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Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code

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INTRODUCTION

Experimentation on humans has taken place for centuries. In the last fifty years, however, and particularly since World War II, it has expanded so that today it is almost a special discipline. It was a necessary prelude to the introduction into general use of many valuable drugs and medical procedures that we now take for granted.

A gift by a living person of a part of his body is likewise far from new, but again new developments have made these gifts an important part of today's medicine. One need only mention blood transfusions and kidney transplants.

So it is with the use of organs and tissues from cadavers. The grafting of corneas of eyes taken from cadavers onto the eyes of living persons to restore sight has been followed by the transplantation of hearts and doubtless other parts of the body will be successfully used before long.

These three developments raise legal as well as ethical questions. Thus it is that the new articles 20-23 of the Civil Code are of general interest, for they deal with all three — experiments, *inter vivos* transplants and transplants from cadavers. The purpose of this article is to examine them in turn and to make some comparisons with legal developments in common law jurisdictions.

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Genesis of Articles 20-23

The new articles have been enacted as part of a general revision of the Civil Code that has been under way for several years — the first comprehensive review since 1866.[1] To assist in the revision a Code Revision Office was established and given the responsibility for making recommendations to the Legislature. One of the Office's several committees is on Civil Rights and Duties. The Chairman of the Committee is Professor Paul-André Crépeau, who is also Chairman of the Revision Office. The other Committee members are Mr Justice Albert Mayrand and Mr Normand Lepine. In July, 1971 the Committee prepared a report entitled "Report on the Recognition of Certain Rights Concerning the Human Body". This report recommended five articles to provide for:

(1) the right of a living adult to make a gift but not a sale, of part of his body or to submit himself to experiments;
(2) his right to give instructions about his funeral and the disposal of his remains;
(3) the right of his family to give these instructions where he has not given them;
(4) the right of a physician in urgent cases to remove part of a cadaver to save human life; and
(5) prohibition of autopsies unless authorized by law or with consent.

These recommendations were circulated for comment, and in October, 1971 the Revision Office submitted to the Legislature its own report. It followed the Committee's report with one important change. The first proposal, which dealt with experiments and *inter vivos* gifts, was extended to a minor who is "endowed with discernment", provided his parents consent and there is no serious risk to the minor.

A Bill to embody the proposed articles was promptly introduced and on 1 December, 1971 was passed. The recommended provisions became articles 20 to 23, replacing articles that had dealt with British subjects, aliens and naturalized persons.[2] The new articles con-

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[1] Crépeau, *Centenaire du Code Civil du Québec*, (1966) 44 Can. Bar Rev. 389; Baudouin, *Le Code Civil Québecois: Crise de Croissance ou Crise de Vieillesse*, (1966) 44 Can. Bar Rev. 391.

[2] S.Q. 1971, c.84. This statute includes also new articles 18 and 19, which the Code Revision Office recommended along with articles 20-23. Article 18 confers legal personality on every person and article 19 says:

> The human person is inviolable. No one may cause harm to the person of another without his consent or without being authorized by law to do so.

tain some changes both in content and form from the recommendations of the Code Revision Office. I shall note them at the appropriate place.

Experiments and 'Inter Vivos' Gifts

The recommendation dealing with human experiments and *inter vivos* gifts of human tissue became article 20. As enacted it contains one provision that goes contrary to the recommendation of both the Committee and the Revision Office: article 20 permits the sale, as well as the gift, of a part of the body that is "susceptible of regeneration".

Article 20 provides:

> A person of full age may consent in writing to disposal *inter vivos* of a part of his body or submit to an experiment provided that the risk assumed is not disproportionate to the benefit anticipated.
>
> A minor, capable of discernment, may do likewise 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.
>
> The alienation must be gratuitous unless its object is a part of the body susceptible of regeneration.
>
> The consent must be in writing; it may be revoked in the same way.

In considering this article, it will be convenient first to deal with experimentation and then with *inter vivos* gifts.

HUMAN EXPERIMENTATION [3]

So far as the writer knows there is no statute in any common law province, or in Britain, or for that matter in the United States (apart

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[3] Of the huge volume of literature since World War II the following texts are both recent and most helpful:

Katz, *Experimentation with Human Beings* (1971).

Freund (ed.), *Experimentation with Human Subjects* (1970), being a revision of *Daedalus*, Spring, 1969, "Ethical Aspects of Experimentation with Human Subjects".

Annals of the New York Academy of Sciences, "New Dimensions in Legal and Ethical Concepts for Human Research" (1970).

Beecher, *Research and the Individual: Human Studies* (1970).

Pappworth, *Human Guinea Pigs* (1967).

The foregoing are all American except Pappworth, which is English. I know of no Canadian text.

Two articles are:

Waddams, *Medical Experiments on Human Subjects,* (1967) 25 U. of T. Faculty Law Rev. 25.

Bowker, *Legal Liability to Volunteers in Testing New Drugs,* (1963) 88 C.M.A.J. 745.

from the *Food, Drug and Cosmetic Act*[4]) that deals with experimentation on humans.

Meaning of Experiment

What does "experiment" mean? It is necessary here to distinguish between experimental therapy on the one hand and scientific experiment (or research study or clinical study or clinical research) on the other. Experimental therapy is a new procedure in the prevention, diagnosis or treatment of disease. It may of course provide important information as well and thus have an aspect of research. However, its immediate purpose is the good of the patient.

Scientific experiment on humans can be defined as something done to the person with the principal purpose of finding out what will happen to the person. Its primary object is the acquisition of new knowledge rather than therapy, and the fact that ultimately it may prove to be beneficial to others or even to the subject does not render it therapy. There may be a sham operation to help determine whether the real operation is of benefit.[5] Moreover, experiments are sometimes performed on healthy persons, and so could not possibly be called therapeutic. Illnesses have been induced, including malaria, typhoid fever and hepatitis. Other procedures have been carried out on healthy persons — for example, the insertion of a cardiac catheter.

The testing of new drugs furnishes another good example of the distinction between the two types of experiment. At one time the drug maker asked practicing physicians to try out the new drug on their patients. Remembering that a new drug is one that has not yet been shown to be safe and effective, this practice is neither good therapy nor good scientific experiment. It is generally agreed today that scientific testing of new drugs should take place before they are put on the market for therapeutic use. It is further agreed that some patients should receive the new drug and others should be used as "controls". The controls may receive either an accepted drug, or a "dummy" drug called a placebo, or no drug at all. This procedure leads to a better assessment of the qualities and effect of the new drug.

A common though not a universal method is to conduct "double-blind" tests. For example, of one hundred patients, fifty may receive the new drug and fifty may receive a placebo. To ensure accuracy in observation of the results, neither the investigator who is conduc-

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[4] 21 U.S.C.A. (1972), s.355(i), 471-72.

[5] Beecher, *Surgery as Placebo*, (1961) 176 J.A.M.A. 1102, quoted in Katz, *supra*, 686-7.

ting the test nor the patient knows whether the patient is receiving the new drug or the placebo. After the drug has been administered and observations taken, someone, preferably a neutral person, ascertains who has received the new drug and who has received the placebo. This procedure leads to a comparatively accurate assessment of the new drug.[6]

It is sometimes said that a test making use of a placebo is therapeutic, even if double-blind. The writer has difficulty with this view. It is true that placebos can sometimes have a good psychological effect. However, in a double-blind test not even the physician administering the capsule knows whether it is the placebo or the unproven drug. In these circumstances the procedure would seem to be research rather than therapy. One might say that the borderline between the two appears to be hazy. Sometimes it is. However, the distinction must be recognized, for it is of practical importance, as we shall see.

When an American war crimes tribunal tried twenty Nazi physicians and three others for crimes against humanity in connection with "experiments" on prisoners in concentration camps, the tribunal in its judgment at Nuremberg laid down ten legal rules that, in its opinion, govern scientific experimentation. We shall have occasion to refer to some of these Nuremberg rules later.[7]

In 1964 the World Health Organization, after lengthy study, published the Helsinki Declaration which prescribes *ethical* as distinct from legal guidelines for human experimentation. This document recognizes the distinction between the two types of experiment. It sets out basic general principles and then in separate sections discusses "clinical research combined with professional care", followed by "non-therapeutic clinical research".[8] The ethical principles of the American Medical Association follow this pattern, distinguishing between clinical investigation primarily for treatment

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[6] There may be cases where administration of a drug to patients for the first time and without the use of controls is unquestionably proper. The first patients to whom insulin was given would have died and they were eager to receive the drug: see *Reminiscences on the Discovery of Insulin*, (1962) 87 C.M.A.J. 1045. In the testing of Salk vaccine on hundreds of thousands of children throughout the United States, a difference of opinion arose on whether double-blind tests were necessary. In the result, some were double-blind and in the others, the controls were children who received nothing: see Carter, *Breakthrough: The Saga of Jonas Salk* (1966), ch. 10.

[7] They are set out in Beecher, *supra*, 227 and in Waddams, *supra*, 52. For an account of the trials, see Mitscherlich and Mielke, *The Death Doctors* (1962); and Katz, *supra*, 293-306.

[8] Beecher, *supra*, 277; Waddams, *supra*, 53.

and clinical investigation primarily for the accumulation of scientific knowledge.[9] The guidelines of the Faculty of Medicine at McGill University do likewise.[10]

The purpose of the above discussion was to emphasize the distinction between the two types of experiment. It is relevant now to look at experimental therapy and to ask what the liability of a physician to his patient is when the patient is harmed because the doctor in the hope of benefiting the patient has used an experimental procedure — one that is new or at least not generally accepted. In the common law there is no automatic liability; in other words there is not a "no-experiment" rule. In the United States on the other hand there was such a rule for a long time but it has been eroded. The argument in favour of it is that it discourages reckless experimentation. The argument against it is that it deters progress. A middle ground is to permit it in the sense of not rendering the physician automatically liable if something goes wrong, but to require a high degree of care and also disclosure to the patient of the fact that the treatment is new and risky. The latter requirement is related to the concept of "informed consent" which we shall consider later. In my opinion this "middle ground" represents the common law position.[11]

Turning to article 20, what is the meaning of "experiment" as there used? It reads: "a person ... may ... submit to an experiment provided that the risk assumed is not disproportionate to the benefit anticipated". The Committee report states that the draft article contains a general principle "applicable to those kinds of operations performed on a person's living body which are outside of the normal context of the doctor-patient relationship". The Code Office Revision Report repeats these words and adds that the article "envisages essentially the cases where a person consents to submit to an incursion upon his physical integrity without himself directly benefiting from what may result"; and both reports say in slightly different words that since such infringements are highly exceptional they may only be permitted to take place if certain special conditions are met. Thus "experiment" in article 20 would seem to refer to scientific or non-therapeutic experiments.

The article permits a person to submit to experiments provided that the "risk assumed is not disproportionate to the hoped for bene-

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[9] Beecher, *supra*, 222.

[10] Notes for the Guidance of Faculty Members doing Clinical Research, 10 Feb. 1967.

[11] See Bowker, *supra*, 745-46; Katz, *supra*, 526-29.

fit". It seems clear that the appraisal of risk and benefit must be determined at the time rather than subsequently. The language raises the question of what is meant by "benefit". Since in the writer's opinion, the article applies to scientific experimentation, it follows that "benefit" means future benefit to persons other than the one submitting to the experiment.

The problem of weighing benefit against risk is inherently difficult. The anticipated benefit may be great, or it may be slight; the likelihood of achieving the benefit may be high, or it may be remote. On the other hand the risk may be great or it may be slight.

The weighing of risk versus benefit is of course an understandable approach to take, and it is found in various ethical codes. For example, the Helsinki Declaration states that "clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject". Dr H. K. Beecher in his own Code argues that:

> ... the gain anticipated from an experiment must be commensurate with the risk involved. Sometimes large risks are to be taken for large gains, but such risks should be taken in almost all cases only when the patient promises to profit directly from the risk involved in needed therapy.[12]

In view of the difficulty in weighing risk against benefit, I would suggest, with some diffidence, that it might have been preferable had article 20 merely said "provided there is no serious risk to his health". In extending article 20 to minors capable of discernment, the Legislature abandoned a risk-benefit criterion and simply permitted the minor to consent "provided that no serious risk to his health results therefrom".

Informed Consent

Article 20 provides that a person may *submit* to an experiment. It does not use the word "consent" as it does in connection with *inter vivos* gifts of a part of the body. I infer, however, that the intent is to require a consent of the same type that is necessary in connection with *inter vivos* gifts. This being so, the question then arises of the amount of information that must be given to the volunteer concerning the nature of the experiment and the attendant risks. It is commonly said that there must be an *informed* consent, which I take to be similar to "le consentement librement donné" or "la volonté librement exprimée"[13] or "le consentement éclairé".[14] This

[12] Beecher, *supra*, 290.

[13] Baudouin, *La personne humaine au centre du droit québecois*, (1966) 26 R. du B. 66, 67-68.

[14] Mazeaud, *Les contrats sur le corps humain*, (1956) 16 R. du B. 157, 167.

concept probably has produced more discussion than any other topic in connection with human experimentation, and indeed is much to the fore in connection with therapeutic treatment.[15]

When a physician advises his patient about a proposed treatment, must he disclose the risks, so that if he fails so to do, the consent will be ineffective and the patient can say that the physician acted without consent? The physician or surgeon must explain the risks to enable the patient to exercise an intelligent judgment on whether to elect to proceed. In Canada the few cases dealing with this subject allow the physician a wide scope in exercising his judgment, bearing in mind the desirability of not upsetting the patient. The two leading cases are from the Ontario Court of Appeal. In *Kenny* v. *Lockwood* [16] it was argued that the surgeon had not explained the risk of stiffness resulting from an operation on the hand. A prominent surgeon, Dr Gallie, testifying as an expert witness, said that if he outlined every risk, including remote ones, some of which were rather frightening, the patients would decline the operation and would damage themselves by waiting to see what would happen without the operation. The court held that the defendants were not liable for failure to disclose the risks. In the second case, *Male* v. *Hopmans*,[17] the patient was treated with neomycin although it was known that this drug could affect the hearing. The patient did in fact become deaf. One of his allegations of negligence was that the defendant had failed to disclose this risk. The alternative treatments were very complicated and the court held that the defendant was under no duty to explain them. It was said that the patient probably could not have grasped the explanation or made an intelligent choice.

In an English case, *Hatcher* v. *Black*, [18] the operation was for a toxic goitre. There was in fact a risk to the voice, and the surgeon admitted that he had told the patient that there was no risk. In summing up to the jury, Denning, L.J. (as he then was) directed the jury that the little white lie was justifiable. This decision is not consistent with the view of the New Zealand Court of Appeal in *Smith* v. *Auckland Hospital Board*.[19] In that case the patient specifically

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[15] Katz, *supra*, devotes the whole of Part 3 to the authority of the subject as guardian of his own fate, 523-724. This Part consists of three chapters of material on informed consent.

[16] [1932] 1 D.L.R. 507 (Ont. C.A.).

[17] (1966), 54 D.L.R. (2d) 592, and on appeal (1967), 64 D.L.R. (2d) 105, 113. The defendant was held liable on another ground.

[18] *The Times*, July 2 1954; quoted in Nathan, *Medical Negligence* (1957), 54.

[19] [1965] N.Z.L.R. 191, rev'g [1964] N.Z.L.R. 241.

asked the surgeon whether there was any risk in a diagnostic procedure called aortography. The surgeon replied that there was none. In fact there was a known risk of loss of circulation which could cause gangrene in a leg and require amputation. This risk materialized. The court found a breach of duty. The difficulty was whether the untruthful answer caused the loss of the leg, for one can only conjecture whether the patient would have rejected the procedure had he been told the truth. The court held that there was evidence on which the jury could find a causal connection between the answer and the loss of the leg.

There has been a difference of opinion on whether, assuming an absence of informed consent, the patient's action is based on negligence or assault. In the *Smith* case the claim was based on negligence. It is submitted that this is the proper basis, though some courts take the view that an uninformed consent is no consent, with the result that the operation is an assault.[20] In the United States the concept of informed consent "has achieved a status in the law of medical practice unmatched both in speed of growth and bulk of commentary".[21] A leading case, *Natanson* v. *Kline*,[22] is consistent with the cases just discussed, though in the United States there may be a greater readiness to find that consent is not informed. At least some members of the medical profession are concerned about the difficulty in achieving informed consent. They feel obliged to show the patient a document that tries to explain the procedure with clarity and the risks with candor; the consequence may be that the patient is confused or frightened or both.[23]

Whatever the duty to explain risks in connection with medical treatment, there is no doubt that in scientific experimentation the duty is very high; and if the disclosure is not made the consent is not an informed consent and therefore is ineffective. The first rule of the Nuremberg Code states that "the voluntary consent of the human subject is absolutely essential". It adds that he must have legal capacity to consent and the power of free choice to enable him to make

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[20] Plante, *An Analysis of "Informed Consent"*, (1967-68) 36 Fordham L. Rev. 639.

[21] Waltz and Scheuneman, *Informed Consent to Therapy*, (1969-70) 64 N.W. L.Rev. 628.

[22] 350 P. 2d 1093 (1960) (Kan. S.C.).

[23] Cf. Oppenheim, *Informed Consent to Medical Treatment*, (1962) 11 Clev.-Mar. L.R. 249, 261-4; and Irwin, "Now Mrs. Blare, About the Complications" in Katz, *supra*, 393. On the other hand, cf. Glass, *Restructuring Informed Consent*, (1970) 79 Yale L.J. 533 says that the law on informed consent should be reshaped to give more consideration to the patient's viewpoint.

an understanding and enlightened decision. The nature and purpose of the experiment should be made known; and the means of conducting it, and "all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come". The Helsinki Declaration provides that:

> Clinical research [which, at least for practical purposes, can be taken as synonymous with scientific experimentation] cannot be undertaken without his free consent, after he has been fully informed.

The definition of "consent" in the Regulations under the United States *Food, Drug and Cosmetic Act,* in connection with the testing of new drugs, requires the most complete disclosure.[24]

There are two important cases in connection with informed consent to scientific experimentation. The first is *Halushka* v. *The University of Saskatchewan* [25] and the other is the disciplinary proceeding in the New York cancer-cell case.[26] In *Halushka,* the investigators advertised for volunteers to take part in a study of a new anaesthetic. The fee was fifty dollars. Halushka was a university student who volunteered. The procedure called for the insertion of a catheter in an arm and on to the heart, and the giving of the general anaesthetic that was being tested. While Halushka was under the anaesthetic, he suffered a cardiac arrest. He was revived but the harm to his health was considerable. He had signed a consent form in which he said: "I understand fully what is proposed to be done." At the trial he testified that he had "skimmed through" the form and had asked what "accidents" meant, and was told it meant such things as falling down at home after the test.

It was agreed that the experiment had been well conducted. Moreover it was assumed that the anaesthetic, not the catheter, had caused the arrest. The doctors did not testify at the trial. The jury found that the plaintiff had not consented to the performance of the test that was made; that the doctors "committed a trespass" and were negligent. Of three particulars of negligence one was "lack of full explanation to the plaintiff of the test at the time of the so-called 'consent' ". The defendants appealed, the main issue being the validity of the consent. The Court of Appeal held that in research

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[24] F.R. (1967) 8753 in Katz, *supra,* 573-4.

[25] (1965), 53 D.L.R. (2d) 436 (Sask. C.A.).

[26] The Jewish Chronic Disease Hospital Case, *Disciplinary Proceedings,* reported in Katz, *supra,* ch. 1. Proceedings by a director of the hospital against the hospital to compel disclosure of its records in connection with the experiment are reported in *Hyman* v. *Jewish Chronic Disease Hospital,* 248 N.Y.S. 2d 245, on appeal 21 App. Div. 2d 495, 251 N.Y.S. 2d 818 (1964), final appeal N.Y. 2d 317, 206 N.E. 2d 338 (1965).

the duty of explanation is at least as great as, if not greater than, that owed by a physician to his patient.

> The example of risks being properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The 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.[27]

One of the investigators had told Halushka that a new drug was to be tested but did not inform him that the new drug was an anaesthetic of which he had no previous knowledge, nor that there was risk involved in the use of the anaesthetic. Neither did he tell him that the catheter would be advanced to and through his heart. Halushka said he was given to understand that it would be merely inserted in the vein in his arm.

> While it may be correct to say that the advancement of the catheter to the heart was not in itself dangerous and did not cause or contribute to the cause of the cardiac arrest, it was a circumstance which, if known, might very well have prompted the respondent to withhold his consent.[28]

It will be noted that in this case the basis of the judgment was that of trespass, or assault, though the jury found negligence as well.

In the New York cancer-cell case,[29] a physician distinguished in cancer research was carrying out a proper and important investigation to determine how quickly the human body rejects implanted cancer cells. The experiment had been carried out on a group of healthy persons (inmates in a prison) who rejected the cells quickly, and then on persons with advanced cancer who rejected them slowly. It then was proper to try to determine whether the slower rejection in the cancer patients was because of their cancer or merely because they were seriously ill. A New York hospital for the chronically ill agreed to provide patients for this purpose. Cells were implanted in a number of patients. They were not told that this was being done. There was no informed consent, and in some cases real consent was impossible because of the patient's state of health or the language barrier. Disciplinary proceedings were brought, on charges of fraud and unprofessional conduct. After extensive hearings the New York Board of Regents upheld its committees' findings that the charges were established. One basis was failure to obtain proper informed consent.

Few would deny that the investigator should be candid. In the cancer-cell case he justified his nondisclosure by saying that he did

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[27] (1965) 53 D.L.R. (2d) 436, 444.
[28] *Ibid.*, 444-5.
[29] *Supra*, f.n. 26.

not want to disturb the patients. This is understandable in therapy, but the fact that patients would be disturbed is the very reason for forbidding the experiment in the absence of consent obtained after explanation.

There are difficulties in connection with the securing of informed consent. Known risks can be explained, but as Dr Beecher has said: "frequently the difficulty is that no one knows what the risks or the benefits really will be".[30] Then there is the question of communication. Some explanations are in technical language, and even where they are simplified, it is hard to be sure that the volunteer understands them.

Article 20 does not specifically require informed consent. However the Committee recognized that informed consent is essential:

> ... according to the general law of contract, the person of major age must be sane, free and capable of understanding the consequences of his act. The doctor or experimentalist has, moreover, the duty to inform him adequately of the effects and dangers to which the gift or experiment may give rise.

Consent by a Minor Endowed with Discernment

It will be recalled that the Committee had recommended that a person submitting to an experiment must be an adult. At that time the age of majority was still twenty-one, though the Committee doubtless knew it would soon be reduced to eighteen.[31] When the Revision Office made its own report, it had received suggestions that the age limit should be moved downward to include minors "endowed with discernment" subject to two safeguards — parental consent and absence of serious risk. This recommendation went forward to the Legislature which adopted it with a further safeguard, namely, the consent of a judge of the Superior Court. What is the age of discernment? In the common law provinces one speaks of a child of tender years, and indeed Parliament has done so in connection with the testimony of children.[32] It may be that a child beyond tender years is the same as a child endowed with discernment. Neither term is precise.

It might help to look at the common law to see when it permits a person to give his own consent to medical treatment. One recent American work states that:

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[30] Beecher, *supra*, 20. See also Bowker, *supra*, 747 for a similar statement.

[31] S.Q. 1971, c.85, ss.3 and 4, amending articles 246 and 324 of the Civil Code.

[32] *Canada Evidence Act*, R.S.C. 1970, c.E-10, s.16(1); cf. also the *Juvenile Delinquents Act*, R.S.C. 1970, c.J-3, s.19.

> The general rule is that parents or guardians must consent to treatment on minors. ... In some instances, however, a minor approaching majority may give a valid consent if he fully appreciates the nature and the consequences of his act.[33]

In the writer's opinion, the common law of England and Canada permits a minor approaching majority to give his own consent. Lord Nathan, writing in 1957 at a time when the age of majority in England was still twenty-one, said:

> It is submitted therefore that there is no rigid rule of law that an infant is incapable of consenting or to the administration of medical treatment.[34]

and later:

> It is suggested that the most satisfactory solution of the problem is to rule that an infant who is capable of appreciating fully the nature and consequences of a particular operation or a particular treatment can give an effective consent thereto, and in such cases the consent of the guardian is unnecessary...

In England the *Family Law Reform Act*, 1969, reduced the age of majority to eighteen. However, it included a special section to provide that a minor who has attained the age of sixteen years may give effective consent to medical treatment.[35]

In Canada most provinces have reduced the age of majority but none has yet passed legislation dealing with the age of consent for medical treatment. There is, however, a recent case in the Ontario High Court holding that a twenty year old could give his own consent to treatment for facial scars. This was at a time when Ontario's age of majority was still twenty-one. The court specifically accepted Lord Nathan's statement of the law.[36]

If the common law has been in some doubt on the minimum age of consent to medical treatment, it is still more uncertain in connection with the right of a minor to consent to experimentation on himself. An expression of opinion can be little more than a description of what one thinks the law should be. When the age of majority was twenty-one, the writer expressed the opinion that a mature minor might give a valid consent to submit to scientific experiment.[37] Now that it is eighteen in most provinces, the more mature minor of the past is now an adult and the question could only arise in connection with a person of seventeen years of age or younger. I shall not attempt a prediction here. The problem arises again in

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[33] Curran and Shapiro, *Law, Medicine and Forensic Science* 2d ed. (1970), 574-5.

[34] Nathan, *supra*, 174-176.

[35] 1969, 17 and 18 Eliz. II, c.46, s.8.

[36] *Johnston* v. *Wellesley Hospital* (1971), 17 D.L.R. (3d) 139 (Ont. H.C.).

[37] Bowker, *supra*, 748.

connection with the capacity of a minor to donate an organ such as a kidney, which will be discussed below.

Quebec's provision is not clear on the lower limit of consent, just as is the common law. However, Quebec has reduced the risk of abuse by the safeguards that article 20 has placed around experimentation on the minor of the age of discernment.

The Minor Below the Age of Discernment

Article 20 does not cover experiments on children below the age of discernment. The inference is that they are forbidden. Does this mean that Quebec law completely forbids scientific experiments on children? Does the child have a cause of action if he has been the subject of an experiment? Does he have to prove damage? The writer cannot even guess the answers to these questions in Quebec law. It is relevant however to look generally at the question of non-therapeutic experiments on children. Sharp differences of opinion exist on the propriety of using children for research, or at least of exposing them to risk. A strict no-experiment rule would not be realistic. As one British writer pointed out, there are experiments such as a minor change in diet or clothing that could not possibly be harmful.[38]

What of procedures that bear a risk of injury to the child? They might either be forbidden or else might be permissible with the informed consent of the parent or guardian. The legal position is uncertain and ethical opinion is far from unanimous. I shall refer first to a number of statements that say or imply that there should be no experimentation on persons who cannot give their own consent, and then to a number that treat it as permissible with the consent of parent or guardian.

In the Nuremberg judgment, the first rule flatly says that "the person involved should have legal capacity to give consent". Further, article 7 of the United Nations' International Covenant on Civil and Political Rights provides that:

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

The first sentence of course has its origin in the English Bill of Rights of 1688 and the Eighth Amendment to the United States Constitution. Although it might seem strange to link experimentation with cruel and inhuman punishment, those who framed this article doubtless had in mind the actions of the Nazi doctors. Thus

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[38] Mitchell, *The Child and Experimental Medicine*, (1964) 1 B.M.J. 721.

the article treats medical or scientific experimentation that is conducted without the subject's free consent as cruel, inhuman or degrading treatment.[39]

The British Medical Research Council in its 1963 statement on Responsibility in Investigations on Human Subjects stated:

> The situation in respect to minors and mentally subnormal or mentally disordered persons is of particular difficulty. In the strict view of the [English] law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and which may carry some risk of harm. Whilst English law does not fix any arbitrary age in this context, it may safely be assumed that the Courts will not regard a child of 12 years or under (or 14 years or under for boys in Scotland) as having the capacity to consent to any procedure which may involve him in an injury.[40]

An American writer has recently said:

> I do not myself believe that there is such a thing as legitimate third-party consent for children or other incompetents to enter without their wills into research that is not even remotely in their behalf medically.[41]

In the same vein, Warren E. Burger, now Chief Justice of the United States, has stated that "no *adult* has the legal power to consent to experiments on an infant unless the treatment is for the benefit of the *infant*".[42]

Contrariwise, the following statements approve of non-therapeutic experimentation on those who are incompetent to give their own consent including children.

The Helsinki Declaration says: "if he is legally incompetent the consent of the legal guardian should be procured". This implies that the consent will render the experiment ethically proper.

The 1966 guidelines of the American Medical Association provide in paragraph 4(c) that:

> Minors or mentally incompetent persons may be used as subjects [in non-therapeutic situations primarily for the accumulation of scientific knowledge] only if:
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> i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.
>
> ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent

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[39] Beecher, *supra*, 247 sets out amendments submitted, issues discussed and the voting on article 7.

[40] Quoted in Beecher, *supra*, 265.

[41] Ramsay, *The Ethics of a Cottage Industry in an Age of Community and Research Medicine*, (1971) 284 N.E.J.M. 700, 705-6.

[42] Burger, *Reflections on Law and Experimental Medicine*, (1968) 15 U.C.L.A. L.Rev. 436, 438.

> adult would reasonably be expected to volunteer himself or his child as a subject.[43]

An American case that has relevance to this question is *Bonner* v. *Moran*.[44] A fifteen-year old boy donated skin without obtaining his mother's consent. His action against the physician failed at trial but the Federal Court of Appeals directed a new trial because the judge had declined to direct the jury that the mother's consent was necessary. The court held that it was and that a minor could not give an effective consent to this type of procedure. The court was not prepared to make an exception for any minor, for the operation was not for his benefit. The significant point in the judgment, however, is the inference by the court that the mother's consent would prevent any recovery by her son. This is the point of principle on which I disagree.

This does not mean that experimentation on children is always unethical. As Dr Beecher states:

> Parents still have the right to decide whether their children will participate in experimentation, even if not for their direct benefit, provided the studies contemplated have no discernable risk and have been approved by a high level review committee as necessary and valuable for human progress and do not unfairly take advantage of the child.

and

> Research that entails discernable risk may not be performed on subjects too young to give mature and informed consent, unless for their direct benefit.[45]

In spite of the fact that the researcher scrupulously follows these guidelines, the child may still be injured in the course of the experiment. The position I have taken permits him to bring an action against the researcher. In other words the parents' consent and any release they give are not binding on the child. Some may object that a procedure that is ethical should never expose the researcher to legal liability, at least in the absence of negligence, and that my proposal will discourage needed research. It is suggested, however, that this position avoids the extreme of a rigid "no experiment on children" rule, and the opposite extreme of permitting a parent to bar his child from claiming damages for harm from a non-therapeutic intervention. If guidelines like Dr Beecher's are followed the risk of harm is slight; but if it materializes the loss should not fall on the child.

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[43] Quoted in Beecher, *supra*, 223.

[44] 126 F. 2d 121 (1941). The opinion of the solicitors to the Peter Bent Brigham Hospital in connection with a proposed kidney transplant from one minor twin to the other was that the dictum in *Bonner* v. *Moran* probably would not be followed in Massachusetts: see Katz, *supra*, 964-966.

[45] Beecher, *supra*, 67-68.

The problems just discussed in relation to children are similar to those which arise in connection with the mentally incompetent. Article 20 by inference excludes experimentation on adults who cannot give their own consent. On this issue the common law is no more settled than it is in the case of children. The need to conduct research and yet to show respect for the individual are just as great as in the case of children.[46]

Experimentation with "Captive Subjects" [47]

The last point to be mentioned about consent to experimentation relates to the use of persons who are adults of sound mind but who may nevertheless be thought to be under some form of constraint so that their consent is not truly voluntary. In the United States prisoners in jails are frequently used in experiments.[48] They may be subject to affirmative pressure that is explicit or, more likely, implicit. Some pressure is perhaps inherent in the status of the prisoner, no matter how much the researcher tries to secure a truly voluntary consent. The question is whether the risk of coercion can only be prevented by excluding the use of prisoners completely. A recent statement commends itself to the writer:

> I am one who happens to believe that prisoners have not been and should not be drummed out of the human race. They ought, therefore, not to be excluded in principle from the community of risk-filled human consent to good purposes, even if the needed practical protections for them are so formidable as to prohibit the general use of prisoners in medical research.[49]

Other groups of whom advantage may be taken are students, employees, and those in the armed services. I do not think one can say that they should all be automatically excluded, but it is clear that special care must be taken to avoid coercion. The reports that produced article 20 do not refer to this problem.

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[46] See Katz, *supra*, ch. 12, "Experimentation with Uncomprehending Subjects".

[47] See Katz, *supra*, ch. 13. I have borrowed his title.

[48] For a robust criticism of experiments on prisoners in United States' jails, see Mitford, "Experiments Behind Bars", *The Atlantic Monthly*, January 1973, 64. For an account of the concern of the Department of Health Education and Welfare, see Marston, *Research on Minors, Prisoners and the Mentally Ill*, (1973) 288 N.E.J.M. 158.

[49] Ramsay, *supra*, 705.

INTER VIVOS GIFTS OF TISSUE [50]

Article 20 permits a person of full age to make a gift of part of his body. As we have seen, the implication is that he must be of sound mind. There is no provision for consent by a guardian of a mental incompetent. A minor endowed with discernment may likewise make such a gift subject to the consent of his guardian and of the Superior Court, and provided that there is no serious risk.

Article 20 does not permit a person to be a donor if he is below the age of discernment. What does the common law permit? The answer is not clear. However, there have been cases in the United States of donations of a kidney by a minor or a mental incompetent. These cases show how the law is developing in that country.

The first kidney transplants were performed in a Boston hospital in 1954. The parties were adult identical twins. Two years later the same hospital had three more cases of identical twins. However, one set was nineteen years of age and the other two were fourteen. There was no special problem concerning the recipients, for the parents had power to consent to the operation as in the case of any medical treatment for a child. A serious question arose, however, about whether the hospital could rely on the parents' consent on behalf of the donor. The hospital's solicitors gave an opinion that the parent "has no power to give effective consent to an operation which is both hazardous and personally detrimental to this child".[51] In each case the parents then brought a petition in the Supreme Judicial Court of Massachusetts. The three petitions were heard by three different judges. In each case the court held that it had jurisdiction and gave an order approving the transplant. In all these cases the donor was intelligent and received a candid explanation and gave consent. The psychiatric evidence was to the effect that there would be a beneficial emotional result to the donor if he were permitted to give the kidney to his brother. The court accepted this, finding that if the operation were not performed and the sick twin were to die, there was a danger "of serious emotional impact" upon the healthy twin; that because the risk of emotional disturbance would be reduced and the donor enabled to have the continued companionship of his twin, the donor would benefit; and that the

[50] Examples of recent literature include: Wolstenholme and O'Connor (ed.), *Ethics in Medical Progress* (1966); Dworkin, *The Law Relating to Organ Transplantation in England,* (1970) 33 M.L.R. 353, 354-64; Castel, *Some Legal Aspects of Organ Transplantation in Canada,* (1968) 46 Can. Bar Rev. 345, 345-78; Kusanovich, *Medical Malpractice Liability and the Organ Transplant,* (1971) 5 U. of S.F. Law Rev. 223, 225-38.

[51] The opinion is set out in Katz, *supra,* 964-966.

operation was necessary to the donor's future welfare and happiness.[52]

It is relevant to note here the comments of Professor W.J. Curran: (1) on the facts the court might have held that each donor was capable of giving his own consent; (2) the "psychological benefit" to the donor is rather "the prevention of possible detriment than it is the conferring of a positive gain".[53]

In a 1969 case from Kentucky, *Strunk* v. *Strunk*,[54] the sick brother, Tom, was twenty-eight years old. The healthy brother, Jerry, was twenty-seven and an inmate of a state institution for the feeble-minded with the I.Q. of a six-year old. He was the only member of the family who was medically acceptable as a donor. The mother applied to the court for authority to proceed. The court gave the order "because Jerry was greatly dependent upon Tommy, emotionally and psychologically, and ... his well-being would be jeopardized more severely by the loss of his brother than by the removal of his kidney".[55] An appeal was taken on behalf of Jerry to the circuit court which upheld the original judgment, and then a further appeal was taken to the Court of Appeal. That court upheld the order by a majority of four to three. The prevailing judgment relied on the opinion of the State Department of Health that the sick brother's life was vital to Jerry's well-being and that the Department "must take all possible steps to prevent the occurrence of any ill feelings Jerry would have if Tom were to die";[56] and it held that a court of equity has inherent jurisdiction to take action to protect the mentally incompetent.

The dissenting judgment of Steinfeld,J. points up the issue. The first and last paragraphs of the dissent are as follows:

> Apparently because of my indelible recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies I have been more troubled in reaching a decision in this case than in any other. My sympathies and emotions are torn between a compassion to aid an ailing young man and a duty to fully protect unfortunate members of society.
>
> I am unwilling to hold that the gates should be open to permit the removal of an organ from an incompetent for transplant, at least until such time as it is conclusively demonstrated that it will be of significant benefit to the incompetent. The evidence here does not rise to that pinnacle. To hold

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[52] See Katz, *supra*, 967-72 for an account of one of the cases.

[53] Curran, *A Problem of Consent: Kidney Transplantations in Minors*, (1959) 34 N.Y.U. Law Rev. 891, 897-8.

[54] 445 S.W. 2d 145 (1969) (Ky. C.A.).

[55] *Ibid.*, 146.

[56] *Ibid.*, 146-7.

> that committees, guardians or courts have such awesome power even in the persuasive case before us, could establish legal precedents, the dire result of which we cannot fathom. Regretfully I must say no.[57]

The latest case is *Hart* v. *Brown*,[58] from Connecticut. Again there is an important difference in the facts. The child who required the transplant was just under eight years old and the prospective donor was her identical twin. The parents requested the operation. Without the transplant the sick twin would probably not have survived, and a transplant from the identical twin was more likely to succeed than one from anyone else. A psychiatrist testified that a successful operation would be of immense benefit to the donor "in that the donor would be better off in a family that was happy than in a family that was distressed and that it would be a very great loss to the donor if the donee were to die from her illness." The court held this evidence to be of "limited value", but did attach weight to the opinion of a clergyman that the parents' decision to consent was morally sound. The court held that the parents were entitled to substitute their consent for that of their minor children; and "to prohibit the natural parents and the guardians *ad litem* of the minor children the right to give their consent under those circumstances, where there is supervision by this court and other persons in examining their judgment, would be unjust, inequitable and injudicious".[59] The order was granted.

How would article 20 apply to the three cases we have just described? In the case of the nineteen year old twins, they would now be adults in Quebec and so the donor could decide for himself. What about the fourteen year old twins? Are they capable of discernment? In the Massachusetts judgment the court said of the donor: "He is a boy of fourteen with good understanding and intelligence. He has been fully informed of and understands the nature of the operation and its possible risks and consequences." This seems to mean that the donor was capable of discernment. Of course the judge in deciding whether to give consent would look carefully into the donor's capacity, as did the Massachusetts court. The difficulty in fixing a minimum age is shown by the difference of opinion at a discussion of kidney transplants. The opinions range from complete prohibition of donations by infants down to permitting them at the age of twelve or thirteen.[60]

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[57] *Ibid.*, 149, 151 *per* Steinfeld,J., Neikirk and Palmore,JJ., concurring, dissenting.

[58] 289 A. 2d 386 (1972).

[59] *Ibid.*, 391.

[60] Wolstenholme and O'Connor, *supra*, 203.

The question of risk of harm would also have to be considered. It appears that in the case of a healthy donor this risk is not substantial.[61]

Under article 20 the Strunk donation would not have been permitted because the donor was mentally incompetent and could not give a valid consent. The result would be the same in *Hart* v. *Brown,* because the donor was under eight years of age and by no stretch of the imagination could be said to be "capable of discernment".

Should the law permit the transplant on the facts of *Strunk* and of *Hart* v. *Brown?*

It is submitted that in general persons incapable of making up their own mind should not be subject to harmful procedures that have no therapeutic value for them. It seems somewhat specious to find therapeutic value to the donor in the psychological prevention of harm to him, as was done in the Boston cases. The situation that is most troubling is that of the eight-year old identical twins. The likelihood of saving one twin's life is great and the physical risks to the other twin are not very great. Besides the parents strongly favour the transplant. Should the law permit the donation even on these facts?

Notwithstanding the forceful judgment in *Hart* v. *Brown,* I think not. The taking of the kidney from the healthy twin means that his body has less inviolability than that of anyone else. I think that this is what Lord Kilbrandon had in mind when he asked the question:. "What is the ethical basis for a doctor respecting the prejudices of parents if he is convinced that they are inimical to the welfare of the child?", and when he commented that identical twins are two personalities.[62]

Inter Vivos Gifts under The Uniform Human Tissue Act

In the common law provinces there was until recently no legislation governing *inter vivos* gifts of human tissue. By 1970 a committee of the Medico-Legal Society of Toronto had studied this subject and prepared a draft Act. It came before the Conference of Commissioners on Uniformity of Legislation in Canada the same year. That body adopted it as Part One of a revised *Human Tissue Act.*[63] (The original *Uniform Human Tissue Act* of 1965 dealt only with gifts of cadavers which I shall discuss below.) The Uniform Act was amend-

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[61] *Ibid.,* 19-20, 209-10.
[62] *Ibid.,* 39, 203.
[63] Proc. Conf. of Comm'rs on Uniformity of Leg'n in Can. (1970), 151.

ed in 1971 and re-named the *Human Tissue Gift Act*,[64] but Part One was unchanged.[65] The essential provision is section 3(1):

> Any person who has attained the age of majority, is mentally competent to consent, and is able to make a free and informed decision may in a writing signed by him consent to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person.

This has much in common with article 20. The donor must be of age, though a later provision validates the consent of a minor where there was no reason to believe that he was not an adult capable of consent. The requirement of writing is present and it will be noted that the phrase "free and informed decision" is used.

One feature of the Act is that tissue is defined to exclude "tissue that is replaceable by natural processes of repair". This seems synonymous with "regenerative tissue" and the result is that Part One is confined to non-regenerative tissue like kidneys. This reduces the scope of Part One and raises the question whether gifts from minors of skin, bone, or blood are by inference prohibited or whether they are permitted and not circumscribed by the safeguards of Part One. Probably it is the latter for section 10 in Part Three forbids the *sale* of tissue or of any part of the body except blood. This implies that parts of the body other than tissue may be *given*.

Three provinces have passed the Revised Uniform Act.[66] It is likely that most of the others will soon enact it.

The Sale of Blood

The Quebec Committee had taken the firm position that no part of the body should be an article of commerce. "The human body cannot be made a marketable commodity or the object of commercial dealing." And again: "Nor would it be desirable to treat human blood, or any other renewable human tissue differently from other parts of the body. It is not readily obvious why, for example, blood should exceptionally be admitted as the object of a sale or a business." Then follows a quotation from Professor Savatier who said that the human body should not be given for money but can be given for love. The Code Revision Office supported this view. "The

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[64] The 1970 revised Uniform Act was recommended by the Ontario Commissioners, but when the Ontario Legislature enacted it in 1971 it made some changes, including the title. The 1971 version of the Uniform Act is virtually identical with the Ontario Act of 1971 (S.O. 1971, c.83).

[65] Proc. Conf. of Comm'rs on Uniformity of Leg'n in Can. (1971), 152.

[66] *Human Tissue Gift Act*, S.O. 1971, c.83; *Human Tissue Act*, S. Nfld 1971, no. 66; *Human Tissue Gift Act*, S.B.C. 1972, c.27.

gratuitousness of the act is essential. The human body cannot become merchandise, an object of commercial transactions."

However, the Legislature must have been persuaded that it is proper to permit the sale of regenerative tissue, for article 20 provides that "the alienation must be gratuitous unless its object is a part of the body susceptible of regeneration". This means that sale of skin or bone, as well as blood, is permitted. There is a similar provision in the *Revised Uniform Human Tissue Gift Act*, 1971.[67] Section 10 of that Act forbids the sale of any part of the body but makes an exception for blood. This is somewhat narrower than Quebec's exception, for the latter includes all regenerative tissue.

Should the sale of regenerative tissue, or even of blood alone, be permitted by law? Perhaps the issue can be stated with reference to a book by Richard Titmuss. Under the cryptic title, *The Gift Relationship*,[68] this book states in a most persuasive way the case for true donations as distinct from sale of blood. There are two main arguments. The first is that the quality of blood or blood product is better. People who come off the street to sell their blood are often derelicts who conceal their medical history and in whom the incidence of such conditions as hepatitis is higher than it is in donors who contribute gratuitously through organizations like the Canadian Red Cross. The second argument is a moral one, that it is healthier for society if its members take an altruistic interest in helping others. This is the gift relationship in the title of the book.

In the United States commercial blood banks are commonplace. Mr Titmuss estimates that they account for almost half of the blood taken from humans. In Canada the Canadian Red Cross Society collected blood from volunteers in World War II for the use of the armed forces. Near the end of the war, hospital associations and provincial Departments of Health asked the Society to continue the service in peace time. Thus a national system, now called the Canadian Red Cross Blood Transfusion Service, came into being. It relies on donors, and the public has supported it. It is "as complete as any in its development and scope. It is said to be unique among similar services in the world".[69] It is disappointing to a Canadian that Mr Titmuss in his thorough examination of transfusion systems throughout the world, makes no mention of Canada, for the writer's impression is that our system meets the ideal of Mr Titmuss as closely as any in the world.

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[67] S.O. 1971, c.83.

[68] Titmuss, *The Gift Relationship* (1970).

[69] *The Gift of Life*, undated, published by the Canadian Red Cross.

The question remains, however, should blood *ever* be sold? In Edmonton and northern Alberta in 1972 the Red Cross collected 45,408 units of blood, all donated. In addition, however, there is a special program involving a small number of people, less than twenty in number, who have unusual blood that is valuable in the production of serum. It is only the plasma that is needed and the procedure is called plasmapheresis. The donors spend about three hours at a time to go through the process. These people receive an honorarium. The burden on the donors is such that this compensation seems reasonable and a justifiable exception to the principle of donations.

Another reason sometimes given for permitting the sale of blood in Canada is the possibility of a major disaster that would create an urgent and heavy demand that could only be met by the purchase of blood.

The writer's view is that it would be preferable, contrary to article 20 and the Uniform Act, to forbid the sale of any human tissue with an exception for the Red Cross program of plasmapheresis.[70] If an emergency occurs, the public can be counted on to respond.

GIFTS OF CADAVERS: AUTOPSIES [71]

It will be noted that article 20 deals with two of our main topics, experiments and *inter vivos* gifts, whereas article 21 provides for gifts of cadavers, in whole or in part. Article 22 permits the taking of parts of a cadaver with the consent of the spouse or next of kin, and without that consent in urgent cases to save life. Article 23 provides for autopsies. We shall now examine articles 21-23.

Article 21 provides:

> A person of full age may, in writing, determine the nature of his funeral and the disposal of his remains.
>
> A minor, capable of discernment, may do likewise with the consent of the person having the paternal authority.
>
> The consent must be in writing; it may be revoked in the same way.
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> In the absence of instructions by the deceased, usage is followed.

It combines the Committee's recommendations two and three. The former is unchanged but the latter, which had listed the persons who in the absence of instructions by the deceased, could decide on

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[70] As one of the Alberta Commissioners on the Uniformity Conference, the writer queried and then acquiesced to section 10 of the 1971 Uniform Act, which permits the sale of blood. Perhaps it ill becomes him now to criticize that section. The fact is that his misgivings have since increased.

[71] See Castel, *supra*, 378-405; and Dworkin, *supra*, 364-76.

the funeral and the disposal of the remains, is replaced by the simple provision that "usage is followed".

The report of the Committee and that of the Revision Office say that the first paragraph:

> ... states a recognized principle of the civil law. It gives to the person of major age the right to specify in advance the ceremonies to take place after his death, as well as that to decide the manner in which his body will finally be disposed of (for example, by burial, cremation or otherwise). This provision is also intended to cover the gift of the whole or of a part of the cadaver for therapeutic or other legitimate purposes.

In other words this brief article confers on a person two important powers: to make binding provisions for his funeral and to make a gift of all or a part of his body after death. In a common law jurisdiction I doubt that the brief first paragraph of article 21 would be adequate to confer authority on a person to donate an organ for therapeutic or scientific purposes. It is clear, however, that the Code Revision Office is satisfied that it is sufficient in Quebec.

What is the common law on these matters? No one could own a dead body and from this consequence grew the rule that a person could not himself make a binding disposition of his cadaver after death. The latter rule is a *non sequitur*. Even if a cadaver is incapable of ownership it should not follow that a living person cannot make binding directions on the disposal of his body after death. However, the rule is firmly entrenched.

It is accompanied by another rule having to do with burial. In Blackstone's words, the executor had a duty "to bury the deceased in the manner suitable to the estate which he leaves behind him".[72] This duty became converted into a right vested in the executor or the family. These rights are hard to define. For example, does the family have a cause of action when an unauthorized autopsy has been performed? An Alberta case, *Edmonds* v. *Armstrong Funeral Home*,[73] held that those responsible for the burial have certain rights over the body. From this the court went on to find that the unauthorized autopsy was an infringement of these rights. In truth the court was seeking a theory on which to found an award of compensation for the family's injured feelings. Prior to the Alberta decision, a Quebec case had reached the same result in an action by the widow.[74]

The paradoxical result of the common law rules was that the executor or members of the family of the deceased had the power of disposal of his body: he himself did not. Another weakness of the

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[72] 2 Bl. Comm. 507.

[73] [1931] 1 D.L.R. 676.

[74] *Phillips* v. *Montreal General Hospital* (1908), 33 C.S. 483.

common law is that it was uncertain — or at least it seemed so to the person who wanted to dispose of the body[75] or possibly to remove an organ. He might well be in doubt about who could give him authority, and when in doubt the ordinary course is to refrain.

The English *Anatomy Act*[76] of 1832 was passed to put an end to the "stealing" of bodies from graves to sell to physicians for anatomical study. This Act enabled a person having lawful custody of a body to permit an anatomical examination. It also enabled a person in his own lifetime to direct a post mortem examination on his body. However, this Act showed the same solicitude for the feelings of the family that the common law had shown, for it permitted the spouse or relative to require interment without such examination.[77]

It was only in recent years that the therapeutic use of any organ from a cadaver became feasible. The first tissue that could be successfully used was the cornea of the eye. It is a transparent hard substance that covers the colored portion. When it is damaged sight is affected or lost. Sight can be restored if the damaged cornea is removed and replaced by a healthy one. A cornea from a cadaver is satisfactory provided it is obtained promptly. The *Anatomy Act* did not cover such a use of any part of the body. To deal with this special situation, the British Parliament in 1952 passed the *Corneal Grafting Act.*[78] It permitted a person to request that his eyes be used after his death to restore the sight of a living person. However, the influence of the common law remained, for even with a request the Act still left the decision to the surviving spouse or near relative, who was given the power but not the obligation to authorize removal of the eyes.

The Canadian National Institute for the Blind was of course anxious to have legislation in Canada to permit gifts of corneas. In 1957 New Brunswick passed an Act[79] similar to the English one and in 1959 the Conference of Commissioners on Uniformity of Legislation in Canada adopted a Uniform Cornea Transplant Act on the same lines.[80] It was promptly adopted in most common law provinces.

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[75] *Hunter* v. *Hunter,* [1930] 4 D.L.R. 255 (Ont. H.C.) held that in a dispute between the executor (a son) and the widow on the place of burial, the executor's wishes should prevail.

[76] 2 and 3 Will. IV, c.75, ss.7 and 8.

[77] *Ibid.*

[78] 15 and 16 Geo. VI and 1 Eliz. II, c.28.

[79] *Corneal Grafting Act,* S.N.B. 6 Eliz. II, c.7.

[80] Proc. Conf. of Comm'rs on Uniformity of Leg'n in Can. (1959), 77.

By this time, it had become apparent that other parts of a cadaver could be used to aid the living. For this reason Britain in 1961 replaced the original Act by a *Human Tissue Act.*[81] It extends to all human tissue for therapeutic, educational or scientific purposes. However, it leaves the final decision to the person lawfully in charge of the body. The common law solicitude for the feelings of the family is maintained.

The Uniformity Conference made use of this Act in adopting a Uniform Human Tissue Act in 1965.[82] However, the Uniform Act took away the need for authorization by the family of the deceased where he himself had authorized the use of his body. In other words the 1965 Uniform Act puts the wishes of the deceased ahead of those of his family and makes them prevail. This might wound the sensibilities of members of the family, but the Conference thought they should give way to the wishes of the deceased. After all, his purpose is humanitarian — to assist the living.

Another change from the English Act of 1961 has to do with the case where the deceased has given no direction. The Uniform Act lists in order of priority by relationship those persons who may give consent, and puts at the bottom "the person lawfully in possession of the body".

Soon after our Uniform Human Tissue Act came into being, and about the time when several provinces were adopting it, the completion of the first heart transplants raised in acute form an issue that did not arise in connection with corneas. In heart transplants the urgency is so great that questions have arisen about whether the prospective donor might be permitted to die sooner than he otherwise would have, in order to make his heart available to someone who is near death. This has led to a widespread discussion of the question when death occurs. This was one of the reasons why suggestions were made to the Uniformity Conference to make some revisions in the Human Tissue Act. (Another was to provide for *inter vivos* gifts, already discussed.) As a result, a revised Uniform Human Tissue Act was adopted by the Conference in 1970.[83] It underwent minor changes in 1971 including a change in name to the *Human Tissue Gift Act.*[84] For convenience I shall refer to the 1971 version. It contains several provisions that were included because of problems that arise in connection with heart

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[81] 9 and 10 Eliz. II, c.54.
[82] Proc. Conf. of Comm'rs on Uniformity of Leg'n in Can. (1965), 104.
[83] *Supra,* f.n. 63.
[84] *Supra,* f.n. 64.

transplants. For example the consent of the spouse or other member of the family does not have to await death. Section 5(1) provides that where the person "is incapable of giving a consent by reason of injury or disease and his death is imminent" the spouse or other designated person may consent. Again, there may be a case where death is imminent and the physician in charge thinks there will be a coroner's inquest. In that event, section 6 permits the coroner, notwithstanding that death has not yet occurred, to give directions for the removal of tissue. The last provision of interest is one dealing with time of death. The Conference was not prepared to define it. Section 7(1) states that "the fact of death shall be determined by at least two physicians in accordance with accepted medical practice". The remaining subsections of section 7 provide in effect that the physicians who determine the fact of death must be independent of the donor and donee except in the case of cornea transplants.

Ontario, Newfoundland and British Columbia have passed the revised Uniform Human Tissue Act either in its 1970 or 1971 form.[85]

The American Uniform Anatomical Gift Act, 1968, which has been adopted, sometimes with variations, in all States except Massachusetts and Nebraska should now be mentioned.[86] Its basic principle is that of our 1965 Uniform Act; that is to say, it gives priority to the wishes of the deceased over those of his family. Where the deceased has given no directions, the persons who may do so in order of priority are almost identical with those in our 1965 Uniform Act.

The American Act does however have some provisions of interest that are absent both from article 21 and our Uniform Act. It spells out the persons and institutions to whom the gift may be made, and provides that a donee need not be specified. In addition it deals with delivery of the document of gift, with the methods of amending or revoking the gift, and acceptance or rejection of the gift.

If legislation of this kind is to be effective, the public should know about it. They should be assisted in making gifts and the fact of the gift should be known immediately on the donor's death. The Canadian National Institute for the Blind has long provided an "eye bank card" which the donor can carry on his person. However the writer knows of no cards that are available in Canada

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[85] *Supra*, f.n. 85.

[86] 8 Uniform Laws Annotated, Master Edition (1972), 22.

covering parts of the body other than eyes. The American Uniform Act provides in section 4(b) that the document of gift may be a card designed to be carried on the person.

The American Act does not prescribe a form of gift, but the Uniformity Commissioners noted the usefulness of cards and the desirability of standard forms for use by the donor and by the next of kin. Indeed they prepared "suggested forms" which are set out in the note to the Uniform Act.[87] These forms are of course in conformity with the American Uniform Act. It seems to the writer that it would be helpful in Canada to have forms that could be used under the Canadian Uniform Act and under Quebec's article 21.

We have seen that the existing Acts do not define death. The State of Kansas broke new ground in 1970 in providing a definition. Its Act states that a person is dead if there is an absence of spontaneous respiratory and cardiac function or if there is absence of spontaneous brain function; and if in the absence of brain function attempts are made to maintain or restore spontaneous circulatory or respiratory function and it appears that they will not succeed, death will have occurred when these conditions first coincide. There is a further provision that death is to be pronounced before artificial means are terminated and before any vital organ is removed.[88]

Returning to article 21, it is notable for its brevity. It does not attempt to define death or to refer to certification of death by a physician. Directions for disposition must be made in writing. Like the Uniform Act, it does not require testamentary form. However, there is no alternative of oral consent in the presence of at least two witnesses during the last illness, as there is in our Uniform Act.

A last comment on article 21: it permits a person to regulate the style of his funeral. The Code Revision Office Report states that the civil law had always recognized a person's right to specify in advance the ceremonies to take place after his death and whether his body will be disposed of by burial, cremation or otherwise. I know of no comparable legislation in the common law provinces. As the common law stands, at least in Canada, there is no way

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[87] *Ibid.*, 31-33.

[88] *An Act Relating to and Defining Death*, Sess. Laws Kan. 1970, c.378, reprinted in Katz, *supra*, 1085. Compare Beecher, *supra*, 152-57, 311-18. For an adverse comment, see Kennedy, (1971) 285 N.E.J.M. 946, quoted in Katz, *supra*, 1085. For criticism of s.7 of the American Uniform Act, which provides that a physician shall determine death, see Kusanovich, *supra*, 246-53.

of enforcing the wishes of the deceased about his funeral. It would seem desirable to make effective the direction of the deceased as Quebec has done, though an enactment to that effect could not appropriately go into the Human Tissue Gift Act.[89]

Gifts by Relatives: Gifts in Emergency

Article 22 provides:

> A physician may remove a part of the remains, if in the absence of instructions by the deceased, he obtains the consent of the consort or nearest relative of the deceased.
>
> This consent is not necessary when two physicians attest in writing to the impossibility of obtaining it in due time, the urgency of the operation, and the serious hope of saving a human life.
>
> The death of the donor must be ascertained by two physicians who do not participate in any way in the removal or in the transplantation.

The first paragraph requires no comment. It is similar in purpose to the Uniform Tissue Gift Act, and simply authorizes members of the family to make a gift of part of the body where the deceased has not done so.

The second paragraph has no counterpart in any of the legislation that has been discussed. It is notable in permitting the use of part of a cadaver where consent cannot be obtained in time, and where the purpose is to save a human life. This provision doubtless contemplates heart transplants, though it applies to any part of the body.

The Committee referred to this provision as highly exceptional, and they justified it on humanitarian grounds. Solicitude for the family's wishes must give way to save a life. The Commission pointed out the moral duty to go to the assistance of another — and the taking of an organ is a form of "rescue" of the person whose life will be saved by the transplant. Once again there has been a weighing of human need against the rights of the family over the cadaver and article 22 comes down on the side of human need.

It is relevant here to note that in Britain there have been proposals to change the scheme of the *Human Tissue Act* of 1961 so as to permit the taking of organs unless the deceased had forbidden it. Lord Kilbrandon once drafted a section which he put forward for consideration:

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[89] The Memorial Society Association of Canada advocates legislation "giving a person the right to decide how his body is to be disposed of after he is dead": *Edmonton Journal*, 22 May 1973, 3.

> In any designated hospital it shall be lawful to remove from a dead person any organ required for medical or scientific purposes unless the hospital authorities have reason to believe that the deceased in his lifetime had forbidden this to be done, provided that such removal shall not disfigure the dead body.[90]

This has been called a "contracting out" provision which is the reverse of the "contracting in" provision of the Uniform Acts and article 21. For the present at least it seems that "contracting out" legislation in Britain is unlikely.[91]

It seems to the writer that the second paragraph of article 22 creates an exception to the "contracting in" principle of article 21. That is to say, it permits the taking of a part of the body without consent of the person himself, or of his kin.

Autopsies

The last article is 23 C.C. which provides:

> An autopsy may be performed only in the cases provided for by law or with the written consent of the deceased.
>
> It may be required by the attending physician or by one of the persons mentioned in article 1056.

The persons mentioned in article 1056 are spouse and "ascendant and descendant relations". This excludes brothers and sisters.

When the Committee prepared the draft article it did not include the attending physician. He was added in the Code Revision Office. The article states that the physician or relations may "require" an autopsy. This would seem to imply that it must be held, though it may be that "require" means "request", which would mean that the decision remains with the coroner.

Traditionally autopsies have been linked with investigations and inquests into the cause of death where violence or foul play is suspected. The *Coroner's Act* of Quebec, like those of the common law provinces, specifically permits an autopsy in these circumstances.[92] In addition, however, there is a provision in the *Study of Anatomy Act* which deals with the case of patients dying in a public institution in which they are supported. The superintendent may order an autopsy when it is necessary to determine the cause of death.[93] In the case of the Notre Dame Hospital in Montreal its private Act was amended in 1924 to permit the at-

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[90] Wolstenholme and O'Connor, *supra*, 158.

[91] Dworkin, *supra*, 371-72; Zellick, *Organ Transplantation*, (1972) 122 New Law Journal 1078.

[92] S.Q. 1966-67, c.19, ss.11, 12 and 18.

[93] R.S.Q. 1964, c.250, s.4.

tending physician or chief house physician to hold an autopsy on the non-paying patients where desirable from a scientific point of view and to establish the true cause of death.[94]

In the common law provinces the Coroner's Act invariably authorizes a post-mortem examination in connection with a coroner's investigation or inquest.[95] The three western-most provinces have, however, gone further. Saskatchewan and Alberta have similar provisions in the case where a person has died in a hospital after an operation. Either the hospital or the next of kin may request an examination, and the coroner may authorize it.[96] British Columbia's provision differs in that it applies only to a request by a hospital, not next of kin, and it specifies that the examination "may be carried out notwithstanding objection thereto by a person entitled to the custody of the body".[97]

Under Quebec's new article 22 a problem would arise when the attending physician "requires" an autopsy and the relatives object. The Act does not deal specifically with this situation. I think the inference is that the coroner could order the autopsy, but in practice he might defer to the wishes of the family. As in the case of transplants from cadavers, sensibilities are involved. Perhaps the public can be educated to accept the idea of post-mortem examinations. They add to our knowledge. At the same time those conducting the examination should try to guard against disfigurement that would cause the family distress.

CONCLUSION

Sometimes the relations between law and medicine are uneasy. A distinguished Australian judge has spoken of law "marching with medicine, but in the rear and limping a little".[98] To the medical profession the law is often uncertain or unduly restrictive. No lawyer would say that all of the problems that arise in experimentation and transplantation can be solved by a legal code. In safeguarding the human subject and at the same time giving proper scope for medical and scientific progress, there are many non-legal sanctions or controls. They must supplement the law, or perhaps it would be better to say the law should supplement them.

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[94] S.Q. 1923-24, c.117, s.15, and, as amended, s.20; and see *Ducharme* v. *Hôpital Notre-Dame* (1933), 71 C.S. 377.

[95] E.g., *Coroner's Act*, S.O. 1972, c.98, s.23.

[96] *Coroner's Act*, R.S.A. 1970, c.69, s.18(8); *Coroner's (Amendment) Act*, S.S. 1966, c.94, s.6.

[97] *Coroner's (Amendment) Act*, S.B.C. 1968, c.11, s.12.

[98] Sir Victor Windeyer in *Mount Isa Mines* v. *Pusey* (1971), 45 A.L.J.R. 88, 92.

The most obvious of these controls is the ethical code. It does not provide an automatic solution to every problem. However, it is a healthy reminder to the investigator to be solicitous of the person who has submitted to the experiment. An ethical code is not to be read the way Mr Justice Holmes' bad man looked at the law — how far can I go without getting into trouble? It prescribes a minimum of proper conduct, not a maximum, and it encourages one to keep above the borderline.

Another instrument to protect the volunteer is the research committee. It now exists in many institutions;[99] indeed the United States Department of Health, Education and Welfare will make grants only to institutions having one.[100] This committee sets guidelines, and either by itself or through subcommittees reviews each application and approves, rejects or modifies it. Sometimes researchers object to this procedure in the name of academic or scientific freedom. Assuming wisdom and common sense, these committees are in my opinion helpful and the opposition in the name of academic freedom is untenable.

Another sanction that some favour is to persuade professional journals not to publish the results of research unless it is made "unmistakably clear in the publication that the proprieties have been observed".[101]

It is also suggested in discussions of ethics (legal as well as medical) that the most important factor is the character of the members of the profession. Dr Beecher has put emphasis on the prime importance of "an intelligent, informed, conscientious, compassionate, responsible investigator".[102]

These controls should not be regarded as alternatives. Each has its place and reinforces the other. The more effective they are, the less the need for legal sanctions.

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[99] See McGill's Guidelines, *supra*. The University of Toronto's Research Board has for some years had a Human Experimentation sub-committee. The University of Alberta Hospital has a Special Services and Research Committee and the University of Alberta itself recently established a committee structure and guidelines. See Melmon, Grossman and Morris, *Emerging Assets* and *Liabilities of a Committee on Human Welfare and Experimentation*, (1970) 282 N.E.J.M. 427 and editorial in same volume at 449.

[100] Protection of the Individual as a Research Subject, U.S. Gov't Printing Office, 1969.

[101] Beecher, *Ethics and Clinical Research*, (1966) 274 N.E.J.M. 1354, 1359-60; see also Editorial, *Ethics of Experiments on Children*, (1973) 288 N.E.J.M. 791.

[102] Beecher, *supra*, 1360.

These observations have had reference to experimentation but to a considerable extent they are applicable to transplants.

A final word in connection with Quebec's provisions: the common law has tended to resist codification whereas a Civil Code like Quebec's is designed to cover the whole body of law. In times of quick development there is a temptation to codify too soon, but on the other hand it is no credit to the law and is frustrating to the medical and legal practitioner if it is uncertain and hard to find. Quebec's new articles are easy to find and remove much, though not all, uncertainty.

One cannot always foresee how any new legislation will work. However, Quebec's new articles have the virtue of stating the main principles without going into undue detail. Moreover, it is manifest from the Report of the Committee and the Code Revision Office that the framers not only have a knowledge of the subject but a compassionate and humanitarian attitude. It is no coincidence that these articles follow immediately articles 18 and 19 which declare the personality and inviolability of every human.[103]

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[103] The writer acknowledges with thanks the information that he received from Dr D. I. Buchanan, Medical Director at Edmonton of the Blood Transfusion Service of the Canadian Red Cross Society; and the helpful comments of Dr Bernard Snell, Medical Director of the University of Alberta Hospital, who read an earlier draft; and the benefit of discussions with Mrs Margaret Shone, Legal Officer of the Institute of Law Research and Reform, Edmonton, who also read an earlier draft.