

Minors and Mental Incompetents: Consent to Experimentation, Gifts of Tissue and Sterilization

Introduction

My concern in this paper is with minors and mental incompetents as subjects of research, as donors of human tissue and as subjects of sterilization. In each case one must ask who, if anyone, can properly give consent, and in what circumstances. The question is both legal and ethical. One must look at the question of consent to these procedures where the subject is a mentally competent adult, but first one must examine the subject of consent to medical treatment.

I. Consent to medical care

Medical care or treatment is the diagnosis, prevention and treatment of illness. The term "health care" may seem synonymous with medical care but it is intended to be wider. For example, the World Health Organization says: "[H]ealth is the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."¹ With this definition of health, the administration of contraceptives is probably within health care, whereas it is outside the term "medical care".

In general a competent adult may make up his own mind as to whether to receive medical treatment. Thus the physician should not treat him without his consent or, of course, in the face of a prohibition. It was in the context of a prohibition that Mr Justice Cardozo uttered his oft-quoted statement, that "[e]very 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".²

Consent may be by conduct or it may be specific, whether verbal or written. Hospitals have their own consent forms and sometimes questions arise as to whether they are too wide or whether the

¹ Preamble to Constitution, quoted in Curran & Shapiro, *Law Medicine and Forensic Science*, 2d ed. (1970), 974.

² *Schloendorff v. Society of the New York Hospital* 105 N.E. 92, 93 (N.Y. 1914).

patient actually understood them. This is, of course, a problem that can come up in any document. A consent prepared by a physician or institution should be fair and in simple language. There should be no coercion of the patient to sign it, and every effort should be made to see that he understands it. Today the main question is whether the consent must be an "informed consent". What is the duty of the physician to disclose the proposed treatment and alternatives and the risk of each procedure (or both) in order for the consent to be genuine?

Fifty years ago, the Court of Appeal of Ontario held in *Kenny v. Lockwood*³ that the decision as to disclosure of risks is for the physician on the basis of good medical practice. This was the prevailing rule in the United States until about ten years ago. Critics of that rule said it was too paternalistic or authoritarian; that there should be a partnership between doctor and patient, which is only achieved by complete candor that enables the patient to make an intelligent decision.⁴ Since then there have been a number of decisions supporting this thesis. The two leading cases are *Canterbury v. Spence*⁵ and *Cobbs v. Grant*.⁶ The ratio of *Canterbury* is this: "[t]o enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential".⁷ The physician has a duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved. The patient is not bound by the profession's tradition as to what should be disclosed.

Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.⁸

As to the scope of the duty of disclosure, the patient must be given enough information for an intelligent choice. The standard is objective: would the reasonable person be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy?

In *Cobbs v. Grant* the Court asked whether the doctor's duty to disclose and his discretion to withhold information are governed by medical practice or imposed by law? They are imposed by law. The patient is medically ignorant and is entitled to determine

³ [1932] O.R. 141 (C.A.).

⁴ See, e.g., Glass, *Restructuring Informed Consent* (1970) 79 Yale L.J. 1533.

⁵ 464 F. 2d 772 (D.C. Cir. 1972).

⁶ 502 P. 2d 1 (Cal. *in banco* 1972).

⁷ *Supra*, note 5, 781.

⁸ *Ibid.*, 784.

whether to submit to treatment. His consent must be informed and he depends on the doctor to inform him. Thus the doctor has "a duty of reasonable disclosure of the available choices with respect to the proposed therapy and of the dangers inherently and potentially involved in each [The] evaluation and decision is a non-medical judgment reserved to the patient alone."⁹ But what degree of disclosure is required? Full disclosure is too broad. The doctor need not give a lengthy polysyllabic discourse on all possible complications nor need he discuss "the relatively minor risks inherent in common procedures, when it is common knowledge that such risks inherent in the procedure are of very low incidence."¹⁰ For example, the doctor may be obliged to inquire as to allergies to avoid adverse reactions. Where the procedure is more complicated, the jury should be told that "[w]hen a given procedure inherently involves a known risk of death or serious bodily harm, a medical doctor has a duty to disclose to his patient the potential of death or serious harm, and to explain in lay terms the complications that might possibly occur."¹¹ Then follows this rather vague addition: "[b]eyond the foregoing minimal disclosure, a doctor must also reveal to his patient such additional information as a skilled practitioner of good standing would provide under similar circumstances."¹² The scope of the required disclosure is measured by the patient's need for whatever information is material to the decision.

These two cases and some from other states have caused a stir in the United States, both favourable and unfavourable. A recent text says that eighteen states in 1975 and 1976 enacted statutes that either defined or restricted the application of the doctrine of informed consent in reaction to the crisis in malpractice insurance. The authors add that "[m]ost of the statutes attempt, in one way or another, to make it more difficult for a patient to be successful in a suit against a physician for failure to obtain informed consent".¹³

Where do we stand on informed consent in Canada today? The answer is found in the Supreme Court's judgments in *Hopp v. Lepp*¹⁴ and *Reibl v. Hughes*,¹⁵ both decided in 1980. The first of

⁹ *Supra*, note 6, 10.

¹⁰ *Ibid.*, 11.

¹¹ *Ibid.*

¹² *Ibid.*

¹³ Annas, Glantz & Katz, *Informed Consent to Human Experimentation: The Subject's Dilemma* (1977), 38: see also Horan & Halligan, *Authority for Medical Treatment* (1980) 22 For the Defence 12, 22.

¹⁴ (1980) 112 D.L.R. (3d) 67.

¹⁵ (1980) 114 D.L.R. (3d) 1.

these cases was from Alberta. The issue was the adequacy of the defendant's answer to the plaintiff's concern about the seriousness of an operation for a slipped disc. The trial judge, Brennan J., found it adequate¹⁶ but a majority of the Court of Appeal¹⁷ held otherwise and found the defendant liable. He appealed to the Supreme Court, which restored the trial judgment. Chief Justice Laskin, speaking for the Court, reviewed the cases on informed consent. After discussing the concept of probable risks (as against the merely possible) and material risks (as against immaterial), and of special or unusual risks, the Chief Justice set out the following conclusion:

In summary, the decided cases appear to indicate that, in obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon generally should . . . , without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. However, having said that, it should be added that the scope of the duty of disclosure and whether or not it has been breached are matters which must be decided in relation to the circumstances of each particular case.¹⁸

This passage shows a move toward the proposition that the consent must be informed.

The second case, *Reibl v. Hughes*, follows this trend. The defendant operated on the plaintiff for a "plugged" artery near the brain. A serious stroke resulted. The defendant had not mentioned the risk of a stroke. Haines J. held that if the defendant had told the plaintiff of the risk (4% of dying and a further 10% of stroke) the plaintiff would have refused. Thus Haines J. gave judgment for the plaintiff.¹⁹ The Court of Appeal of Ontario ordered a new trial because the trial judge's statement of risk misunderstood the evidence. No one would put the risks to the plaintiff the way Haines J. proposed. He ignored the risks of not operating. Moreover, the plaintiff failed to show that he would not have consented had the defendant disclosed the risk.²⁰

The plaintiff appealed to the Supreme Court. Again Chief Justice Laskin wrote the judgment for a unanimous Court. He dealt at length with the causation question: should the Court use an objective or subjective test in deciding whether the plaintiff would have refused the operation had the defendant disclosed the risk? Earlier

¹⁶ (1977) 77 D.L.R. (3d) 321 (Alta S.C., T.D.).

¹⁷ (1979) 98 D.L.R. (3d) 464 (Alta S.C., App. Div.).

¹⁸ *Supra*, note 14, 81.

¹⁹ (1977) 16 O.R. (2d) 306 (H.C.).

²⁰ (1978) 21 O.R. (2d) 14 (C.A.).

cases in the provincial courts had been divided on this issue. The Chief Justice held the objective test to be preferable and added “[i]n saying that the test is based on the decision that a reasonable person in the patient’s position would have made, I should make it clear that the patient’s particular concerns must also be reasonably based; otherwise there would be more subjectivity than would be warranted under an objective test”.²¹

The Chief Justice reviewed the evidence at length and the findings in the courts below. He concluded that the defendant, in merely advising the plaintiff that he would do better to have the operation than not to have it, did not give an adequate disclosure of the risks. The Chief Justice then asked what the reasonable person would have done if the risks had been properly disclosed? He took into consideration that the plaintiff was only a year and a half from his pension, that there was no apparent “neurological deficit”, no immediate emergency and yet there was a grave risk of stroke from the operation, whereas the risk of stroke without the operation was in the future. Another factor was that the defendant had not made clear to the plaintiff the fact that the operation would not cure his headaches, whereas the plaintiff thought it would. In conclusion the Chief Justice said that in his opinion “a reasonable person in the plaintiff’s position would, on a balance of probabilities, have opted against the surgery rather than undergoing it at the particular time”.²² Thus the Supreme Court restored the trial judgment.

Doubtless these two cases will produce a spate of comment. One can scarcely object to the proposition that the patient should receive enough information to make his own decision. It would be unfortunate, however, if the physician’s obligation, as now established, were to force him into a wooden and mechanical recitation of all risks as a defence to the possibility of a complaint that he has failed in his duty of disclosure. I am sure the Chief Justice intended to confine the obligation of disclosure of risks to those that are serious. However, even seriousness is relative. Risks that might be regarded as serious in a cosmetic operation would not necessarily be serious in an open-heart operation. Where the proposed procedure is elective, as it was in *Reibl*, then there should be an obligation to describe the alternatives to the operation and the comparative risks. Where, however, an operation is from a medical standpoint not only desirable but urgent, it seems to me that the doctor

²¹ *Supra*, note 15, 17.

²² *Ibid.*, 35.

should not have to go into details of the risks of the operation and then go on to describe the possibilities of serious harm or death that would occur if nothing were done.

I shall now make four short comments on the state of the law in the light of these two decisions. First, we have had cases holding that in the absence of informed consent the plaintiff's action lay either in battery or negligence or both.²³ Fortunately, *Reibl* has not only put an end to the confusion but has placed the action on its proper basis. Disclosure is part of the duty of care and its breach is actionable negligence. Battery "should be confined to cases where surgery or treatment has been performed or given to which there has been no consent at all or where, emergency situations aside, surgery or treatment has been performed or given beyond that to which there was consent".²⁴ Later in his judgment Laskin C.J.C. said that "unless there has been misrepresentation or fraud to secure consent to the treatment, a failure to disclose the attendant risks, however serious, should go to negligence rather than to battery".²⁵ What of the case where the surgeon, through a misunderstanding, removes thirteen teeth instead of two,²⁶ or operates on the spine instead of the foot?²⁷ In these cases the judgments point to the possibility of an action in either battery or negligence. It may be that Chief Justice Laskin would classify these cases as battery, though one can argue that the action is in negligence. There is no question, of course, where the patient says, of a proposed anaesthetic, "Don't touch my left arm." The touching is clearly a battery.²⁸ Likewise an unauthorized biopsy for purposes of research is a battery.²⁹

²³ In *Halushka v. University of Saskatchewan* (1965) 53 D.L.R. (2d) 436, the Saskatchewan Court of Appeal upheld a jury's findings of both battery and negligence with a single award. In *Zimmer v. Ringrose* (1978) 89 D.L.R. (3d) 646 (Alta S.C., T.D.), the Court awarded \$5,000 for negligence and \$1 for battery: the Court of Appeal, in a judgment of 13 February 1981 ([1981] 4 W.W.R. 75), reversed the finding of battery and upheld the judgment in negligence. In *Lepp v. Hopp* (*supra*, note 17), the Ontario Court of Appeal gave an award of \$15,000 in both battery and negligence. In *Reibl v. Hughes* (*supra*, note 19), the trial judge found the defendant liable in both and gave a single award of \$225,000.

²⁴ *Supra*, note 15, 10.

²⁵ *Ibid.*, 11.

²⁶ *Parmley v. Yule* [1945] S.C.R. 635.

²⁷ *Schweizer v. Central Hospital* (1974) 6 O.R. (2d) 606 (H.C.).

²⁸ *Allan v. New Mount Sinai Hospital* (1980) 109 D.L.R. (3d) 634 (Ont. H.C.).

²⁹ In *Cryderman v. Ringrose* (1978) 89 D.L.R. (3d) 32 (Alta S.C., App. Div.) this question arose but the Court did not have to decide it. The defendant was liable in negligence for other non-disclosures.

Secondly, both cases confirm that in instances of a nervous or apprehensive patient the surgeon has some latitude in deciding how much information of risks to give. *Reibl* also mentions the possibility of a patient waiving his right to an explanation of risks.

Thirdly, the Chief Justice makes a strong case for the objective test in determining causation. Although some judgments and some writers³⁰ have argued that it is unfair to plaintiffs, I do not object to it as a general rule. One situation, however, is troubling. It is that of the patient who asks a direct question: for example, "if I have the operation for migraine headaches, what are the risks?" Let us assume that the answer is "none", when in fact loss of the sense of smell is a known risk.³¹ Then let us take an even more pointed question: "if I have the eye operation will I have double vision?" Again let us assume a negative answer, although the known risk is in fact substantial.³² In these cases the patient has shown to the doctor his direct concern. It seems to me that, especially in the second case, a court has a strong indication that whatever the reasonable person would have decided, the plaintiff would have decided against the operation.

Fourthly, there is a point that the Supreme Court did not have to consider. It is this. Let us assume a finding that the patient would not have consented had the risk been disclosed. In order to succeed, must he show that the risk that materialized was the one that should have been disclosed? *Canterbury v. Spence* says yes: *Halushka v. University of Saskatchewan*³³ says no. Doubtless one could write an essay on the application of *Palsgraf*³⁴ and *Wagon Mound No. 1*³⁵ to this question. I merely offer the suggestion that on modern tort principles much is to be said for the position taken in *Canterbury*.³⁶

³⁰ See, e.g., Bamberg, *Informed Consent after Cobbs — Has the Patient been Forgotten?* (1973) 10 San Diego L. Rev. 913, 924-6; Annas, Glantz & Katz, *supra*, note 13, 30-1.

³¹ *Koehler v. Cook* (1975) 65 D.L.R. (3d) 766 (B.C.S.C.).

³² *Calder v. Gilmour* [1978] 3 A.C.W.S. 57 (Sask.).

³³ *Supra*, note 23.

³⁴ *Palsgraf v. Long Island Ry* 162 N.E. 99 (N.Y. 1928).

³⁵ *Overseas Tankship (U.K.) Ltd v. Morts Dock & Engineering Ltd (The Wagon Mound No. 1)* [1961] A.C. 338 (P.C.).

³⁶ The uncertainty as to the law on consent to medical treatment has produced endless commentary in the United States. In Canada there is an excellent study paper in the Law Reform Commission of Canada's "Protection of Life" series, *Consent to Medical Care*, written by Professor Margaret Somerville and published in 1979: unfortunately, she was unable to consider the Supreme Court's judgments in *Lepp* or *Reibl*. Among recent

A. *Minors*

A mature minor can give his own consent just as an adult can. There seems to have been a contrary rule in the United States but never in England or Canada. Indeed, Professor Somerville has pointed out that Coke said "an infant may bind himself for his . . . necessary physic".³⁷ *Johnston v. Wellesley Hospital*³⁸ did much to remove widespread, though unwarranted, doubts. Even with the reduced age of majority there is room for the mature minor who can give his own consent. The problem is that as the age decreases uncertainty as to capacity increases. For this reason there should be legislation.

England has put the age at sixteen.³⁹ It is fourteen in Quebec.⁴⁰ In British Columbia, it is sixteen, but the physician must first try to get the parents' consent.⁴¹ The Uniform Medical Consent of Minors Act⁴² also fixes the age at sixteen with the important addition that where the minor is under that age he may give his consent if two doctors are of the opinion that the minor understands the procedure and that the treatment is in his best interests.

In Alberta, the Institute of Law Research and Reform in December, 1975 made a report⁴³ recommending the age of sixteen, but with a special provision whereby the patient could consent to treatment in connection with communicable diseases, drug or alcohol abuse, prevention of pregnancy, and termination of pregnancy. The Alberta Legislature has not yet passed a statute on the subject. My prediction is that the government will bring in a bill before long that is either based on the Institute's report or on the Uniform Act. In Saskatchewan the Law Reform Commission has re-

Canadian writings, see also Picard, "The Tempest of Informed Consent" in Klar, *Studies in Canadian Tort Law* (1977), ch. 4; Castel, *The Nature and Effects of Consent . . . in the Medical Field: Criminal and Private Law Aspects* (1978) 16 Alta L. Rev. 293; Sharpe, *Informed Consent* (1979); Jazvac, *Informed Consent: Risk Disclosure and the Canadian Approach* (1978) 36 U. of T. Fac. L. Rev. 191; Scaletta, *Informed Consent and Medical Malpractice: Where Do We Go from Here?* (1980) 10 Man. L.J. 289.

³⁷ Co. Littleton 1722, cited in Somerville, *supra*, note 36, 73: see also Dickens, *Contractual Aspects of Human Medical Experimentation* (1975) 25 U.T.L.J. 406, 414.

³⁸ [1971] 2 O.R. 103 (H.C.).

³⁹ *The Family Law Reform Act, 1969*, 1969, c. 46, s. 8.

⁴⁰ *Loi sur la protection de la santé publique*, L.R.Q., c. P-35, s. 42.

⁴¹ *Infants Act*, R.S.B.C. 1979, c. 196, s. 16.

⁴² Uniform Law Conference, 1975 Proc. 30 and 162; Consolidation of Uniform Acts, 31-1.

⁴³ *Consent of Minors to Medical Care* (1975).

commended a different type of scheme.⁴⁴ A minor who has capacity to consent may do so. The court has power to declare whether a minor has that capacity and power to dispense with parental consent where the law requires it. It is hard to say whether the Legislature will act on the recommendation.

Where the plaintiff is too young to give his own consent the common law always recognized the parents' right to give it. Indeed at common law the parent has a duty to look after the child's medical care. Modern child-welfare laws provide that parental neglect or refusal to give medical care is a form of negligence.⁴⁵ Problems arise where the parent refuses on religious grounds to permit a certain medical procedure, such as the transfusion of blood. In Alberta there is specific provision that as soon as a child is apprehended the authority who apprehended him may authorize medical care without parental consent.⁴⁶

One provision in the English Act is hard to interpret. It says: "Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section has not been enacted." Does this preserve the mature minor rule for persons under sixteen, or does it permit parental consent for them, or does it refer to emergencies? The Uniform Act and the Alberta recommendations both omit that provision. In my opinion, this is wise. I see no need to preserve the mature minor rule when the general age of consent has been brought down to sixteen and where, in addition, there are provisions permitting consent by the minor himself in specific cases even where he is under sixteen.

The only province that has enacted the Uniform Act to date is New Brunswick.⁴⁷ In that province, the definition of "medical treatment" omits "any procedure undertaken for the purpose of preventing pregnancy."

A final comment that I should like to make before leaving this topic has to do with the controversy as to whether minors should be able to arrange for themselves contraceptive measures and, in the case of girls, abortion. There has been a tendency to refrain from meeting this problem directly. The Alberta Report⁴⁸ is an exception. This is the most emotion-laden issue in the whole area of medical

⁴⁴ *Proposals for a Consent of Minors to Health Care Act* (1980).

⁴⁵ See, e.g., *Loi sur la protection de la jeunesse*, L.R.Q., c. P-34, and, in Ontario, *The Child Welfare Act*, S.O. 1978, c. 85, s. 19 (ix).

⁴⁶ *The Child Welfare Act*, R.S.A. 1970, c. 45 (as am.), ss. 16(2) and 17.

⁴⁷ *Medical Consent of Minors Act*, S.N.B. 1976, c. M-6.1.

⁴⁸ *Supra*, note 43.

consent. In the United States the Supreme Court has held unconstitutional blanket requirements for parental consent to abortion,⁴⁹ and at present there is a case before that Court challenging a state law requiring mere notice to the parents.⁵⁰ The Court has struck down a state law prohibiting the sale of contraceptives to minors.⁵¹ I do not care to see these questions resolved as constitutional issues. Nor do I contemplate with any satisfaction the fact that in some cases the minor refuses to take the parents into his or her confidence, or indeed the sexual permissiveness which makes the problem acute. However, when the minor wishes to exclude the parents from participation in the decision, he or she should have the capacity to decide for himself or herself.

B. *Mental incompetents*

It is customary to distinguish between the mentally retarded or defective (Blackstone's idiot) and the mentally incompetent (Blackstone's lunatic).⁵² They will be treated together here. Neither is necessarily incapable of giving consent, for the retardation may be mild, and the mental incompetent may have lucid intervals. As a general rule, however, someone else must authorize medical treatment for persons in both categories.

In connection with mentally incompetent adults, the *Criminal Code* imposes a duty on everyone to provide necessities for a mentally ill person under his charge.⁵³ In Alberta, *The Mental Health Act* provides that the Board in charge of a facility for such patients "is under a duty to provide such diagnostic and treatment services as the patient is in need of and that the staff of the facility are capable and able to provide".⁵⁴ *The Dependent Adults Act* in Alberta permits the court to appoint a plenary guardian or a partial guardian.⁵⁵ In the case of a plenary guardian, section 9 says that the guardianship order confers on the plenary guardian power "to consent to any health care that is in the best interests of the dependent adult". In the case of an order appointing a partial guardian, section 10 enables the court to include the power I have just quoted. Section

⁴⁹ *Planned Parenthood of Central Missouri v. Danforth, Attorney General of Missouri* 428 U.S. 52 (1976); *Bellotti v. Baird (No. 2)* 443 U.S. 622 (1979).

⁵⁰ *H.L. v. Matheson*, from Utah: see 48 U.S.L.W. 2482.

⁵¹ *Carey, Governor of New York v. Population Services International* 431 U.S. 678 (1977).

⁵² 1 Bl. Comm. 303, 304.

⁵³ R.S.C. 1970, c. C-34, s. 197(1)(c).

⁵⁴ S.A. 1972, c. 118, s. 24(1).

⁵⁵ S.A. 1976, c. 63.

1 defines "health care" to include "any procedure undertaken for the purpose of preventing pregnancy". (The other parts of the definition are obvious.) The question arises whether the guardian can consent to sexual sterilization of the dependent. I shall deal with this later under "Sterilization".

II. Consent to research on humans

Research on humans is doing something to a human being for the purpose of gaining knowledge. The term "experimentation" can be given the same definition, but the difficulty is that it is often used to describe innovative therapy. That is to say the purpose is both to gain knowledge and to help the patient. Every medical procedure was innovative at one time. Until thalidomide and the Kefauver hearings⁵⁶ in the United States that led to the amendments to the *Food, Drug and Cosmetic Act*⁵⁷ in 1962, it was commonplace for drug companies simply to ask physicians to try out a new drug on their patients. It is now recognized that this is not the proper way to determine the safety and efficacy of the drug. There must be systematic research in which the new drug is compared to an accepted drug or to a placebo (inert substance), or both. To make the conclusions scientifically sound this is usually done, at least in the early stages, on a double-blind basis. Neither the patient nor the person administering the drug knows which substance the patient receives. This procedure is obviously research, not therapy.

When ethical codes or statutes speak of experimentation they may mean experimentation that excludes therapy or they may mean experimentation that includes an element of therapy. For example, the Helsinki Declaration⁵⁸ gives guidelines for medical research combined with professional care and other guidelines for non-therapeutic research. However, some recent ethical codes define experimentation or research to include experimental therapy as long as the experimental element is important. Thus the Medical Research Council of Canada has said that the distinction between therapeutic and non-therapeutic research should be abandoned: both should come under the heading of research.⁵⁹ Later the National Commission for the Protection of Human Subjects of Bio-medical

⁵⁶ See Mintz, *The Therapeutic Nightmare* (1965).

⁵⁷ 21 U.S.C.A. § 355. See Talalay, *Drugs in Our Society* (1964); Landau, *Regulating New Drugs* (1973).

⁵⁸ World Medical Association, *Declaration of Helsinki* (1964), revised at Tokyo, 1975.

⁵⁹ *Ethics of Human Experimentation* (1977), 6-7.

and Behavioral Research in the United States pointed out that the distinction between research and therapy is blurred because both often occur together. Its report takes the position that radically new procedures should be treated as research because formal research today provides the best method of determining whether the new procedure is safe and effective.⁶⁰

In *Zimmer v. Ringrose* the defendant used a silver nitrate treatment to bring about sterility. The plaintiff was not rendered sterile and subsequently became pregnant and had an abortion. The trial judge accepted testimony of an expert that the defendant's procedure was experimental and should have been handled through a clinical trial — that is, treated as research. On appeal the Court of Appeal did not agree with this finding.⁶¹

Even if there are two accepted procedures but complete disagreement as to which is better, a study to settle the question must be done on a systematic basis as research. In the case of breast cancer there may be utter uncertainty as to whether a radical or simple mastectomy is better in the removal of a tumor of a given size. Is it proper for those trying to find the answer simply to alternate the surgery without telling each patient that the actual operation she received was the result of drawing lots? The answer is no.⁶² Today there are studies to compare partial as against complete mastectomies. The fact that the operation is being performed on a randomized basis is clearly explained in the consent forms that have come to my attention.

The basis of all modern statutes and ethical codes is the Nuremberg Rules or the Helsinki Declaration (revised at Tokyo in 1975).⁶³ They require informed consent. Nuremberg says the consent must be that of the subject, whereas Helsinki permits the substituted consent of the guardian of an incompetent or the parent of a minor.

An example of an effort to ensure that the consent of the subject is informed is the United States *Food, Drug and Cosmetic Act*⁶⁴ and the Regulations made thereunder.⁶⁵ Where the purpose is

⁶⁰ *The Belmont Report* (1978), 2-4.

⁶¹ *Supra*, note 23. Compare the duty of disclosure as laid down by the Court of Appeal with that prescribed in *Cryderman v. Ringrose, supra*, note 29. The Court of Appeal upheld the judgment in negligence because of negligent after-care. It also found negligence in the failure to disclose risks but found an absence of causation.

⁶² See Fried, *Medical Experimentation* (1974), esp. ch. 3.

⁶³ *Supra*, note 58.

⁶⁴ 21 U.S.C.A. § 355.

⁶⁵ § 130.37, Federal Register, June 20, 1967, p. 8753.

solely research, the consent of the subject himself must be obtained. If there is a therapeutic element the consent of his representative must be obtained if the subject cannot consent. The definition of consent is as follows:

“Consent” means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of pertinent information concerning the investigational drug, and/or his possible use as a control, as to enable him to make a decision on his willingness to receive said investigational drug. This latter element means that before the acceptance of an affirmative decision by such person the investigator should carefully consider and make known to him (taking into consideration such person’s well-being and his ability to understand) the nature, expected duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; the hazards involved; the existence of alternative forms of therapy, if any; and the beneficial effects upon his health or person that may possibly come from the administration of the investigational drug.⁶⁶

Quite apart from the *Food, Drug and Cosmetic Act*, the American Department of Health and Human Services (HHS, replacing HEW) has guidelines governing institutions that receive HHS assistance. They must give to HHS an undertaking or assurance, as it is called, to follow these guidelines. They require that a research committee (called an Institutional Review Board or IRB) must pass on all protocols (research proposals). The definition of informed consent is as follows:

- (c) “Informed consent” means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:
- (1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
 - (2) A description of any attendant discomforts and risks reasonably to be expected;
 - (3) A description of any benefits reasonably to be expected;
 - (4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
 - (5) An offer to answer any inquiries concerning the procedures; and
 - (6) An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.⁶⁷

⁶⁶ *Ibid.*, at 8754.

⁶⁷ 45 C.F.R. § 46.107 (1975).

It will be seen that this definition has much in common with the definition of consent under the *Food, Drug and Cosmetic Act*. An additional requirement was recently made whereby the institution must tell the subject whether it provides compensation in case of injury.⁶⁸

For some time in the United States there has been intensive re-examination of the ethical requirements for research on humans. In July, 1974 an Act of Congress established the National Commission for Protection of Human Subjects of Bio-Medical and Behavioral Research. The Committee worked for four years and produced reports on ethical guidelines for research (Belmont Report), psychosurgery, research on institutionalized mentally infirm, research on the fetus, research involving children, IRB's, and on ethical guidelines for delivery of health care by the federal government. Since these reports came out, Congress has considered a number of bills, and HHS has made a number of proposals for new regulations. They are still in a state of flux. The latest I have is a set of proposed regulations by HHS. The requirements for informed consent include the present ones and several more.⁶⁹

In Canada there is nothing comparable to the HHS guidelines but some research institutions in fact follow them. Of course we have reached the stage where these institutions, including universities, have not only framed their own guidelines but have established a research committee or IRB to pass on proposals for research and to scrutinize the forms of consent to be used. Under Canada's *Food and Drugs Act*⁷⁰ there are regulations designed to prevent the sale of new drugs until the manufacturer has filed a submission with the Minister, but the manufacturer may sell new drugs to qualified investigators on complying with the requirements in the regulations. These regulations are far less exacting than those in the United States under the *Food, Drug and Cosmetic Act*.⁷¹

Apart from the Canadian statute just mentioned, the only legislation of which I am aware on the subject of research on humans is

⁶⁸ Federal Register, Nov. 3, 1978; see Levine, *Advice on Compensation* (1979) 1 I.R.B. 5.

⁶⁹ § 46.112 Federal Register, August 14, 1979, p. 47696.

⁷⁰ R.S.C. 1970, c. F-27.

⁷¹ Food & Drugs Regs., Division 8; Consol. Regs. 1978, c. 869 at 6293-6301. In *R. v. Kripps Pharmacy* [1980] 6 W.W.R. 579 the accused was charged with selling a new drug without having filed a submission. A County Court judge in British Columbia held the regulation invalid not merely as unauthorized by the Act but as unconstitutional. One might hope the case goes further.

Article 20 of Quebec's Civil Code. It permits a person of full age to consent in writing to submit to an experiment provided the risk assumed is not disproportionate to the benefit anticipated.⁷²

In the great expansion of research on humans since World War II, there have been remarkable advances, but at the same time there have been instances of imposition on subjects, including research without consent. An English doctor wrote a book alleging improper research on patients.⁷³ In the United States research has sometimes attracted wide criticism; for example, the Tuskegee study on blacks inflicted with syphilis⁷⁴ and the Willowbrook study in which defective institutionalized children were given hepatitis with a view to finding a way to control it in the institution.⁷⁵ Dr Beecher, in his "bombshell" article in 1966, condemned many studies he regarded as unethical.⁷⁶ In the New York cancer-cell case the proceedings were disciplinary.⁷⁷ There has been very little civil litigation. Indeed, so far as I know, *Halushka v. University of Saskatchewan*⁷⁸ is the only case. The plaintiff volunteered to take part in the study of a new anaesthetic but was not told that there was risk involved or that the catheter placed in his arm would go to the heart. He suffered cardiac arrest. In upholding the jury's verdict for the plaintiff, the Court of Appeal said that "[t]he duty imposed on those engaged in medical research. . . to those who offer themselves as subjects for experimentation . . . is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient",⁷⁹ and "[t]he subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent".⁸⁰

The particular problem in the case of experimentation is that all the risks cannot be known. Generally, previous tests on animals have helped to eliminate a substantial amount of risk, but the researcher cannot know that the risks of which he is aware are the only ones. Another basic problem that arises both in therapy

⁷² See Bowker, *Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code* (1973) 19 McGill L.J. 161.

⁷³ Pappworth, *Human Guinea Pigs* (1967).

⁷⁴ See Annas, Glantz & Katz, *supra*, note 13, 59-61.

⁷⁵ *Ibid.*, 79-81.

⁷⁶ Beecher, *Ethics and Clinical Research* (1966) 274 New England J. Med. 1354.

⁷⁷ See Katz, *Experimentation with Human Beings* (1972), Pt 1, ch. 1.

⁷⁸ *Supra*, note 23.

⁷⁹ *Ibid.*

⁸⁰ *Ibid.*

and in research, but which is particularly acute in the latter, is this. Even if the consent form is completely candid and as lucid as possible, there is no guarantee that the subject who gives consent really does so with knowledge and free will. There can be subtle pressures on him both from the outside and because of his position (e.g., as a prisoner). In addition, by reason of sickness, lack of intellect, or inability to speak English, he may not truly give an informed consent. It is for this reason that many people urge that the institution or its IRB should "monitor" the taking of consents.⁸¹

Should there be legislation in each province on the subject of informed consent to research on humans? One should not denigrate the attempts in the United States food and drug law, and in the various state laws,⁸² and in Quebec's Article 20. I am not sure, however, that, for the present, legislation is as useful as ethical guidelines and IRB's. In addition, it is helpful to remember Dr Beecher's observation:

One must never minimize the importance of striving for truly informed consent, but the patient's greater safeguard in experimentation, as in therapy, is the skilful, informed, intelligent, honest, responsible, compassionate physician.⁸³

A. *Research on children*

While the "mature minor" rule of the common law or a statute specifying the age at which an older minor may give his own consent to medical treatment is sensible, it is arguable that this should not apply where the procedure is research. None of the common law provinces has legislated as yet and there is no case law. In Quebec, Article 20, to which I have referred, says:

A minor, capable of discernment, may [submit to an experiment] with the consent of the person having the paternal authority and of a judge of the superior court, provided that no serious risk to his health results therefrom.

A minor capable of discernment is the mature minor. He may agree to take part but only if there is no serious risk and with the further safeguard of parental and judicial consent.

In the common law provinces, what is the situation where the minor is not mature but is a child? Can the parent or guardian

⁸¹ See Gray, *Human Subjects in Medical Experimentation* (1975), 243-56.

⁸² The most significant state laws are those of New York and California. See King, *Health Policy — Ensuring Informed Consent in Human Experimentation: A Comparison of the Approaches of Two States* (1979) 58 N. Carolina L. Rev. 137.

⁸³ *Research and the Individual* (1970), 25.

properly give consent to the child's participation in research on the same basis, as though he were volunteering himself? Some people think that the substituted consent or permission of the parent or guardian is adequate. I do not agree that the child should be exposed to risk on this basis. Opinion is, of course, sharply divided. If advances are to be made in paediatrics then research must be done on children. I do not think, however, that they should be exposed to risks for the ultimate benefit of others. The child should not be exposed to experimentation that carries anything more than minimal risk. Minimal is, of course, hard to define⁸⁴ but it is more protective of the child than is the usual risk/benefit formula. There may be rare cases where slightly greater risks are justified. The testing of Salk vaccine might be an example. I am not sure that the nationwide tests in the United States caused merely minimal risk to the children who were first given the vaccine and yet it turned out to be a boon.

The National Commission, in the United States, has made ten recommendations respecting research on children. They support research on children with the approval of an IRB and prescribed safeguards. The research should not involve more than minimal risk and the permission of the child and the parent should be given. Where the risk is more than minimal but the research may benefit the child himself it may be done if the IRB approves. It may also be done where the risk is more than minimal if the research may in future benefit children with the same disease. (This recommendation was not unanimous.) In other cases where there is a serious problem in children's health the research may be done subject to approval at the national level. There are special protections for children who are wards of the state or in institutions.⁸⁵

The MRC report agrees that research must be done on children and incompetents. It proposes consent by parent or guardian and, if that consent is given, a further consent by an ombudsman or advocate of the child or incompetent. The majority would balance risk and benefit just as is done where the subject is a competent adult. Professor Crépeau refused to expose the minor or incompetent to risk for the benefit of others. The guardian is in a fiduciary position and has no right to expose his ward to the risks of an

⁸⁴ The National Commission's *Report on Research Involving Children* (1978) defines minimal risk as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical or psychological examination, of healthy children" (p. xx).

⁸⁵ *Ibid.*, 1-20.

experiment of no direct benefit to himself. I agree with Professor Crépeau.⁸⁶

B. *Research on the mentally infirm*

This category of person is analogous to the child. It is quite possible that in the past drugs have been given and operations (e.g., pre-frontal lobotomy) have been performed in circumstances that would not meet the ethical requirements of today. In an American case, *Wyatt v. Stickney*,⁸⁷ a class action was brought on behalf of patients in Alabama's two mental hospitals to compel them to improve their facilities and treatment so as to bring them up to constitutional standards. The Court ordered that this be done and laid down the minimum standards. These show a humane concern for the welfare of patients. Two of the standards are relevant here. The first says that the patient has a right not to be subjected to experimental research without his informed consent or that of his guardian and after approval by the institution's IRB and in compliance with HHS's rules, which I have set out earlier. The second says that "patients have a right not to be subjected to treatment procedures such as lobotomy, electro-convulsive treatment, aversive reinforcement conditioning or other unusual or hazardous treatment procedures without their express and informed consent after consultation with counsel or interested party of the patient's choice". In a companion case⁸⁸ the Court made a similar order in connection with institutions for the mentally retarded.

The recommendations of the National Commission in its Report on Research Involving Those Institutionalized Infirm⁸⁹ are much like those for children though there is provision for research being done over the patient's objection if a court so authorizes.

In Canada I know of no statute dealing with research on mental patients. If research is performed and harm befalls them, then the person doing the research should be legally responsible. Such a case is unlikely to arise but I know of no common law principle which permits the guardian or anyone else to expose a mental patient to risk that does not come within the concept of health care. When *The Dependent Adults Act* was introduced in the Alberta Legislature in 1975, the Honourable Helen Hunley, the Minister sponsoring the

⁸⁶ *Supra*, note 59, 30-1.

⁸⁷ (1972) 344 F. Supp. 373 (D.C. Ala 1972).

⁸⁸ *Ibid.*, 387, *aff'd sub nom. Wyatt v. Aderholt* 503 F. 2d 1305 (5th Cir. 1974).

⁸⁹ (1978), 1-22.

bill, in referring to the guardian's power to authorize medical treatment, said this:

Note that the medical treatment must be in the best interests of the dependent adult as an individual, not the best interests of society. This is not a provision to give effect to consents to experimental surgery or involuntary sterilization.⁹⁰

III. *Inter vivos* transplants

It is helpful to remember that some human tissue is non-regenerative. The principal organ of this type in demand for transplants is the kidney. The gift is not fatal to the donor because he has a remaining kidney. Other tissues are regenerative. The main ones for transplant purposes are blood, bone marrow and skin, although skin grafts from one person to another are not usually successful.

Since transplants are modern, there is little authority as to one's right to make a donation. In the case of a competent adult, the only possible argument against it is that it is a maiming. This is simply not the case where the tissue is generative. There may be a stronger argument in the case of a kidney, but even there the donor is not like the man who cuts off his toes to escape military service, and it is farfetched to suggest that there is anything unlawful in the self-sacrifice of the donor of a kidney. There is of course the real possibility that the donor consents under pressure or without knowing the consequences of his sacrifice.

In Canada there is a Uniform Human Tissue Gift Act⁹¹ which is in effect in seven provinces and the Northwest Territories. Part 1 provides for *inter vivos* gifts of tissue. It is limited however to non-regenerative tissue, which for practical purposes means the kidney. The donor must be of the age of majority and "able to make a free and informed decision". The inference is that his consent must be an informed consent. In my view Part 1 makes no change whatever in the common law in the case of a competent adult, though doubtless physicians like to have legislation that spells out the right to remove a kidney.

Since the Act does not apply to regenerative tissue, the common law must still apply. In other words, such gifts by competent adults are permissible. I have no doubt that any court would require

⁹⁰ Discussion paper, undated, released 8 July 1975. The passage quoted is at p. 16.

⁹¹ See Sugiyama, *Inter Vivos Transplantation and the Human Tissue Gift Act* (1976) 34 U. of T. Fac. L. Rev. 124; Clements, *The Human Tissue Gift Act* (1979) 3 Legal Med. Q. 39.

informed consent. As to the mature minor, I know of no authority on the subject. It will be recalled, however, that a mature minor can agree to run the risks of another person's negligence.⁹² By analogy one can argue he should be able to consent to run risks of a gift of tissue in the interest of another's life or health. When the age of majority was twenty-one the Canadian Red Cross accepted donations of blood from eighteen-year-old donors.⁹³ In the United States, on the other hand, where the view that no minor can consent even to medical treatment was at one time widely held, the first marrow and kidney transplants were approved not only by the parents but by a court.⁹⁴ One cannot state with confidence the position as to these transplants under the Canadian common law. It is possible that the courts would recognize the capacity to make the donations but would be exacting in the requirement of informed consent. In Quebec, Article 20 permits a minor "capable of discernment" to make a gift of tissue on the authority of both parent and court, and no distinction is made between generative and non-generative tissue.

The Uniform Human Tissue Gift Act does not deal with regenerative tissue, and forbids gifts by minors of non-regenerative tissue. Should it be amended to permit gifts by mature minors? At one time the present writer was opposed but is now of the view that with consent of the parents and approval by a court, a provincial board and adequate representation of the mature minor, such legislation can be justified. One can debate whether the provision should apply to a mature minor (who is like the minor in Quebec of the age of discernment) or whether it should be fixed at a given age. The writer prefers the latter, and would keep the age at sixteen. There is, of course, room for difference of opinion on this issue.

The excellent report of the Australian Law Reform Commission on Human Tissue Transplants is instructive. The basic recommendation is that the donor be an adult of sound mind. However, in the case of minors, there is a recommendation that the transplant may

⁹² *Miller v. Decker* [1959] S.C.R. 624; *Kubbernus v. Frost* (1978) 10 A.R. 445 (S.C., T.D.). In these cases minor passengers were held to be *volens* in relation to their driver's negligence.

⁹³ The writer ascertained this from officials of the Red Cross at Edmonton in 1963; see Bowker, *Legal Liability to Volunteers in Testing New Drugs* (1963) 88 Can. Med. Assn J. 745, 748, n. 33.

⁹⁴ See Baron, Botsford & Cole, *Live Organ and Tissue Transplants from Minor Donors in Massachusetts* (1975) 55 Boston U.L. Rev. 159; Katz, *supra*, note 77, 964-72.

be carried out where the tissue is regenerative, and the minor is of sound mind and agrees to the donation, and a parent consents and an independent doctor has discussed the proposed removal with the minor. In the case of non-regenerative tissue, the majority (four of six) thought it should be lawful when the donor is old enough to consent and the parents agree and the recipient is a member of the family, and a special committee of three has approved. One of the two dissenters was Sir Zelman Cowen, now Governor-General of Australia. He would simply have prohibited the removal of non-regenerative tissue from a minor.⁹⁵ Division 3 of the draft Ordinance included in the report embodies the majority's recommendation.

In the Capital Territory, a Transplantation and Anatomy Ordinance embodying the draft Ordinance has been passed with only minor changes. Queensland and the Northern Territory each passed an Act on the lines of the draft Ordinance, but omitting Division 3.⁹⁶

In the United States under the common law it is now generally agreed that the parents cannot give a valid consent to the donation of a kidney by their minor child. The consent of the court is required. In the first case, from Boston in 1957, donor and recipient were nineteen-year-old identical twins. The judge found that the healthy twin understood the proposed operation and had consented. Then he accepted psychiatric evidence that the brother's death would have a grave emotional impact on the healthy twin. He held that the operation was necessary for the healthy twin's continued health and well-being and that the operation would confer benefit on him as well as upon the recipient. In the case of fourteen-year-old twins the same reasoning was applied.⁹⁷ Professor Curran's observation was that the "benefit" was more the prevention of possible detriment.⁹⁸

In the Connecticut case of *Hart v. Brown*⁹⁹ the children were identical twins just under eight years of age. In authorizing the transplant, the Court relied more on the right of the parents to make a substituted judgment than on the theory of psychological

⁹⁵ The Law Reform Commission of Australia, *Report No. 7* (1977), 50-1 (para. 112).

⁹⁶ Letters from Mr Justice M. D. Kirby, Chairman of the Australian Law Reform Commission, to the writer, dated respectively 25 March 1980 and 30 June 1980.

⁹⁷ Katz, *supra*, note 77, 971 sets out the judgment.

⁹⁸ Curran, *A Problem of Consent: Kidney Transplantation in Minors* (1959) 34 N.Y.U. L. Rev. 891; see also Sharpe, *The Minor Transplant Donor* (1975) 7 Ottawa L. Rev. 84, 96-9.

⁹⁹ 289 A. 2d 386 (Super. Ct 1972).

benefit. However the Court accepted the opinion that the donor would enjoy a better future life if her ailing sister were kept alive and found "some benefit" for the donor.

In the last case, *Little v. Little*¹⁰⁰ from Texas, Anne was a fourteen-year-old girl with Down's syndrome. Her younger brother was threatened with death from kidney failure. On the mother's application the Court authorized the transplant. It did so not on the basis of the "substituted judgment" doctrine,¹⁰¹ but in view of the psychological benefits that Anne would receive in the preservation of her brother's life and satisfaction in making the donation.

We have been speaking of the minor as a transplant donor. The position of the mentally incompetent adult is analogous. In the United States the leading case is *Strunk v. Strunk*.¹⁰² Jerry was twenty-seven years old with the mental age of six. His brother Tommy required a kidney in order to survive. The only donor in the family who was suitable from a medical standpoint was Jerry. The evidence was that he was greatly attached to Tommy and that Tommy's visits were important to Jerry as therapy, so that there was justification for authorizing the transplant. A majority accepted this evidence. One should not overlook the forceful dissent. In two subsequent cases, *Re Richardson*¹⁰³ and *Re Pescinsky*¹⁰⁴ the Court refused the order. In the first case, from Louisiana, the Court found that the transplant would not be in the best interest of the proposed donor. In the second case, from Wisconsin, the Court held that it had no jurisdiction to make the order.

As a matter of policy, should there be legislation authorizing the guardian or the court to give permission to the donation of tissue by a person who is incompetent either because of age or mental incapacity? Often the argument is advanced that this is a matter for the parent or guardian and that the courts and legislature should not intervene.¹⁰⁵ This assumes that the parent or guardian

¹⁰⁰ 576 S.W. 2d 493 (Civ. App. 1979).

¹⁰¹ For a strong argument in favour of the substituted-judgment doctrine, see Robertson, *Organ Donations by Incompetents and the Substituted Judgment Doctrine* (1976) 76 Colum. L. Rev. 48.

¹⁰² 445 S.W. 2d 145 (Ky 1969).

¹⁰³ 284 So. 2d 185 (Ct App. La 1973), 284 So. 2d 338 (La 1973).

¹⁰⁴ 226 N.W. 2d 180 (Wis. 1975).

¹⁰⁵ See, e.g., Goldstein, *Medical Care for the Child at Risk; on State Supervention of Parental Autonomy* (1977) 86 Yale L.J. 645. At 668-70 the author criticizes *Hart v. Brown*, not for the result, but because the Court was not endowed with the capacity to determine what risks to take for someone else's child.

will always act in the best interests of the child. This assumption may often be true but certainly not universally. That is why we have child-welfare statutes. The strongest case for authorization of the transplant by a court or other tribunal is in the case of identical twins. From the parents' standpoint one can understand their wish to have the donation made. However, the doctrine of the substituted judgment is questionable and the argument that the donation is in the best interests of the child is hard to accept. The Ontario Bill mentioned earlier¹⁰⁶ (s. 17(3)) permits the representative of a child or mental incompetent to consent to a donation of tissue, both regenerative and non-regenerative, but the approval of a Health Procedures Protection Committee is required. I cannot find in the Bill any criteria to guide the Committee.¹⁰⁷ The idea of a Committee to check abuses is commendable, but particularly in the case of a proposed kidney transplant, one might think that if it is to be permitted at all when the donor has not capacity to give his own consent, it should be restricted to a donation between brother and sister. Indeed I am not persuaded it should be done even in that case.

IV. Sexual sterilization

Where the person is an adult of sound mind, there is nothing in the *Criminal Code* or elsewhere to prevent him or her from undergoing this procedure.¹⁰⁸ The *dictum* of Lord Denning in *Bravery v. Bravery*¹⁰⁹ seems to have misled some people. He said that it is illegal even when the person agrees to it. This is simply wrong. However, the operation is, for practical purposes, irreversible, and certainly the physician is obliged to explain this to the patient.

The problem arises in connection with minors and mental incompetents, and particularly with the retarded, whether minor or

¹⁰⁶ *The Child Welfare Act*, S.O. 1978, c. 85.

¹⁰⁷ The nearest relative of one not mentally competent to consent to a health care service may authorize that service (s. 8(2)); and he must act in good faith having regard to the best interests of the proposed recipient (s. 12); and health care service means a service provided by a person under *The Health Disciplines Act*. The question remains: is the removal of a kidney a health care service for the donor?

¹⁰⁸ See Kouri, *The Legality of Purely Contraceptive Sterilization* (1976) 7 R.D.U.S. 1; Dickens, *Eugenic Recognition in Canadian Law* (1975) 13 Osgoode Hall L.J. 547, 556-62; Wilson, *Voluntary Sterilization: Legal and Ethical Aspects* (1979) 3 Legal Med. Q. 13; Kouri, *Non-therapeutic Sterilization* (1979) 57 Can. Bar Rev. 89, 92-4.

¹⁰⁹ [1954] 3 All E.R. 59, 67-8 (C.A.).

adult. The early statutes in the United States authorizing sterilization, sometimes without consent, were principally concerned with eugenics. In Alberta *The Sexual Sterilization Act* was along these lines. Enacted in 1928,¹¹⁰ it was repealed in 1972.¹¹¹ As the Act stood just before repeal, a statutory board could authorize sterilization of patients with psychosis, mental retardation, syphilis, epilepsy and Huntington's chorea. The grounds for sterilization were the risk of transmission of disease to offspring and the risk of mental injury to progeny or to the patient. Consent of the patient was required, except in the case of psychosis, where substituted consent of the parent or guardian was permitted, and in the case of mental defectives, where no consent was needed.

The Act attracted criticism on both genetic and procedural grounds. Two geneticists made strident attacks on the Act.¹¹² The motion to repeal¹¹³ shows that the Government relied on them heavily. In moving repeal, Mr King had three grounds — medical, legal and moral. As to the first, the Act was genetically unsound and the Eugenics Board had not the expertise nor the information to make sound decisions. Secondly, the Act was ambiguous and had other flaws (here Mr King relied on Professor McWhirter's opinion that those involved in the procedure were guilty of a crime under the *Criminal Code*). Thirdly, the Act violated the fundamental human right to procreate by permitting the government to order the sterilization of certain people without consent. "It is our view that this is a reprehensible and intolerable philosophy and program for this province and this government", said Mr King. He did not seem troubled about substituted consent, for he said sterilization could still be carried out with parental consent.

Since repeal, sterilization of minors has been performed under Alberta's health insurance plan. In the period 1976-1978 inclusive, a total of seventy-eight hysterectomies were performed, eleven other sterilizations on girls and eight on boys. The reasons given are retardation and birth defects. As best I can gather, the hysterectomies were related to inability of the females to attend to personal hygiene.

In Ontario, which has never had a Sterilization Act, there were in 1976 three hundred and eight sterilizations of minors — fifty of

¹¹⁰ S.A. 1928, c. 37.

¹¹¹ S.A. 1972, c. 87. The only other province ever to have a *Sexual Sterilization Act* was British Columbia: enacted by S.B.C. 1933, c. 59 it was repealed by S.B.C. 1973, c. 79.

¹¹² McWhirter & Weijer, *The Alberta Sterilization Act, a Genetic Critique* (1969) 19 U.T.L.J. 424.

¹¹³ Alberta Hansard (31 May 1972), 58-33 to 58-41.

boys and the rest of girls, of which one hundred and nine were hysterectomies.¹¹⁴

As to adult mental defectives in Alberta, I do not know the position. When *The Dependent Adults Act* was introduced, the responsible Minister stated it was not the intention to cover sterilization. The definition of health care includes contraception but, quite apart from the Minister's disclaimer, it would be odd to find that a legislature which repealed *The Sexual Sterilization Act* out of solicitude for the fundamental right to procreate had by a side-wind conferred on the guardian of a dependent adult the power to authorize sterilization in the name of contraception.

Turning now to the common law, can a parent give valid consent to the sterilization of a minor child? Here one must note the common distinction between therapeutic and non-therapeutic sterilization. If an organ is diseased and the operation is a by-product of the removal of the organ, it is obviously therapeutic. Sterilization for genetic purposes, that is to prevent the birth of a defective child, is not considered therapeutic, though one could argue that the birth of such a child might affect the mother's health. Sterilization for simple contraceptive purposes is also non-therapeutic whatever be the motive.

There may be cases where it is hard to classify the sterilization. Frequently a hysterectomy is performed on retarded girls because of inability to attend to personal hygiene. The Ontario Association for the Mental Retarded classifies this as non-therapeutic,¹¹⁵ whereas at least some physicians tend to regard it as therapeutic.¹¹⁶

In many cases the parents seek sterilization of a minor daughter because she is more or less retarded and they fear pregnancy. In England Heilbron J. in *Re D*¹¹⁷ held this to be non-therapeutic and made the child a ward to prevent the sterilization. The trend of decisions in the United States is the same in the case of the minor and also of the defective adult.¹¹⁸

¹¹⁴ Cited in Law Reform Commission of Canada, *Sterilization* (1979), 155, from Zarfas, *Sterilization of the Mentally Retarded* (a speech given to the Ontario Psychiatric Association, 5 October 1978).

¹¹⁵ *Ibid.*, 96-7.

¹¹⁶ This is my understanding from conversations with gynaecologists and pediatricians, and is at least implied by the Ontario Medical Association guideline (c) for the sterilization of mentally retarded persons, set out in the Working Paper, *ibid.*, 102-3.

¹¹⁷ [1976] Fam. 185, [1976] 1 All E.R. 326.

¹¹⁸ See Holder, *Legal Issues in Pediatrics and Adolescent Medicine* (1977), 274-80.

In the latter category there is in Canada an important case now in the courts. It is *Re Eve* from Prince Edward Island. The mother applied to be made a committee of her daughter and for authorization to consent to a tubal ligation. Mr Justice McQuaid concluded that he had no authority to exercise the role of *parens patriae*, much as he sympathized with the mother's worry over the danger of pregnancy.¹¹⁹ In appeal, this judgment was reversed by a divided Court.¹²⁰ Mr Justice Campbell held that the court by reason of its *parens patriae* jurisdiction could authorize non-therapeutic sterilization of a mentally retarded person. He then held that the sterilization would be in Eve's best interest and that her committee should be able to exercise a "substituted right" to choose sterilization. The operation would not cause Eve substantial injury. Finally, Campbell J. held that the decision as to the type of operation, tubal ligation or hysterectomy, should be left to the committee.

Mr Justice Large agreed with the order proposed by Campbell J. After a lengthy review of the evidence, he distinguished the English case of *Re D* on the facts. His conclusion was that the procedure is a medical one. Just as the court could authorize a blood transfusion for a child in the face of parental objection, so it can order the sterilization. It is for her protection.

Mr Justice MacDonald dissented. He held that the proposed operation was not for Eve's benefit, welfare or protection, but rather a deprivation of a basic human right. He said the Court had jurisdiction in exceptional cases to authorize non-therapeutic sterilization but that this was not one of them. He listed fourteen factors that should be considered. After quoting at length from a working paper published by the Law Reform Commission of Canada¹²¹ he concluded that on the facts before the Court the operation was not for Eve's benefit. He expressed a fear that the precedent set in authorizing her sterilization would mean authorization of sterilizations for mere convenience, and that the Court's power might be abused.

One point to note about this case is that the mother did not attempt to have the sterilization performed without judicial authorization, which, as mentioned above, has in recent years been commonplace in the case of defective minors in Ontario and Alberta. In *Re Eve* the courts are at least trying to articulate the principle

¹¹⁹ Reported *sub nom. Re E.* (1979) 10 R.F.L. (2d) 317 (P.E.I.S.C.).

¹²⁰ (1980, 1981) 115 D.L.R. (3d) 283 (P.E.I.S.C. *in banco*), now in appeal before the Supreme Court of Canada.

¹²¹ *Supra*, note 114.

on which the authorization should be granted. In my opinion this should be provided by legislation. The Law Reform Commission's working paper has a number of useful suggestions. The trend today is to provide for sterilization of minor defectives on the basis of the best interest of the patient, or, in the language of the New Zealand statute,¹²² for the good of the patient. This may include reasons that would not be within the phrase "therapeutic sterilization". The difficult problem is to decide whether to leave the statute there or whether to spell out criteria. The latter is preferable but there is always the danger of making them too wide. Any Sterilization Act, in addition to specifying the grounds for the sterilization, should provide a careful set of safeguards to ensure that the patient's interest will be protected by the court or other tribunal that is making the decision.

Conclusion

In all of the procedures — medical care, experimentation, transplants and sterilization — there is need for special solicitude for those who cannot consent for themselves. Their "best interests" are of some help. The National Commission had three basic ethical principles for research on humans — respect for persons, beneficence and justice.¹²³ Professor Charles Fried says that in medical care and research the patient has a right to lucidity, autonomy, fidelity and humanity.¹²⁴ Dr Paul Ramsey speaks frequently of the "canon of loyalty" which a parent owes to his child, the doctor to his patient, and the investigator to his subject.¹²⁵ Although the application of these various principles is not always self-evident — indeed one of them may compete with others — their general acceptance will help to ensure against the overreaching of those who cannot consent for themselves.

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¹²² *Contraception, Sterilization and Abortion Act, 1977*, (set out in *Sterilization, supra*, note 114, 149; and the relevant section is s. 10).

¹²³ See *The Belmont Report, supra*, note 60, 4-10.

¹²⁴ Fried, *Medical Experimentation, supra*, note 62, 101-4.

¹²⁵ See *Patient as Person (1970)*, *passim*.

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