

THE LAW GOVERNING HUMAN EXPERIMENTATION IN QUÉBEC

by Robert P. KOURI*

This article is intended to provide an overview of the law governing human experimentation in Quebec as such law presently stands, and to examine certain innovations introduced by the proposed Civil Code of Québec. It examines more particularly, the conditions under which human experimentation may take place and the liability of the parties involved in research.

Cet article constitue un survol des règles applicables en matière d'expérimentation humaine en droit québécois actuel, ainsi qu'un examen de certains changements apportés par le projet de Code Civil du Québec. L'article aborde plus particulièrement les conditions susceptibles de valider l'expérimentation humaine ainsi que la responsabilité des parties impliquées dans la recherche.

*. Professor of Law, Faculté de droit, Université de Sherbrooke. Ce texte se fonde sur une communication présentée à la XIII Conférence de l'Académie Internationale de Droit Comparé tenue à Montreal, en août 1990.

TABLE OF CONTENTS

| | |
|--|-----|
| INTRODUCTION | 79 |
| A - Conditions under which human experimentation may take place | 80 |
| 1 - Consent | 83 |
| 2 - Proportionality between risk and benefit | 92 |
| B - Liability of the parties involved in research | 94 |
| 1 - The Researcher | 96 |
| 2 - The Institution | 98 |
| 3 - The Research Subject | 100 |
| C - The new law governing experimentation | 101 |
| 1 - Capacity | 102 |
| 2 - Other criteria of validity for experimentation | 105 |
| CONCLUSION | 107 |

INTRODUCTION

The primary purpose of this paper is to describe and analyze the law of Quebec as it relates to research upon humans. It accepts the fundamental premise that scientifically valid research is not merely useful, but in reality, necessary for the development and improvement of the human condition. Accordingly, the law must set out parameters within which research is encouraged and not merely tolerated. This paper also postulates that as a corollary of this premise, research must be pursued only in a manner consonant with human integrity and dignity¹. These notions in turn call into play considerations relating to enlightened consent and to the protection of persons who are vulnerable due to their youth, their mental incapacity or their social status. Through an examination of Quebec positive law, we shall see if these noble standards are met.

The legality of non-therapeutic experimentation in Quebec is presently governed by art. 20 of the *Civil Code of Lower Canada* (hereinafter C.C.L.C.). It should be emphasized at the outset that the present *Civil Code* is in the process of being revised and indeed, certain provisions of the new code as they concern experimentation have already been adopted², but have not and will never come into force. This somewhat unusual situation results from the fact that on the 18th of December 1990, the Minister of Justice introduced before the National Assembly, yet another proposed *Civil Code of Québec* (hereinafter C.C.Q.) which is intended to replace the *Civil Code of Lower Canada* as well as those parts of the *Civil Code of Québec* which have previously been adopted³. Consequently, in order to provide as complete a picture as possible, this paper will first describe the present state of the law concerning experimentation and then will allude to those changes which will be brought about by this most recent *Civil Code* project. Also, it should be mentioned immediately that it is quite likely the proposed *Civil Code of Québec* will be amended prior to its coming into force. Therefore, the reader is well advised to note that these comments on the new code are based on its text as presently drafted and must thus be viewed as somewhat tentative.

-
1. The Law Reform Commission of Canada, in its working paper entitled *Biomedical Experimentation Involving Human Subjects*, (Ottawa, Law Reform Commission of Canada, 1989), refers to «respect for the dignity and autonomy of human beings» (at p. 3), an ongoing theme in its *Protection of Life Series*.
 2. *An Act to Add the Reformed Law of Persons, Successions and Property to the Civil Code of Québec*, 1987 S.Q. c.18, assented the 15th of April 1987.
 3. Bill 125, *Civil Code of Québec*, 1st Sess., 34th Leg. Que., 1990, presented by Gil Rémillard, Minister of Justice, the 18th of December 1990.

This study is divided into three parts; the first dealing with the conditions imposed by law for effecting research on humans, the second involving issues of liability, and the third describing the proposed revision of the law on experimentation, insisting more particularly on the changes which these revisions will bring to present law.

A - Conditions under which human experimentation may take place

Looking at the law of Quebec as it presently stands, art. 20 C.C.L.C. reads as follows:

«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 authorization of a judge of the Superior Court and with the consent of the person having parental authority, 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.»

As may be noted, the conditions enumerated in art. 20 involve issues of consent as well as the relationship between the potential risks and the benefits sought through experimentation. Before dealing with these aspects, there are two preliminary questions which must be addressed and concerning which the code is somewhat reticent.

The first relates to the type of experiment to which art. 20 is deemed to apply. Generally speaking, the notion of research can pertain to both therapeutic and to non-therapeutic experimentation, the distinction between these two branches being founded on the presence or absence of direct therapeutic benefit for the patient. There is some debate amongst Quebec legal writers as to whether the provisions of art. 20 C.C.L.C. are intended to apply to experimentation in all its forms or merely to non-therapeutic or purely scientific research⁴. The

4. W.F. Bowker, «Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code», (1973) 19 McGill L.J. 161 at p. 166; J.-L. Baudouin, «L'expérimentation sur les humains: un conflit de valeurs», (1981) 26 McGill L.J. 809 at p. 819; *contra*: F. Heleine, «Le dogme de l'intangibilité du corps humain et ses atteintes normalisées dans le droit des obligations du Québec contemporain», (1976) 36 R. du B. 2 at pp. 29-30. In connection with the distinctions between therapeutic and non-therapeutic research and the problems related

predominant opinion favours restricting the application of art. 20 only to research of a non-therapeutic nature. The basis for this position is grounded on the concept that art. 20 is destined to regulate certain medical acts which do not inure to the benefit of the person whose integrity is in question, except possibly in an indirect manner⁵. However, upon closer examination, it may be perceived that this bipartite division between therapeutic and non-therapeutic experimentation lacks nuance since non-therapeutic research can be pursued for reasons not entirely of an unselfish nature. For example, a patient undergoing purely contraceptive sterilization⁶ or cosmetic surgery could be willing to submit to an innovative instead of a standard surgical procedure, provided the desired end result were attained. As this illustrates, although the intent is not therapeutic, the patient is actuated primarily by considerations relating to direct personal benefit.

Is it appropriate therefore that this type of activity be placed on the same footing as experimentation destined to increase knowledge or advance medical science without conferring a direct benefit upon the research subject?

If one bear in mind that the provisions of art. 20 C.C.L.C. were adopted in order to validate infringements of a person's physical integrity for the advantage of others⁷, this would seem to indicate that non-therapeutic acts of an experimental nature intended for the immediate benefit of the patient would best be governed by the *droit commun* rather than by the exceptional rules of this article of the *Civil Code*⁸.

The second controversial aspect which is not clearly dealt with by the code relates to the question of altruism in experimentation. Must the consent of

thereto, we highly recommend an article written by M.A. Somerville entitled «Therapeutic and Non-Therapeutic Medical Procedures - What are the Distinctions?», (1981) 2 Health Law in Canada 85.

5. A. Mayrand, *L'inviolabilité de la personne humaine*, Montréal, Wilson & Lafleur, 1975 at p. 16, no 6.
6. *Zimmer v. Ringrose*, (1979) 89 D.L.R. 3d. 646 (Alberta Trial Division), (1981) 124 D.L.R. 3d. 215 (C.A.). In the Court of Appeal, it was decided that although sterilization by silver nitrate was innovative rather than experimental, it was viewed as a therapeutic act. In *Cryderman v. Ringrose*, [1977] 3 W.W.R. 109; [1978] 3 W.W.R. 481, (1979) 89 D.L.R. 3d. 32 (Alberta Supreme Court, Appellate Division), the Court treated the sterilization method as experimental.
7. According to A. Mayrand, *op. cit. supra* note 5 at p. 17, no 8, the law has always admitted the possibility for an individual to allow infringements to one's integrity when they were in pursuit of a personal advantage or benefit.
8. In practice, the only consequences of this finding would relate to the requirement of a writing as a condition of validity, and to allowing certain non-therapeutic acts to be performed on incapable or protected persons, whereas the other rules pertaining to enlightened consent and to the evaluation of risk and benefit would be the same since they are straightforward applications of general legal principles.

the volunteer be «untainted» by economic incentives or can a person derive a financial benefit from his or her participation in an experiment?

Although art. 20 forbids any remuneration for the alienation of human organs or tissue unless they are susceptible of regeneration, it does not prohibit payment for participation in experimentation⁹. Interestingly enough, the present text of art. 20 constitutes a substantial departure from the text originally proposed by the Civil Code Revision Office which would have banned all forms of venality both in matters of organ or tissue donation as well as in cases of experimentation¹⁰. However, as the proposed law was being debated before the National Assembly, the Canadian Red Cross requested that it be modified to allow for the remuneration of blood donors¹¹. While heeding this suggestion, the National Assembly added to projected art. 20 C.C.L.C. a provision that alienations of human tissue would have to be gratuitous unless involving body parts susceptible of regeneration. In so doing, it failed to address the specific issue of rewarding volunteers for research. As a result, it may be affirmed that Quebec law does not forbid the payment of fees or honoraria to volunteers for experimental projects. Indeed, said sums could go beyond the mere reimbursement of expenses or indemnification for inconvenience.

These preliminary points having been resolved, we will examine the conditions set out by law for the validity of research on human volunteers.

1 - Consent - The consent of the experimental subject must not only be free and enlightened, it must also be expressed in writing and must be provided by a person having discernment.

i) Free and enlightened consent - It is trite to state that art. 19 C.C.L.C. allows for the infringement of a person's integrity as long as the individual concerned has been adequately informed of the nature and risks of the act contemplated and has expressed a valid consent thereto. In those medically-related matters where the goal pursued is not therapeutic in nature, the most contentious aspect concerning the obtaining of valid consent involves the extent

-
9. A. Mayrand, *op. cit. supra* note 5 at pp. 81-82, no 61; F. Héleine, *loc. cit. supra* note 4 at pp. 62-63; P.-A. Crépeau, «Le consentement du mineur en matière de soins et traitements médicaux ou chirurgicaux selon le droit civil canadien», (1974) 52 Can. Bar. Rev. 247 at p. 258; A. Lajoie, P. Molinari, J.-M. Auby, *Traité de droit de la santé et des services sociaux*, Montréal, Presses de l'Université de Montréal, 1981 at pp. 362-363, no 583.
 10. Committee on the Law of Civil Rights and Duties, *Report on the Recognition of Certain Rights Concerning the Human Body*, (Montréal, Civil Code Revision Office, 1971) at pp. 6-7.
 11. Québec, Assemblée Nationale, *Journal des débats* at p. 4551 (30 Nov. 1971).

to which the physician or researcher must provide information to the research subject.

In dealing with the quality of information which must be presented to the potential subject, Quebec jurisprudence is explicit - the experimenter must «...reveal without reservation all the risks involved in the undertaking»¹². The goal is not to «proffer threats» nor «offer a lesson in medicine», but merely to permit the person concerned to reflect thoroughly before risking his or her health for non-therapeutic reasons. This obligation to inform the candidate for research can be quite extensive. In the recent Quebec case of *Weiss v. Solomon, Kaback and the Jewish General Hospital*¹³, the Court held that «in matters of purely experimental research, the physician must reveal all known risks including those which are rare or remote, especially if they may entail grave consequences»¹⁴.

The *Weiss* case went even further. It held that a research program as well as activities ancillary thereto constituted a unified undertaking with the consequence that the obligation to inform would include not only the risks inherent in the actual experiment but also those pertaining to non-experimental examinations or tests which serve to monitor the outcome of the research itself. The *Weiss* case involved risks resulting from an injection of fluorescein in the course of angiography in order to verify the efficacy of experimental ophthalmic drops. Although angiography *per se* could be considered a routine medical procedure, it nonetheless entailed some risk, the existence of which should have been communicated to the patient. In the opinion of the court, this failure to inform was a fundamental reason for holding the researcher liable.

The duty, as set out by *Weiss v. Solomon*, of informing the patient of all known risks refers to all risks concerning which a reasonably competent researcher would have been aware, given the particular scientific context. Yet, this duty as so described raises serious questions when the research undertaken involves, of necessity, some degree of deception. Under certain circumstances, it seems obvious that some equivocation cannot be avoided when, for example, blind or double blind testing occurs. In cases such as these, would Quebec law countenance a lack of candour in the interests of science? One writer, adopting a utilitarian approach to the question, would favour allowing this type of

-
12. *Dulude v. Gaudette*, [1974] C.S. 618 at p. 621, Vallerand, J. (my translation). Note also art. 2.03.29 *Règlement concernant le code de déontologie*, (1980) 112 G.O.Q.1877. Thus the notion of «therapeutic privilege» is excluded when the goal pursued is not the actual treatment of a pathological state.
 13. (1989) 48 C.C.L.T. 280; [1989] R.J.Q. 731, (Superior Court), L. De Blois, J.
 14. (My translation). *Id.* C.C.L.T. at p. 303, R.J.Q. at p. 743. It is interesting to note that *Halushka v. University of Saskatchewan* ((1965) 53 D.L.R. 2d 436) was cited with approval by the court (in C.C.L.T. at pp. 302-303; in R.J.Q. at p. 742).

experiment to take place provided the risks involved remained negligible¹⁵. He adds as a precondition that it would have to be demonstrably impossible to properly carry out the experiment were the research subject wholly enlightened¹⁶. Since the basic rule in research posits the requirement of fully informing the subject, the safest approach would be to avoid deception since, in appropriate circumstances, any intentional infringement of a persons's inviolability would give rise to more than nominal moral and exemplary damages¹⁷. Obviously, some modification of the law to cover this type of situation may be deemed desirable.

In experiments involving blind and double blind testing, it may be possible in some cases to obtain informed consent without having recourse to actual deception. In blind tests of pharmaceutical products for example, would it not be reasonable to argue that provided the subject were properly advised of the research protocol and of the possibility of receiving an innocuous substance rather than the actual product under trial, the researcher's legal obligations would be validly fulfilled in this regard?

Finally, it should be emphasized that in the interest of maintaining an atmosphere of mutual trust and respect for the autonomy of the subject, all persons conducting research would have to advise the participants not only of the risks involved but also of the scientific purposes of the experimentation. It is evident that the reason for this prerequisite is to enable volunteers to avoid becoming involved in research which they may find morally repugnant even though, in the eyes of most, the goals pursued are highly ethical¹⁸.

ii) Necessity of giving consent in writing - The law specifically states that the consent of the experimental subject must be given in writing. The

15. J.-L. Baudouin, *loc. cit. supra* note 4 at p. 821.

16. *Ibid.*

17. *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12, sec. 49.

18. J.-L. Baudouin, *loc. cit. supra* note 4 at p. 823. This is an instance where the controversy whether *Reibl v. Hughes*, [1980] 2 S.C.R. 880 and *Hopp v. Lepp*, [1980] 2 S.C.R. 192 apply to Quebec law becomes more than a mere academic discussion. Under the *Reibl* rule, the question that the court would ask would be «Had a reasonable person known the goal of the experiment, would he or she have consented?» whereas under Quebec law, the court would inquire whether «Had the subject known the goal of the experiment, would he or she have consented?»; cf R.P. Kouri, «La causalité et l'obligation de renseigner en droit médical québécois», (1987) 17 R.D.U.S. 493 and authorities cited. The Court in *Weiss (op. cit. supra* note 13) adopted the *in concreto* criterion in order to determine whether there was causation: «L'ensemble de la preuve permet à la Cour de conclure que Weiss n'aurait pas accepté de participer au programme de recherche accompagné d'angiogrammes à la fluorescéine, s'il avait été placé en présence d'une possibilité, même éloignée, de risque de décès ou même uniquement de collapsus dû à sa cardiomyopathie hypertrophique» (in C.C.L.T. at p. 296; in R.J.Q. at p. 742).

apparent goal of this requirement is not only to lessen the chances of a volunteer acting rashly, but also to facilitate proof that consent has indeed been given. Yet, one may query the actual nature of the written consent. Does it constitute fulfillment of an *ad solemnitatem* requirement or does it merely serve *ad probationem*? It is now generally admitted in Quebec that consent in writing is a condition of validity for any infringement of corporal integrity sanctioned by art. 20 C.C.L.C.¹⁹. Consequently, without written permission, purely scientific experimentation constitutes an illicit act. Nevertheless, the rather laconic manner in which art. 20 is drafted implies that while a writing is obligatory, its actual form remains unimportant. Thus, it is not necessary that the consent be made before witnesses (although this precaution could prove to be useful) nor, by the same token, is it necessary that consent be given by notarial deed.

Art. 20 goes on to mention that the revocation of consent may also be made in writing. Some controversy surrounding the form of the revocation has arisen in Quebec legal writing²⁰ because a careful reading of the French version of the Code appears to imply that consent may be revoked only in writing. However, a consensus has emerged that this ambiguity was merely a result of poor drafting and that the actual intent of the National Assembly was to allow revocation of consent at any time and without formality, although preferably in writing as a means of proof²¹. In any case, it should be noted that the continuation of an experiment contrary to the wishes of the experimental subject, whether expressed in writing or verbally, would constitute a criminal assault²² as well as a civil delict²³.

iii) Consent of a person having discernment - In its original draft of what was to become art. 20 C.C.L.C., the Quebec Civil Code Revision Office proposed that only capable adults be permitted to donate organs and tissue or consent to experimentation²⁴. In the course of the National Assembly debate on the bill, it was decided to amend the project and extend the right to give tissue or participate in experimentation to certain minors as long as there were no serious risks to health involved. Another proviso added coincidentally included the requirement that the minor act with the «consent» of the person having

19. F. Heleine, *loc. cit. supra* note 4 at p. 35; A. Mayrand, *op. cit. supra* note 5 at p. 44, no 35; J.-L. Baudouin, *loc. cit. supra* note 4 at p. 820.

20. J.-G. Castel, «Nature and Effects of Consent with Respect to the Right to Life and the Right to Physical and Mental Integrity in the Medical Field: Criminal and Private Law Aspects», (1978) 16 *Alta L.R.* 293 at p. 305; Baudouin, *ibid.*

21. F. Heleine, *loc. cit. supra* note 4 at pp. 35-36; Lajoie et al, *op. cit. supra* note 9 at p. 173, no 286; Baudouin *ibid.*

22. Sec. 265 Cr.C.

23. J.-L. Baudouin, *loc. cit. supra* note 4 at p. 820.

24. Committee on the Law of Civil Rights and Duties, *op. cit. supra* note 10 at p. 6.

parental authority as well as with the authorization of a judge of the Superior Court.

It is clear from the terms of arts 19.3 and 20 C.C.L.C. that adult mental incompetents cannot be subjected to experimentation, even with the concurrence of their legal representatives, for the simple reason that this type of activity is not in the immediate best interest of the person unable to consent²⁵. (We exclude the somewhat facile notion of research helping mankind and thus indirectly helping the experimental subject).

As for minors, the law sets out discernment as the criterion for eligibility to participate in purely scientific research. Therefore, unlike the provisions of the *Public Health Protection Act*²⁶ which arbitrarily determine an age²⁷ at which a minor may, without assistance, consent to treatment required by his or her state of health, the *Civil Code* does not set out an age at which a minor's integrity may be infringed in the interest of others. In practical terms, this means that discernment will vary from one minor to another depending upon the maturity, intelligence and knowledge of the child involved. By thus allowing discernment to be treated as a pure question of fact, there will always exist a degree of uncertainty since interpretations of given fact-situations will inevitably vary from one judge to another.

Moreover, one may query whether the notion of discernment to which art. 20 alludes relates to the capacity to be held civilly liable (i.e. the capacity to discern right from wrong)²⁸, or whether it relates to the capacity to contract (i.e. the capacity to understand the nature of the juridical act to be entered into and its consequences)? When the question is presented in this manner, it becomes obvious that the notion of discernment is not monolithic but rather is one which varies according to the legal context under scrutiny. For example, it may be possible for a particular child to discern right from wrong at a relatively early age and thus be held civilly liable while this same child would not necessarily have sufficient discernment to be bound by contract²⁹. By the same token, could

25. Art. 19.3 C.C.L.C. provides: «A person who consents to or refuses care for another person [unable to consent] is bound to act in the sole interest of that person taking into account, so far as possible, any wishes expressed by that person.» See also M. Ouellette, «La loi sur le curateur public et la protection des incapables», (1989) 3 C.P. du N. 1 at p. 14.

26. R.S.Q. c. P-35.

27. *Id.* sec. 42. The lower limit is set at fourteen years.

28. For example see *Ginn v. Sisson*, [1969] C.S. 585.

29. Yet in the case of *Cayouette v. Mathieu*, [1987] R.J.Q. 2230 (Superior Court), dealing with an application to grant a 5 year-old child permission to give bone marrow to his 3 year-old brother, V. Melançon, J. held that: «Donner exclusivement à ces mots 'doué de discernement' le sens général signifiant celui qui a atteint l'âge de raison serait limiter la portée de l'article qui traite aussi du 'bienfait' que l'on attend de l'intervention.» (at p. 2232) As a result, the

it not be argued that the capacity to comprehend the risks and consequences of a gift of human tissue or of participating in an experiment would have to be even greater than for making decisions of a patrimonial nature, considering the fact that one's actual integrity is at stake³⁰?

One writer has suggested that it is difficult, in practical terms, to envision a child less than fourteen years of age as having the discernment necessary to submit to non-therapeutic experimentation³¹. Nevertheless, the disquieting fact remains that a number of decisions have been rendered by Quebec courts in which children of two, three, four and five years of age³² have been deemed sufficiently capable of consenting to gifts of bone marrow for purposes of transplantation into a sibling. Yet, one must place these decisions in their proper context. In all cases, a close family relative was in immediate danger of death, and all other potential donors were not histocompatible with the donee. Also the risks for the donor were minimal (if one accepts general anesthesia as entailing little risk), and the child «donor's» entourage was in favour of the operation. One would almost tend to categorize this type of situation as a case of necessity³³. However, it seems clear that these or similar redeeming considerations would not be present when it becomes a question of submitting a young child to purely scientific experimentation.

In the case of older minors, art. 20 imposes the restraining influences of parental «consent» and judicial authorization in order to protect a child having discernment from excessive enthusiasm, generosity or lack of mature reflection³⁴. As one writer properly points out, there is an obvious error in the language of this article³⁵. The parents and a Superior Court judge may only authorize the child having discernment to consent to the experiment. They

judge held that since the 5 year-old understood that he would be giving something to his sick brother, he was able to understand or discern the nature of the intervention and appreciate its advantages for his brother.

30. This is especially striking when one recalls that as a rule, minors are not allowed to make gifts of property, cf art. 763 C.C.L.C.

31. A. Mayrand, *op. cit. supra* note 5, at p. 68, no 54.

32. See for example *Cayouette v. Mathieu*, *op cit supra* note 29; P. Deschamps, D. Sauvé, «Aspects juridiques de la transplantation de moelle osseuse», (1981) *Le Médecin du Québec* 51.

33. One should emphasize the word «almost» since necessity constitutes a defence to having committed an otherwise wrongful act. More particularly, when necessity is invoked as a matter of course in all cases of this nature, then its pertinence becomes highly questionable since the essence of necessity is that it occurs when a wrongful act is committed in order to avoid a greater harm, and this wrongful act is the only reasonable way to avoid such harm. See generally J.-L. Baudouin, *La responsabilité civile délictuelle*, 3rd ed., Cowansville, Les Editions Yvon Blais, 1990 at p. 69, no 115 and references.

34. F. Heleine, *loc. cit. supra* note 4 at p. 51.

35. B. Knoppers, «Les notions d'autorisation et de consentement dans le contrat médical», (1978) 19 C. de D. 893.

cannot consent in his or her place. It should also be noted that the father and mother exercise parental authority together³⁶ and both must authorize the child to submit to experimentation. In cases of conflict between the parents as to whether giving their authorization would be opportune, the *Civil Code* states that difficulties relating to the exercise of parental authority may be referred to the court, which must then decide the issue in the best interest of the child³⁷. It seems fair to state that any disagreement between the parents would tend to discourage the court from authorizing participation in experimentation since in most cases, judicial conservatism would favour the safest course.

As another general condition of validity for experimentation upon minors having discernment, the law requires that no serious risk result therefrom. Since this aspect is pertinent to the discussion of the relationship between risks and benefits, it will be analysed in that context (*infra*).

It is disturbing to note that by restricting participation in purely scientific experimentation only to capable adults or to minors having discernment, the present *Civil Code* seems to be somewhat out of touch with scientific imperatives³⁸. To begin with, certain highly useful experiments entail absolutely no risk to the research subject. Is there any reason why they should be forbidden? Moreover, in the field of pediatric medicine, research on children remains essential. Indeed, the Medical Research Council in its report on *Ethics in Human Experimentation*³⁹ noted that a ban on all research involving persons unable to give an informed consent,

«... would drastically curtail research on such diseases as the serious mental illnesses, respiratory distress syndrome, childhood leukemia, sudden infant death syndrome (crib death), cystic fibrosis and a variety of other genetically determined diseases that affect the young and frequently cause early death»⁴⁰.

36. Art. 648 C.C.Q.

37. Art. 653 C.C.Q.; art. 30 C.C.L.C.

38. See for example G. Reback, «Fetal Experimentation: Moral, Legal and Medical Implications», (1974) 26 Stanford L.R. 1191 at pp. 1195-96; J.M. Burchell, «Non-Therapeutic Medical Research on Children», (1978) 95 S.A.L.J. 193 at p. 196; D. Langer, «Medical Research Involving Children: Some Legal and Ethical Issues», (1984) 36 Baylor L.R. 1, at pp 2-6; M. Clapp, «State Prohibition of Fetal Experimentation and the Fundamental Right of Privacy», (1988) 88 Columbia L.R. 1073 at p. 1086 *et seq.*

39. Report no 6, Ottawa, Minister of Supply and Services Canada, 1978.

40. *Id.* at p. 30.

Likewise, the code is conspicuously silent regarding research on embryos and fetuses. Can we assimilate the unborn to children lacking discernment and extend the research ban to pregnant women or to cells fertilized *in vitro* prior to implantation? Or should we lean in the opposite direction and treat the unborn (excluding fertilized eggs *in vitro*) as *pars viscerum matris*? If one is mindful of the celebrated Supreme Court case of *Montreal Tramways Co v. Léveillé*⁴¹, which viewed an unborn child as an entity capable of sustaining an injury for which an action would lie upon its birth, it would appear problematic that fetuses be exposed to intrusive experimentation. If a foetus were subjected to experimentation from which harm resulted, it is doubtful that the assent of the mother to this research would provide the researcher with immunity from an action in damages brought on behalf of the newborn child. Indeed, in certain cases, the child could even sue his or her own mother for having knowingly participated in risky experimentation.

When one refers to the more recent Supreme Court judgment in *Daigle v. Tremblay*⁴² in which the father of an unborn child sought an injunction to prevent the mother from obtaining an abortion, the legal situation becomes even more clouded. Here, the Court held that until birth, the foetus enjoyed no personality rights and its continued existence would depend upon the decision of the mother. From this finding, it would be reasonable to infer that unless considerations relating to public order and good morals dictated otherwise, a pregnant woman could permit hazardous and intrusive non-therapeutic experimentation to be performed on her foetus provided it were never allowed to come to term. Were the foetus to be born in a viable state, it would acquire legal status retroactively and the rule in *Montreal Tramways Co v. Léveillé*⁴³ would then apply. Consequently, the only sure way a woman could avoid potential liability arising out of foetal experimentation would be to eventually seek an abortion. One can only surmise that this anomaly has led the Law Reform Commission of Canada to recommend that legislation be adopted allowing experimentation on fetuses provided there be at most minimal risk involved⁴⁴.

2 - Proportionality between risk and benefit

Art. 20 states that human experimentation may be performed as long as «the risk assumed is not disproportionate to the benefit anticipated». An appreciation of the notions of risk and benefit may go beyond a simple

41. [1933] S.C.R. 456. See generally, R. Kouri «Réflexions sur le statut juridique du foetus», (1980-81) 15 R.J.T. 193.

42. [1989] 2 S.C.R. 530.

43. *Op. cit. supra* note 41.

44. *Op. cit. supra* note 1 at pp. 54-55.

evaluation of the physical status of the person implicated. It may also entail an evaluation of the psychological, affective and even social consequences for the individual⁴⁵. The law thus sets out criteria which are somewhat vague or imprecise which, in itself, may be viewed as a mixed blessing. On the one hand, it allows the courts a certain latitude or flexibility when called upon to judge the behavior of researchers. Indeed, it is fair to state that in setting out such a broad standard, the National Assembly certainly cannot be faulted for having erected unreasonable obstacles to medical research. On the other hand, the difficulties inherent in evaluating the risks/benefits standard are quite obvious. In some types of research for example, how can one accurately measure the potential risks when, by definition, experimentation aims at exploring the unknown⁴⁶; any hoped-for benefit being only hypothetical or perhaps merely eventual? As well, while not an unworthy goal in itself, any advantage derived from purely scientific research would benefit humanity in general⁴⁷ rather than the research subject in particular. Yet, legally speaking, any appreciation of the notion of risk in proportion to benefit must relate to the situation of the individual directly concerned⁴⁸. Aside from the satisfaction derived from having performed an altruistic act or even of having earned some monetary reward through participation in a research project, how can such «benefits» outweigh the substantial risks involved in many types of experimentation? As a result, it may be argued that the utilization of a risk/benefit standard becomes downright misleading in non-therapeutic circumstances⁴⁹. Nevertheless, the terms of art. 20 remain unequivocal - one may perform clinical research provided, *inter alia* there is a preponderance of benefit over risk⁵⁰.

Taken literally, this would mean that as long as the benefits outweighed the risks, almost any risk could be incurred. For example, it could be argued that a very hazardous non-therapeutic experiment would be legitimized by an important potential benefit for humanity to be derived therefrom. Fortunately, the law is not so simplistic in its application. Public order establishes a limit as to the degree of risk to which one may be exposed no matter how great the

45. J.-L. Baudouin, *loc. cit. supra* note 4 at p. 831.

46. See for example G. Mémeteau, *Le droit médical*, Paris, Litec, 1985 at p. 314, no 471.

47. J.-L. Baudouin, *loc. cit. supra* note 4 at p. 830.

48. A. Mayrand, *op. cit. supra* note 5 at p. 17, no 7; G. Mémeteau, *loc. cit. supra* note 46 at p. 335, no 498.

49. A better approach would be to refer to the notion of public order and require that the experimentation be scientifically useful and ethically valid when no immediate benefit for the research subject is intended. As well, the risks involved would have to be minimal.

50. Regrettably, the Law Reform Commission paper (*op. cit. supra* note 1 at p. 33) fails to address this problem, stating merely that «When the purpose of an experiment is exclusively scientific, such that no personal benefit can be expected by the experimental subject, 'benefit' takes the form of an increase in learning, in scientific knowledge. The benefit becomes general and social in nature, and society as a whole is the beneficiary.»

anticipated benefit⁵¹. Since the rule of inviolability set out in art. 19 C.C.L.C. as well as in sec. 1 of the Quebec *Charter of Human Rights and Freedoms*⁵² and sec. 7 of the *Canadian Charter of Rights and Freedoms*⁵³, has as primary goal the protection of the individual, the magnitude of any risk which may be assumed must remain quite limited.

With regard to experiments relating to minors having discernment, we have already alluded to the legal requirement that no serious risk to the minor's health may result therefrom. Does this standard replace that of comparing risk to benefit already used in conjunction with experimentation on capable adults? While this opinion is entertained by some⁵⁴, it is felt generally that this restriction merely lowers the limit concerning the extent to which risks can be assumed in proportion to benefits⁵⁵. Thus hypothetically, an experiment entailing no foreseeable advantage or usefulness cannot be validly performed even if it does not expose the minor child to any risk. Likewise, an experiment holding out great promise for scientific progress but which exposes the minor to serious risks cannot be undertaken.

It should be noted that the duty of evaluating the risks and benefits, whether for adults or for minors having discernment, must be assumed by the person performing the experiment⁵⁶, since it is this person whose liability will be incurred by any violation of art. 20 C.C.L.C.

B - Liability of the parties involved in research

Before examining the particular situations of the various parties directly or indirectly involved in research, the following observations must be made. To begin with, this paper will not review all aspects of medical liability such as issues of confidentiality, abandonment, proof by presumptions of fact etc. The reader may refer to the usual doctrinal sources and to the principles generally applicable to medical malpractice litigation.

Another preliminary aspect to be dealt with is that of prescription. Art. 2260a C.C.L.C. reads as follows:

-
51. The Law Reform Commission (*id* at p. 34) evaluates risk both in terms of its seriousness as well as in terms of its probability of occurring.
 52. *Op. cit. supra* note 17.
 53. *Canadian Charter of Rights and Freedoms, Canada Act 1982, Schedule B, 1982 (U.K.)* c.11.
 54. J.-L. Baudouin, *loc. cit. supra* note 4 at p. 826.
 55. Cf A. Mayrand, *op. cit. supra* note 5 at pp. 67-68, no. 54; F. Héleine, *loc. cit. supra* note 4 at p. 54; A. Lajoie et al. *op. cit. supra* note 9 at p. 178, no 291.
 56. P.-A. Crépeau, *loc. cit. supra* note 9 at p. 257.

«In matters of medical or hospital responsibility, the action in indemnity for bodily or mental prejudice caused to a patient is prescribed by three years from the date of the fault.

However, if the prejudice becomes apparent gradually, the delay runs only from the day on which it first appeared.»

Although the researcher need not be a health professional nor the research subject a patient in the strictest sense, it is fair to state that since Quebec courts have tended to regroup all malpractice litigation relating to medicine under this provision⁵⁷, liability from non-therapeutic research would be subject to a three year prescriptive period. Yet, the apparent generality of this three year rule must be qualified. It applies only to recourses for «bodily or mental prejudice» caused to the victim. As an exceptional provision, it would not pertain to certain actions for moral damages caused by medical fault. An example which comes to mind would be an intentional breach of confidentiality which could cause harm to reputation and would even give rise to exemplary damages⁵⁸. In this type of situation, the prescriptive period would be one⁵⁹ or two years⁶⁰ in delictual or quasi-delictual matters, and thirty years⁶¹ in cases of contractual liability⁶².

Finally, although the Court of Appeal has held recently that non-liability clauses pertaining to bodily injury were not contrary to public order and good morals⁶³, it should be noted nonetheless that because of specific Health Law legislation, stipulations excluding the liability of certain researchers or institutions would be considered void in Quebec. According to the *Health Services and Social Services Act*,

«No establishment, nor its directors, employees or agents, nor any professional may solicit a renunciation by any person or his agents of the responsibility resulting from professional fault or resulting from the hospitalization or lodging of such person, or from medical examinations, treatments or surgical operations.

57. Cf *Brochu v. Auger*, [1981] C.S. 971; L.-H. Richard, *La responsabilité professionnelle du dentiste*, Sherbrooke, Les Editions Revue de Droit, 1986 at p. 63, note 323.
58. *Charter of Human Rights and Freedoms*, *op. cit. supra* note 17, sec 49.
59. Art. 2262(1) C.C.L.C.
60. Art. 2261(2) C.C.L.C.
61. Art. 2242 C.C.L.C.
62. See generally, A. Bernardot, R. Kouri; *La responsabilité civile médicale*, Sherbrooke, Editions Revue de Droit, 1980 at p. 61, no 88 *et seq.*
63. *Potvin v. Stipetic*, [1989] R.J.Q. 777 (C. A.)

If such renunciation is made, it shall be void»⁶⁴.

For the purposes of this paper, our discussion of civil responsibility will be limited to the liability of the researcher, the institution at which research is taking place, and the research subject.

1 - The Researcher - The researcher's liability may be either contractual or extra-contractual in nature. It is contractual when a valid contract to perform research on a human subject has been formed with a particular individual. This type of liability would be encountered, for instance, in cases where the consent obtained was not sufficiently enlightened or where the research was carried out in a negligent fashion.

Delictual or quasi-delictual liability arises when the subject has withdrawn consent and the researcher proceeds in spite of this refusal to participate⁶⁵, or where a requirement for the validity of experimentation has not been observed, e.g. the failure to obtain consent in writing.

The scope of liability of the researcher in charge of a project may be quite extensive. The *Weiss* case⁶⁶ enunciated the principle that the person responsible for the research protocol is bound to ensure that respect for the security and integrity of the research subject is maintained during the whole course of the experiment, including during all verification and diagnostic procedures effected in conjunction with the actual research⁶⁷. This implies that the researcher would be liable not only for his or her personal acts or omissions, but also for the activities of the individual members of the research team through application of the maxim *qui facit per alium facit per se*⁶⁸. Indeed, in law, when a debtor invites third parties to fulfill his or her contractual obligations, it is logical that non-fulfillment of this duty by a third party will engage the contractual liability of the primary debtor⁶⁹. In addition to a recourse against the researcher, the victim would also have a quasi-delictual claim under art. 1053

64. *An Act Respecting Health Services and Social Services*, R.S.Q. c.S-5, sec 127. At the time of writing, this law was in the process of undergoing revision. This revision has since been completed cf *An Act Respecting Health Services and Social Services and Amending Various Legislation*, S.Q. 1991, c. 42, adopted the 28th of August 1991 and assented to the 4th of September 1991. This rule is now expressed in sec. 16 of the revised act.

65. *Beausoleil v. Communauté des Soeurs de la Charité de la Providence*, [1965] B.R. 37.

66. *Op. cit. supra* note 13.

67. *Id.* at p. 300 (C.C.L.T.), or at p. 741 (R.J.Q.)

68. P.-A. Crépeau, «La responsabilité civile de l'établissement hospitalier en droit civil canadien», (1981) 26 McGill L.J. 673 at p. 722.

69. See *Lapointe v. Hôpital Le Gardeur*, [1989] R.J.Q. 2619 (C.A.) at pp. 2641-2642 (opinion of LeBel, J.).

C.C.L.C. against the person actually causing the harm, such as a research assistant, nurse, technician or other member of the team.

One problem in medical research which remains to be resolved concerns the standard according to which the researcher's behavior is to be judged. Would it be realistic to compare the actions of a physician engaged in research to those of a reasonable physician involved in «ordinary» practice? Wouldn't a higher standard be more appropriate, given the circumstances in which the harm occurs? In Quebec law, taking as analogy the liability of surgeons performing purely cosmetic surgery as compared to that of surgeons carrying out therapeutic operations, the courts have refused to set up stricter standards by which to evaluate the performance of non-therapeutic treatment. However, as previously indicated, the duty to inform has been viewed more stringently in circumstances where the goal of the act was not therapeutic. It seems logical to assume that there would probably be a similar trend in matters relating to pure experimentation. In this connection, it should be noted that as a matter of fact, not all medical experimentation is carried out by physicians. In such cases, should a different, perhaps less exacting standard be imposed for example on a person holding a doctorate in physiology but who is not a physician, than would be expected of a medical doctor? The answer, on grounds of public order, would likely be in the negative since a fundamental role of the law is to ensure the protection of a person's integrity⁷⁰. A variation in standard depending upon the qualifications of the person acting, as opposed to a variation in standard according to the activity being performed, would not be conducive to providing equal protection to all individuals⁷¹.

Therefore, no matter who administered the experimental procedure, the criterion for evaluating whether a fault has occurred would be the standard of a reasonably competent, conscientious and attentive physician acting in similar circumstances⁷².

2 - The Institution - There is an ongoing debate in Quebec law as to the existence of a master and servant relationship between a physician performing medical acts and the institution where such activities occur. The reason for this

70. Art. 19 C.C.L.C.

71. Indeed, in cases of medical malpractice, it has been decided that when a nurse performs acts of a medical nature which only a physician can accomplish, or when a general practitioner performs specialized medical acts, these persons will, in the interest of the patient, be held to the higher standard, cf A. Bernardot & R. Kouri, *op. cit. supra* note 62 at pp. 13-14, no 22 and references therein cited.

72. Note that we refer to the «procedure» or actual experiment as opposed to, for example, the testing of an experimental medication in capsule form and which has been administered by a nurse at the request of the physician-researcher. In this case, it is obvious that the nurse would not be liable for the experimental aspect of the intervention.

debate relates to the determination whether art. 1054 C.C.L.C. imposing vicarious liability on a master or employer can apply in favour of a patient or research subject. The predominant view tends toward denying such a relationship⁷³, although the Supreme Court of Canada has on occasion decided the contrary⁷⁴. The preferable approach would be to exclude vicarious liability except in circumstances where the researcher was acting on the institution's behalf rather than in pursuit of his or her personal interest. In the final analysis, since medical liability in Quebec usually arises out of contract, it is submitted that in most cases, a discussion of whether or not a physician is a *préposé* or servant becomes somewhat less pertinent⁷⁵.

73. Cf A. Bernardot & R. Kouri, *op. cit. supra* note 62 at p. 350, no. 534 *et seq.*; P.-A. Crépeau, *loc. cit. supra* note 68 at p. 719; J.-L. Baudouin, *op. cit. supra* note 33 at pp. 265-266, nos 513-514; see also *Lapointe v. Hôpital Le Gardeur*, *op. cit. supra* note 69 at p. 2639.

74. *Martel v. Hôtel-Dieu St-Vallier*, [1969] S.C.R. 745.

75. Even when the context of liability is extra-contractual, P.-A. Crépeau (*loc. cit. supra* note 68 at pp. 733-734) presents a persuasive argument based upon the *qui facit per alium* rule for dispensing with the necessity of establishing a master-servant relationship as a condition precedent for holding the hospital liable. According to Crépeau, «En ce qui concerne le fait d'autrui, on devra admettre que la faute d'un auxiliaire, professionnel ou non, dans l'exécution de ces prestations personnelles de soins et de services, assumées légalement par l'établissement, entraînera la responsabilité de ce dernier, non pas comme on l'estime parfois, sur la base plus astreignante du régime de garantie du commettant, instauré par l'article 1054, alinéa 7 C.c., mais bien, et plus largement, sur le fondement de la responsabilité personnelle de l'article 1053 C.c. En effet, la maxime *qui agit per alium agit per se (...)* ne joue pas seulement en matière contractuelle, mais bien chaque fois qu'une obligation personnelle est mise à la charge du débiteur, soit qu'il l'ait assumée par contrat, soit qu'elle lui ait été imposée par la loi.» (at p. 733). While S. Nootens («La responsabilité civile du médecin anesthésiste (2e partie)», (1989) 19 R.D.U.S. 317 at pp. 374, 375) and F. Tôth («Contrat hospitalier moderne et ressources limitées: conséquences sur la responsabilité civile», (1990) 20 R.D.U.S. 313 at pp. 324-325) refuse to admit the validity of this point of view, D. Jutras, in his article «Réflexions sur la réforme de la responsabilité médicale au Québec», (1990) 31 C. de D. 821 at p. 830 fails to address Crépeau's thesis. It is worthwhile recalling that while art. 1054 para. 7 C.C.L.C. creates a regime of liability applicable to an employer or *commettant* for the fault of the *préposé*, it is in fact a regime of liability without fault, whereas in the case of a legal obligation to do which is imposed upon a particular person, such person's failure to fulfill this obligation due to the act or omission of another person acting at the behest of the primary debtor would constitute a straightforward application of the *qui facit per alium* rule. Crépeau's point of view is highly plausible in cases where medical treatment is provided in an extra-contractual context because as he properly points out, establishments such as hospitals are under a legal duty to offer such care (*loc. cit. supra* note 68 at pp. 677 - 678). But does his reasoning still hold true when the situation contemplated is one involving pure research? A brief examination of the *Health Services and Social Services Act* (*op. cit. supra* note 64) indicates that Crépeau's thesis does indeed remain applicable. To begin with, the Minister of Health and Social Services has the duty to promote research and teaching (sec. 3(f)). In order to attain this goal, establishments may, in addition to the services which are usually offered, provide «... teaching and research services if bound by a contract of affiliation recognized by the Minister of Education or the Minister of Higher Education and Science and by the Minister of Health and Social Services...» (sec. 125). This leads one to believe that the mission of certain hospital centers may be expanded to include purely scientific research. By implication therefore, sec. 4 of the

According to the *Weiss* case⁷⁶, an institution would be liable not only for the fault of the physician who actually performs the research work but also for the negligence of its research committee in approving, for example, the research protocol or the information to be included in the consent form⁷⁷. This case also suggests that insufficiently selective criteria for the choice of research subjects likewise could be a source of liability of the institution through its research committee⁷⁸. Moreover, the Court in *Weiss* held the institution liable for failing to have appropriate equipment such an electrocardiograph or a defibrillator readily accessible in cases of emergency arising during an experiment. Clearly, the type of emergency equipment which should be available would depend upon the kind of experiment performed and the untoward reactions which could occur.

3 - The Research Subject - Although at first blush it appears unusual to evoke the notion of the research subject's liability, there may arise situations in which substantial harm could be caused to the researcher and other interested parties due to the acts or omissions of the volunteer. This discussion centers around the notions of compliance or collaboration. A lack of compliance on the part of the subject could well be the source of inaccurate data, time lost, wasted effort as well as needless expense. Compliance includes honesty and candour in providing personal information for purposes of identification and selection of the candidates for research. It can also take the form of active collaboration or following instructions during the administering of the experiment itself. It could include returning, if necessary, for any follow-up observation, testing or care⁷⁹.

It should be emphasized that participation in an experiment must always be totally voluntary, which explains why, for example, one must not use prisoners for experimentation⁸⁰, and why the experimental subject may withdraw

Health Services and Social Services Act would apply equally to both research subjects and to those receiving medical treatment in such establishments. Speaking objectively however, situations in which pure research is undertaken without a contract having previously been entered into between the establishment and the subject or his or her representative would be highly exceptional.

76. *Op. cit. supra* note 13.

77. *Id.* at pp. 304-305 (C.C.L.T.) and at pp. 743-744 (R.J.Q.). While this writer would agree with the decision that the hospital be held liable for its own fault or for the fault of its research committee acting in the hospital's interest, the Court merely states that since the researcher committed a fault, this negligent act would also engage the liability of the hospital under art. 1054(7) C.C.L.C. This latter finding is somewhat paradoxical, given the fact that there was a contract between the patient and the principal researcher.

78. *Id.* at p. 304 (C.C.L.T.) and at p. 744 (R.J.Q.)

79. See generally, A. Bernardot & R. Kouri, *op. cit. supra* note 62 at p. 219 *et seq.*

80. See for example *Kaimowicz v. Michigan Dept. of Mental Health*, (1978) 42 U.S.L.W. 2063. See also the *Règlement sur les établissements de détention*, R.R.Q., 1981, c P-26, r 1, art. 21.

his or her consent at any time. One writer suggests that even when participation in this type of voluntary activity may be withdrawn at the last minute, should such a refusal to continue cause damage to others, the subject could be held liable for having abused his or her rights⁸¹. The consequences of this point of view are troubling, especially in matters of pure research. Indeed, one would hesitate to approve coercing ongoing participation in an experiment because of exposure to a potential abuse of rights damages action. Between the freedom of the individual and the possibility of causing inconvenience to others, it is felt that participation in experimentation should be entirely voluntary and free from fear of suit, should a change of heart occur.

C - The new law governing experimentation

As already mentioned⁸², the projected *Civil Code of Québec* sets out rules dealing specifically with medical experimentation. The pertinent provisions are contained in articles 20 to 24 C.C.Q., which read as follows:

«20. A person of full age who is able to give his consent may submit to an experiment provided that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated.

21. A minor or a person of full age who is unable to give his consent may be submitted to an experiment only in the absence of serious risk to his health and of objection on his part, provided that he understands the nature and consequences of the act; the consent of the person having parental authority or of the mandatary, tutor or curator is required.

Furthermore, a benefit to the health of the person concerned or of persons of the same group must be expectable; in the first case, the authorization of the court is required and in the second, the research project as part of which the experiment is carried out must be approved by the Minister of Health and Social Services.

Innovative care required by the state of health of a person who submits to such care is not considered to be an experiment.

22. A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may be used for

81. A. Mayrand *op. cit. supra* note 5 at p. 83, no 62. It should be noted however, that Mayrand was discussing a last minute refusal to go through with a promised gift of tissue. Also, it should be recalled that the notion of abuse of rights *stricto sensu* is based upon something which is done in bad faith cf. *Brodeur v. Choinière*, [1945] C.S. 334.

82. *Op. cit. supra* note 3.

purposes of research, unless the person concerned or the person qualified to give consent for him objects.

23. When the court is called upon to rule on an application for authorization with respect to the alienation of a part of the body, medical care or an experiment, it shall obtain the opinions of experts, of the person having parental authority, of the mandatory, of the tutor or the curator and of the tutorship council; it may also obtain the opinion of any person who shows a special interest in the person concerned by the application.

The court is also bound to obtain the opinion of the person concerned unless that is impossible, and to respect his refusal unless the care is required by his state of health.

24. Consent to the alienation *inter vivos* of a part of a person's body, to medical care not required by a person's state of health or to an experiment shall be given in writing.

It may be withdrawn at any time, even verbally.»

For purposes of our comparison with the law presently in force, we will allude only to those aspects of the proposed legislation which constitute substantial modifications to current law.

1 - Capacity - In a clear departure from the provisions of the *Civil Code of Lower Canada*, it would become possible for an adult or minor lacking discernment to participate in an experiment. In such cases, consent would be supplied by an interested third party such as the person having parental authority, the mandatory or the tutor or curator. Other conditions precedent are also established according to the type of experimentation to be undertaken, since the new code would explicitly regulate both therapeutic experimentation (other than innovative therapy) and purely scientific research⁸³. In the former situation,

83. Therapeutic experimentation can be distinguished from innovative therapy in that the former aims at providing direct benefit to the research subject by utilizing therapeutic modalities, any contribution to the acquisition of knowledge being secondary, whereas in the case of the latter, which also has as its goal the direct benefit of the patient, the acquisition of knowledge is not a mere fortuitous by-product but an end actively pursued. As we can see, the relationship between the two is characterized by the aim of acting in the immediate best interest of the experimental subject. The nature of this relationship leads one to wonder why the drafters of the proposed *Civil Code* have seen fit to recommend controls for the performance of experimental therapy and not for innovative therapy since the risks are arguably similar. Indeed, because of the interest pursued, would it not be more logical to contemplate both activities as facets of therapy and deem them subject to the same legal rules? On the other hand, some writers feel that since both innovative therapy and therapeutic research constitute research, they should be subject to the rules governing

those entitled to act on behalf of the person under protection could do so only with the permission of the court⁸⁴.

The court, before granting authorization, first would be called upon to consult with certain persons such as experts in the field and with the experimental subject's representatives. It could also consult with or obtain the advice of other interested third parties⁸⁵.

Paradoxically, under this legislation, should the research subject in fact be capable of expressing an opinion on his or her participation in an experiment, the court would be bound to respect the subject's refusal unless the experimentation was necessitated by that person's state of health. By definition therefore, therapeutic experimentation implies that in almost all situations, the incapable patient would never be allowed to refuse treatment.

As for purely scientific research, aside from the consent of those entitled to act on behalf of the person under protection, the only other legal safeguard in place would be the necessity of having the research project approved by the Minister of Health and Social Services⁸⁶. Court authorization would no longer be required.

It is interesting to note that despite the pressing need for guidance on the subject⁸⁷, no indication is given by these new provisions whether research may be performed on the unborn. On the one hand, the absence of any formal prohibition of foetal experimentation could be interpreted as a tacit approval of this type of act. On the other hand, it could be posited that the internal logic of the new codal articles on consent would tend to indicate that fetuses or embryos cannot be experimented upon, subject of course to the nuances alluded to above in our discussion of current law. The fact that only under exceptional circumstances would the new code allow «proxy» consents on behalf of those who are under the law's protection, argues in favour of this latter point of view

experimentation. See generally, M. Somerville, *loc. cit. supra* note 4 at p. 86; the Law Reform Commission working paper on biomedical experimentation, *op. cit. supra* note 1 at pp. 4-5; Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects*, (Ottawa, Minister of Supply and Services Canada, 1987) at p. 9.

84. Art. 18 para 2 C.C.Q.

85. Art. 19 C.C.Q.

86. Of course, the research protocol would still be subject to the controls imposed by the funding body such as the Medical Research Council of Canada. These controls, however, derive from the legal relationship between the researcher and the funding body, and do not affect the legality of the research *per se*.

87. See generally the Medical Research Council of Canada's guidelines, *op. cit. supra* note 83 at pp. 32-35; B. Knoppers, *Conception artificielle et responsabilité médicale*, Cowansville, Les Éditions Yvon Blais Inc., 1986 at p. 5.

since it is a fundamental rule that exceptional provisions must be interpreted restrictively. Consequently, a cogent argument may be made that the new code would indeed forbid foetal experimentation, at least *in utero*. However, the drafting of art. 22 C.C.Q. is tantalizingly vague. At first glance, one could dismiss this article as confirmation of the rule that once parts of the human body are obtained as a by-product of surgical or diagnostic procedures, the average patient is generally indifferent as to the disposition of such tissue or substances. In other words, it codifies current practices. Perhaps some would be inclined to view art. 22 C.C.Q. as an attempt to provide a statutory resolution to any potential debate similar to that dealt with in the case of *Moore v. Regents of the University of California*⁸⁸, involving the right of a cancer patient to a portion of the profits generated from the production and sale of a cell-line derived from his cancer cells. But if this were the goal of art. 22, it would seem reasonable that ownership of the human tissue or substances would have to be attributed to the researcher, the hospital or the research institution, which in fact, art. 22 C.C.Q. fails to do. This leads one to the only other hypothesis possible, especially in light of *Daigle v. Tremblay*⁸⁹. Since the Supreme Court dismissed the notion of granting personhood to the unborn, and since under Quebec law, it would not be appropriate to treat foetuses and embryos as objects of ownership⁹⁰, the idea that aborted foetuses could be used for research becomes plausible. By the same token, it leads one to the conclusion that surplus fertilized ova produced in the course of *in vitro* fertilization could also be used for experimentation.

2 - Other criteria of validity for experimentation - Art. 21 C.C.Q. sets out certain conditions which must be met before an experiment involving an incapable person may be carried out. These include the requirement that firstly, the experiment must be performed in the interest of the person concerned or in the interest of persons forming part of the same group, and secondly, there must be an absence of serious risk for that person's health⁹¹.

88. (1988) 249 Cal.Rptr. 494 (Court of Appeal); (1990) 271 Cal.Rptr. 146 (Supreme Court of California).

89. *Op. cit. supra* note 42.

90. See for example the statement of Mr. Justice Vallerand in *Langlois v. Meunier*, [1973] C.S. 301 at p. 305: «Cet enfant à naître n'est certes pas une personne et les principes du droit civil concernant le décès ne peuvent s'y appliquer. Il n'est pas non plus une chose, non plus qu'un membre ou organe de sa mère. Il ne se situe, à vrai dire, dans aucune catégorie de biens ou de personnes qu'identifie la loi.» In this case, parents were suing for damages resulting from the still-birth of their unborn child at an advanced state of gestation, due to the fault of the defendant. See also J.-C. Galloux, «Réflexions sur la catégorie des choses hors du commerce: l'exemple des éléments et des produits du corps humain en droit français», (1989) 30 C. de D. 1011 at pp. 1020-1021.

91. Art. 21 C.C.Q.

The first condition relates mainly to a question of policy in order to avoid any notion of undue exploitation of vulnerable persons. It implies, for instance, that children may be subjects of purely scientific research provided other children are likely to benefit therefrom. The same holds true for the mentally deficient. However, a rule of this nature also connotes that with regard to conditions or diseases which are not exclusive to their group, incapable persons cannot participate in a program of experimentation. Consequently, a mentally deficient adult cannot be experimented upon in order to determine, for example, the causes and potential treatments for ulcerative colitis since colitis affects all segments of the population.

This legislative acknowledgement of group solidarity among the young or the mentally incapable suggests that scientific imperatives have dictated the need to adopt a rule more flexible than the present prohibition on non-therapeutic experimentation on persons lacking discernment.

The second criterion, which requires that the experiment not entail serious risk, constitutes a major improvement upon present law since it dispenses with the evaluation of risks for the individual in relation to the benefits for mankind. A realistic note is introduced in that while the necessity of experimentation is acknowledged as a matter of public policy, strict limits are placed thereon.

With a view to protecting vulnerable persons from undue influence or coercion, especially in light of the legalization of certain medical acts previously forbidden, the new code sets out stringent procedural safe-guards usually having as their focal point the requirement that the permission of the court be secured. Not only must the potential research subject be consulted, the court must also obtain the opinion of others such as the person having parental authority or the mandatary, the tutor or curator, the tutorship council as well as that of experts. A person showing a special interest in the person involved may also be heard.

Oddly enough, no mention is made of the possibility of designating an attorney *ad litem* whose sole duty would be to act on behalf of the person concerning whom the application is made. Without desiring that the procedure for obtaining authorization degenerate into an adversarial process, it is submitted that greater protection for the individual would result from the efforts of a person whose loyalties are less likely to be divided.

CONCLUSION

From this brief study of the legal aspects of experimentation, several points necessitating clarification arise. Firstly, the law is going to have to come to grips with the issue of non-therapeutic experimentation involving the unborn,

both *in vivo* and *in vitro*, rather than leave this type of problem to the vagaries of the judicial system.

Secondly, the proposed code should be modified to eliminate the difference in approach to innovative therapy and to therapeutic experimentation. Since both activities have as primary goal the pursuit of a benefit for the patient, they should be classified as therapy rather than experimentation. Also it would perhaps be advisable to retain the necessity of judicial authorization to perform purely scientific experimentation on minors and incapable adults. The fact that the Minister of Health and Social Services approves a research project does not ensure that in individual cases, the rights of vulnerable persons will be safeguarded. Moreover, one must acknowledge the danger that authorizing non-therapeutic experimentation on incapable subjects could constitute the «thin edge of the wedge» in which greater liberties could be taken than would have been originally contemplated by any enabling legislation.

Thirdly, the law is going to have to deal with the incongruities inherent in requiring that the degree of risk be commensurate with the amount of benefit to be derived from a purely scientific experiment. How can one weigh these two factors when the potential detriment will be assumed by one person whereas the potential benefit will be enjoyed by others? On this point, it would be advantageous to follow the lead of French legislation which deals squarely with this contradiction by declaring:

«Art. L.209-2 Aucune recherche biomédicale ne peut être effectuée sur l'être humain:

...

si le risque prévisible encouru par les personnes qui se prêtent à la recherche est hors de proportion avec le bénéfice escompté pour ces personnes ou l'intérêt de cette recherche»⁹²;

The Law Reform Commission of Canada, in its working paper on *Biomedical Experimentation Involving Human Subjects*⁹³, formulates very specific recommendations concerning the whole question of research and the protection of the individual. While one may dispute certain recommendations

92. *Loi no 88-1138 du 20 décembre 1988 relative à la protection des personnes qui se prêtent à des recherches biomédicales*, J.O. 22 déc. 1988, p. 1603, J.C.P. 1989.III.62199 (emphasis added). For an analysis of this law see, G. Mémeteau, «De quelques droits sur l'homme: commentaire de la loi du 20 décembre 1988 relative à la protection des personnes qui se prêtent à des recherches biomédicales», D.S. 1990 chron.XXX, especially at p. 168 where he quotes Mme Dorlhac as saying before the *Sénat*, «Pour le volontaire sain, la notion de bénéfice escompté n'existe jamais.»

93. *Op. cit. supra* note 1.

or perhaps even the Law Reform Commission's inclination to treat as falling under federal jurisdiction the statutory regulation of experimentation, the fact remains that the Commissioners are correct in stating that one should not wait for an accident or manifest abuse to occur and then have the courts indicate to Parliament what it should have done to avoid the problem⁹⁴.

94. *Id.* at p. 59.