what we are doing in terms of making medical relationship as democratic as possible is surely a step forward to the ideal.

Having sketched general features of participatory democracy we can now in turn draw out some of its implications for informed consent, including the implications for the practice of the medical profession and the role of patients.

2. Informed consent, authority, discretion

The key word for this section in dealing with the practices of the medical profession and the role of patients is legitimation which was touched upon in our discussion of participatory democracy. Habermas is more serious than other participatory democratic theorists about the problem of legitimation. For him, like others, the scheme of a democratic society, action-binding norms and needs to lead a civilized life are not something imposed from above or by inner pressure groups. They should instead be the results of open discussions and argumentations among free and rational citizens. Earlier, Habermas discussed communicative competence of participants in ordinary conversation including physician-patient dialogue. Now his theme is a higher-level discourse which includes political decisionmaking. Habermas calls it ' discursive argumentations for will-formation' and believes that they are democratic processes resulting in legitimizing the agreed-upon arrangements, institutions and values. Only thus legitimized arrangement can have authority. In such a discursive occasion, unlike in Kantian morality, people need not suppress personal desires and interests. They bring them to the discursive table and talk about them. People's needs, namely, generalizable interests, are the objects of argumentation (Habermas, 1975, p.108). In such an argumentation "no force except that of the better argument is exercised". "If ... a consensus about the recommendation to accept a norm arises argumentatively..., then this consensus expresses a 'rational will'". People will want to make compromises in a wise manner because the end result is the better understanding of each other. In Habermas' scheme of this procedure, both theoretical and practical matters are objects of argumentation. Habermas' theory of communicative action serves as the basis for such a procedure. If the social norms and needs are the subjects of argumentation, all the political, economic, educational, and health care systems and norms will be discussed. Meanings and legitimacy of scientific and technological enterprises should also be on the agenda. Accordingly, informed consent would be one of the items that are to be discussed in a discursive argumentation in the "communication community" (p.105), because it is a norm that should be legitimately imposed on citizens of a democratic community when they enter into a physician-patient relationship.

In a society where people are content with a representative form of government, leaving all the political discussions to their surrogates, the importance of Rousseau's and Habermas's proposals has slim chance to be heard. With regard to our concern, namely, informed consent, it is the government, the judiciary and the professional establishment that decide the value of the institution. In the United States the judiciary took the initiative and the medical profession responded, if only very slowly. The whole procedure looked like a normative structure given from above. We only wish such a normative structure were more stable and coherent. In this representative democracy, we are controlled by ever-changing legislative and administrative policy-making and judicial interpretations. Yet, in the United States there occurred something which came close to what Rousseau and Habermas would have envisaged, which might turn out to be a possible future course for Japan. I have in mind what has happened to informed consent in the past decade. The main idea was legal-paternalistically presented, but later it did undergo some sort of public discursive argumentation. The United States President's Commission for the Study of Ethical

Problems in Medicine and Biomedical and Behavioral Research placed the issue on public debate, though in a limited way in the sense that the main participants were mostly expert witnesses and in due course their debate was to be curtailed by conservative political pressures (Benjamin, p.127). Nonetheless, it was remarkable that so many different people debated on difficult questions of medical and biomedical decisionmaking for quite an extension of time and issued reports on their discussions of various topics including informed consent. They let the world know that these are the things that should not be decided solely within a closed circle of power holders. With regard to informed consent they agreed upon the feasibility and legitimacy of the institution to be realized in a democratic way. So at least the legitimation problem of this practice is not disputed in the United States. For the rest of the world, where the Habermasean ideal procedure is not easily implemented, the United States has presented a model procedure to follow. What is left to be done is to disseminate the conclusion of the democratic discussions to the public.

Informed consent needs as one of preconditions for its implementation the demystification of the medical profession. If medical authority is intact and physician discretion is absolute, they can be easily abused to the detriment of ignorant, dependent patients. From the above discussion of legitimation it is a logical conclusion that authority and physician discretion can also be on the agenda of democratic discursive argumentation either in academia or in political, judiciary arena whenever the implementation of informed consent or other democratic practices are questioned by the medical profession.

But the traditional medical profession would regard this kind of suggestion as an impossibility. Vested interests seem to be strongly protected. Philosophical discussion on authority tells us that authority is revealed in different forms. Authority is sometimes categorized as epistemic and executive authority (DeGeorge). As the possessor of medical scientific knowledge and technique the physician is taken for granted to have epistemic authority. Patients come to seek help from her because of that sort of authority. But the physician does not just display a special expertise on a specific subject, but makes a medical judgment, and often makes decision all by herself and act on that judgment. So the physician's authority is not just an epistemic one but an executive one as well. However, the executive part of the physician's authority is derived not from the caliber of the individual physician but ultimately from the medical establishment which supervises medical education, licenses physicians and monopolizes medical knowledge and technique. What is clear from the above discussions of democratic medicine is that a physician's authority has certain important limitation, not as an epistemic authority but as an executive authority.

The medical professional is not to execute her authority on the patient without the latter's consent if that patient is competent and has not already waived his decisionmaking right. That means, physicians should be more careful about exercising their discretion. The authority of the medical profession did not come from the people as a free economic system can sometimes be characterized (DeGeorge, p.175). Earlier in history the medical profession was not recognized as having the kind of authority that it now enjoys in any advanced countries. The historical development of medical authority is partly due to efforts on the part of the professionals, and partly due to the economic condition of the capitalist, technology-oriented society where medicine can be a private, lucrative enterprise easily associated with drug and engineering industries. The traditional unwritten justification for the medical profession is that medical practice is a God-given mission to save life, heal wounds and remove pain of indigents, almost disregarding monetary remuneration. By contrast, the present-day authority of physicians and the medical profession largely lies in the economic factors of medical practice. So much associated with power and wealth, there is always a possibility for "despotism of the experts" (A, p.28) in the medical profession. But if legitimacy of the medical profession can ever also be put on the agenda of people's discursive argumentation, the whole institution can perhaps cease to be authoritarian or despotic. Although I do not see any such possibility in sight, it is encouraging to think that conceptually there is such a possibility. We have a right to urge medical professionals to accept the suggestion that medical authority be placed more in the open, and that they try to accommodate themselves to the realization of democratic values.

To match such a partial relinquishment of authority on the part of the physicians, what is required of patients is that they do not abuse recently recognized rights to self-determination while realizing that a curing process is a democratic, cooperative enterprise. Enlightened patients should not be a threat to physicians. Both side should be open about what they know and what they do not know. Actually in this process physicians are expected to relinquish partially their epistemic authority as well, in the sense that both parties share the uncertainties of medical science. We recall that this is one of the reasons that Katz suggests the institution of shared decisionmaking and shared authority. In this scheme physicians are to let the patients shoulder partly the burden of decisionmaking and of taking responsibility in accepting any untoward consequence which is not a result of the particular physician's ineptitude.

3. Obstacles for democratic medicine

Having laid out these general considerations, we must acknowledge constraints on realizing these democratic goals.

In doing so, we have to recognize the possibility that genuine informed consent is not possible under existing social conditions. On the other hand, we can try to see to what extent some of its features can be realized.

The legal doctrine of informed consent is not the embodiment of a democratic decisionmaking theory in the sense that it does not presuppose the existence of conversation which could allow both parties to express their needs and expectations and make sure of truthfulness and understanding on either side. By contrast, the conversation model of heightened understanding and shared decisionmaking is truly democratic. The patient is an autonomous individual who has informational and decisional needs to be fulfilled by an understanding, democratic physician. Together they deal with the common problem of curing the patient's disease. They exchange their thoughts and information, and arrive at a rational decision about the most reasonable treatment option. The process may take a dialectical route and the participants may get to an unexpected end-result of conversation. Still, the process is nothing other than democratic because of sharedness in decisionmaking. The physician is not motivated by her self-interest to promote medical business instead of healing mission.

As has been stated in the previous chapter, preconditions for the implementation of informed consent are largely unfulfilled. For physicians, informed consent is a nuisance because it requires to break up silence with the patient and explain from ABC's of medical knowledge when the latter is still ignorant and helpless. And their effort for communication is not duly rewarded. Under the present system it does not matter if the consultation goes in a lively conversation or in silence. The ongoing fee for service system discourages conversation. So even in the United Sates, where informed consent is officially endorsed by the profession, it has been taken seriously only by a small number of physicians. Unless physicians are monetarily endorsed for their conversational effort the ideal situation may not happen at all, or if it does, it will be only by an enormous sacrifice of conscientious individual professionals. Ultimately it is social, economic conditions that hinder a true democratic medicine. In the United States enormous medical costs and a poor insurance system make patients shy away from entering an ordinary physician-patient relationship at all. One writer comments: "...the possibility is that a patient's choices in the future will be overwhelmed by powerful economic and structural forces. This makes it critical that patients understand their situation and the rules of the doctor-patient relationship, and that genuine informed consent for treatment be obtained for reasons other than to comply with legal or regulatory requirements, or to ensure against liability" (Loren H. Roth in A, p.ix). Capitalist medicine has often proved to be inhumane, and an individual patient finds herself utterly powerless in the mess of medicine-business complex. All one can say is that medicine should not be a part of market economy, that medical education should be federally subsidized, that private insurance should be mostly replaced by publicly-funded program, that pharmaceutical and medical technology industry should be publicly controlled, that hospitals should be publicly managed, and so on. While these claims are reasonable, and most probably agreed upon by democratically conscious, concerned citizens, they do not seem to be realized in a near future as the decisionmaking of social policies is controlled by various power holders. What we can do is to remind people that the present medical care system including insurance arrangement is the ultimate cause of the situation in which informed consent cannot be adequately realized and invite them to take a close look at it and change the situation first by serious argumentation nationwide.

Although we may not be able to rectify the overall structure soon enough, what can be done immediately is that physicians take more time conversing with patients, that hospitals should reward the health care professionals for their efforts to communicate well with patients, and that every reimbursement system should pay attention to the style of the clinical session. The success of the first item ultimately depends on the modification of the self-understanding of the medical profession as the sole authority of medical matters. But physicians can start the move individually at their own sacrifice and go on to pressure for the reform of the system. They need to change the image of themselves who seemingly want to take advantage of the ongoing system and daily reproduce conveyor-belt medicine. However, it would be far better if both physicians and patients can talk together about the remuneration system, so that the demand for a reform can be a joint effort.

In order for the movement for informed consent to be successful, there should be a complete change in the mentality of the profession. The final section will deal with some proposals for creating the conditions for meaningful, if still perhaps only partially realized, practice of informed consent.

4. Proposals for democratic medicine

As in all other similar situations, such as to alleviate the social problems of crime, drug use, the AIDS epidemic, and homelessness, the best and only solution proposed is found in education. Toward the end of his seminal book Katz remarks:

> "The radically different climate of physician-patient decisionmaking that I envision cannot be implemented by judicial, legislative, or administrative orders. At best, such outside interventions can prod doctors; at worst, they only substitute bureaucratic authority for professional authority. Meaningful change can come about only through medical education and the education of patients" (K, p.229).

Laws and jurisdiction can rectify a wrong when it is done, warn the physicians about how, retrospectively, they should have behaved in order to avoid legal liability, and remind them that patient's right should also be respected. But the legal doctrine does not deal with how best (in an ethically ideal way) informed consent can be implemented. It is in medical education where it is taught that informed consent is a moral imperative for good medical practice, and that it will lessen the physician's decisionmaking burden. On the other hand it would be ineffective for the physician to start teaching the patient when the latter is engulfed by suffering from a disease. Education is required of both future physician and patient-to-be at the earliest possible stage. One American advocate of informed consent writes:

> "Surveys of medical ethics teaching show that nearly all medical schools had some form of medical ethics teaching--however abbreviated--by the mid-to-late 1970s. There are no data on how much teachers' time is actually devoted to informed consent, but this medical ethics instruction--even if minimal--began to present to young physicians the view that informed consent is not merely a legal doctrine, but also a moral right of patients that generates moral obligations for physicians" (F, p.95).

In the meanwhile enormous number of publications on bioethics have appeared. Medical education at some medical schools includes training for "decision-making competence" and skills on "how to converse" (Katz, p.152). This is exactly what is lacking in Japanese medical education. While in the United States people are discussing the need for conversation skills, and of a curriculum incorporating humanities, medical schools in Japan to my knowledge with a couple of exceptions, do not offer any courses for educating humane and open-minded democratic physicians.

Patient education is not an education to make an obedient patient, or something done just to facilitate understanding of disclosed information and decisionmaking within a clinical context; the education I have in mind is given in school in order to prepare people to become a patient who will not suffer from deficient physician-patient relationships. In the United States I would like to someday see the AMA and each state medical society will help establish a course at the secondary school level for health and patient education. When students learn language, government, geography, science, they should also learn basic facts about their own body and mental mechanism and its care. Who would be a teacher of such course? A retired physician or an experienced, registered nurse would make a perfect candidate. And I hope to see similar things happen in my country someday.

Katz's conversation model requires that each person be more interested in her own body and its management. Basic knowledge of our body and psychology should be acquired. The values and needs to become an autonomous individual, an independent decisionmaker, a mature participant in discussions with care-providers should also be discussed so that people will be ready to start conversation with the physician, ask questions, respond to physician's readiness to help. That kind of readiness will reduce the burden on physicians to initiate conversation, and will teach the importance of being a mature person for deciding things about her own body. The course will include elementary exposition of physiology, oncology, first-aid, statutes on medical matters such as the determination of death, abortion, health insurance system, what it means to refuse a proposed treatment. Each citizen should know what statutes are available on deciding the matter of life and death. Students should be involved in philosophical and sociological discussion of death and illness. Myths and misconceptions of diseases, for example, that a cancer disclosure is a death sentence, can be removed in education. So while the mass media may be effectively utilized to enlighten people with health information, formal education on a physically and mentally healthy life should start at the secondary school level.

With regard to informed consent, young students should know about its existence. In the event they become patients what they should know in advance about legal requirements are: (1) physicians have a duty to disclose information to them about treatment, (2) patients have a legal right to make decisions about treatment, (3) physicians cannot render treatment without their consent when they are competent, and (4) the right of decision includes a right to consent to or refuse treatment (A, p.70). And the patients should also know that they have a right to waiver. Waiver is of course a matter of choice. Yet, it would be a more appropriate behavior for an independent member of a democratic society not to opt for a waiver. After adequate education, the patient will know what she wants to know, what she does not understand, and that she will be responsible for a possible consequence of her decision. More importantly, however, the patient should know that shared decisionmaking is the best possible way to deal with her problem and that it is done only through good conversation with the physician.

This chapter started with a discussion of participatory democracy which requires informed consent in medical practice and ended with some proposals of public policy including education for physicians and for patients for the implementation of democratic medicine. From the discussions of Rousseau and other participatory theorists' ideas, and Habermas' idea of legitimation, we derived a conclusion that the institution of informed consent should be an item on the agenda for democratic argumentation. We also considered a possibility that the authority of the medical profession and the practice of physician's discretion can also be placed in the open, discussed and accepted perhaps with certain clearly defined limitations. Education for patients is proposed to make mature, independent, competent, autonomous and responsible decisionmakers.

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CONCLUSION

At the outset I stated two aims of this discussion of informed consent. One was to address the issue of Japanese medical practice which was in need of incorporating informed consent. The other was the need of reconstructing informed consent as a democratic theory. I started by describing the Japanese situation and mentioned that informed consent was beginning to be given serious consideration by the Japanese medical establishment. I suggested that the hierarchical, authoritarian nature of Japanese medical interaction had something to do with the acceptance of German medicine in the last century. It was also pointed out that the Japanese language was poorly utilized for mutual understanding. I also looked into representative philosophical systems that were constructed to endorse the basic social structure and human relationships. Those ethical, philosophical systems of thought were undemocratic and allowed no room for decisional autonomy, intellectual independence or individual integrity of ordinary citizens. Although Japan has a democratic constitution now, the judicial power of the state tends to protect the power holders rather than the weak. As we saw, the JMA's new report on informed consent did not evaluate the role that the United States courts have played in upholding informed consent.

I then examined the American history of the legal doctrine of informed consent in court decisions, in legislation, and in actual medical practice. We noticed a clear difference between the legal doctrine and the ethical theory of informed consent. One of the features that differentiated them was the concept of understanding. Informed consent does not make sense if it ignores the act of understanding of the parties involved. The legal doctrine cannot refer to understanding partly because it is hard to be confirmed. Ethically, understanding is a demanding but necessary condition. Understanding is not just exhausted by patient understanding of the disclosed information. The way it is disclosed and understood hinges on the physician's understanding of her role and the patient's understanding of what he is doing. These and mutual fears and hopes must be placed in the open in the form of conversation. Jay Katz's proposal of the conversation model of informed consent was found most appealing and the only one which could realize the ethical purpose of informed consent. The conversation model of informed consent was philosophically examined and reconstructed. The objectivist approach of understanding implies a one-way relationship and does not aim at mutual understanding. So a hermeneutical approach was invoked. Gadamer provided needed insights about understanding meanings and intentions.

But Gadamer's hermeneutics had limitations, such as perpetuating traditional medical relationship, and failed to give a perspective that could critically approach the object area and change it for the better. So we drew from Habermas' communicative action theory. He spelled out that the possibility of mutual understanding lied in the analysis of speech act. Our intersubjectivity, our inner truthfulness and objective truth are the elements of communication and understanding. In everyday conversation and theoretical, practical discourse these are presupposed and can constitute domination-free interaction. Both physicians and patients are expected to be competent but truthful speakers and free, independent decisionmakers. They share decisional authority and responsibility. They participate in decisionmaking processes in society and are expected to be partners in medical decisionmaking as well.

The nature of participatory democracy should be reflected in informed consent. We learned from Rousseau and other participatory theorists that to learn to be democratic is meaningful and can be done in the exercise of our autonomous decisiomaking rights in our daily life. Habermas added to that thesis that normative structures whose authority we have taken for granted could be put on the agenda of discursive will-formation. They should be discussed, recommended and employed in public policy, including some legal endorsement. Only those which withstand such procedure can have legitimacy and binding power. We now know that neither physician's absolute authority nor informed consent is to be enforced from above. Silent acquiescence to authority is undemocratic. Perhaps what we should do now is to tell the Japanese public that informed consent is indispensable if they really want to have good relationship with physicians, that they should not tolerate the paternalistic arrangement of informed consent by the medical profession, that they should urge a public debate on this subject, and that they should push to have a uniform law protecting patient's rights and full implementation of informed consent through public and medical education.

To reiterate, medical relationship should (and can) be as democratic as possible. Ethical appraisal of informed consent doubtlessly supports the status of a patient as one who should be listened to and take part in a decisionmaking process concerning her medical care. From the above discussions one can conclude that informed consent is a part of democratic theory and the practice of a good medicine in a good society. Informed consent is a part of the theory of participatory democracy, instead of other types of democracy. Participatory democracy is the type of decisionmaking procedure that all mature individuals should want to choose, not only for the governmental institutions, but also for most of their human relationships. Democracy is possible when there are autonomous, independent decisionmakers who can and want to decide on important things on their own and among themselves, even when actual execution of the actions will be done by others. Democracy is also a learning process for hitherto naive people to become interested and engaged in things that concern themselves and others. Informed consent is a part of great many democratic practices that require participation in decisionmaking. Although no perfect democracy is in view, the most plausible proposal for implementing democratic medicine would be to start educating people at earliest stage to become autonomous and caring decisionmakers. Policymakers can both be democratic and paternalistic (caring against ignorant people's wills) to create conditions for producing democratic personalities and opportunities for democratic interaction. Without them I do not know where the process of democratization can start. I hope that this small treatise can serve the purpose of directing the attention of my country's people to the importance of informed consent in medical practice.